BRUNEI DARUSSALAM MEDICINES CONTROL AUTHORITY
MINISTRY OF HEALTH, BRUNEI DARUSSALAM

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

Product Licence Number	Product Name	Indication
BRU08010001P	Pharmaniaga Aciclovir Tablet 200mg	Treatment and prophylaxis of herpes genitalis, treatment of herpes zoster, herpes simplex and varicella (chicken-pox).
BRU08010003P	Pharmaniaga Clarithromycin Tablet 250mg	Treatment of infection caused by pathogens sensitive to clarithromycin. Infection of naso-pharynxtract (tonsillitis, pharyngitis), and of paranasal sinuses. Infection of lower respiratory tract: bronchitis, bacterial pneumonia and atypical pneumonia. Skin infections: impetigo, erysipelas, folliculitis, furunculosis and septic wounds.

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BRU08010004P	Pharmaniaga Fluconazole Capsule 150mg	1. Genital candidiasis. Vaginal Candidiasis, acute or recurrent; and prophylaxis to reduce the incidence of recurrent vaginal candidiasis (3 more episodes a year). Candidal Balanitis. Prevention of oropharyngeal candidiasis in patients with AIDS. 2. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g. pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. 3. Systemic candidiasis, including candidemia, disseminated candidiasis and other forms of invasive candidal infection. These include infections of the peritoneum, endocardium, eye, pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 4. Mucosa candidiasis. These include oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of oropharyngeal candidiasis in patients with AIDS. 5. Prevention of fungal infection in patients with malignancy who are predisposed to such infections as a result of chemotherapy or radiotherapy. 6. Dermatomycosis including tines pedis, tines corporis, tinea cruris, tenia versicolor and dermal candida infections.

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BRU08010005P	Pharmaniaga Ciprofloxacin Tablet 500mg	Consideration should be given to official guidance on the appropriate use of antibacterial agents. Uncomplicated and complicated infections caused by Ciprofloxacin-sensitive pathogens: Infections of the - respiratory tract. Ciprofloxacin can be regarded as an advisable treatment for Pneumonias caused by *Klebsiella, Enterobacter, Proteus, Pseudomonas, Heamophilus, Branhamella, Legionella* , and *Staphylococcus.* - Middle ear (otitis media) of the paranasal sinuses (sinusitis), especially if these are caused by gram negative organisms including *Pseudomonas* or by *Staphylococcus* . - Eyes - Kidney and/or urinary tract. - Genital organs, including adnexitis, gonorrhoea, and prostatitis. - Abdominal cavity (e.g. bacterial infections of the gastrointestinal tract, biliary tract, peritonitis). - Skin and soft tissue - Bones and joints -Septicaemia* - Ciprofloxacin is also indicated for prophylaxis against infection in elective upper gastrointestinal surgery and endoscopic procedures where there is an increased risk of infection. Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or in state of neutropenia). Selective intestinal decontamination in immunosuppressive patients. * Pharmaniaga Ciprofloxacin should be only used: • When *Pseudomonas* is considered and the patient is allergic to antipseudomonal penicillins/cephalosporins. • For resistant organisms with no other alternative antibiotics available.
BRU08020012P	Pharmaniaga Cephalexin Capsule 500mg	Cephalexin is used to treat septicaemia, bone and joint infections, including burn wound infections and urinary tract infections caused by susceptible bacterial organisms. They are not effective in treating meningitis. Cephalexin is used as a possible alternative to the penicillins for staphylococcus and nonenterococcal streptococcal infections including pneumonia, bone and joint infection and bacterial endocarditis.

BRU08020013P	Pharmaniaga Metronidazole Tablet 200mg	Metronidazole is indicated: • For the treatment of symptomatic trichomoniasis in females and males when the presence of the trichomonad has been confirmed by appropriate laboratory procedures (wet smears and/or cultures). • In the treatment of asymptomatic females when the organism is associated with endocervicitis, cervicitis, or cervical erosion. Since there is evidence that presence of the trichomonad can interfere with accurate assessment of abnormal cytological smears, additional smears should be performed after eradication of the parasite. *T.vaginalis* infections is a venereal disease. Therefore, asymptomatic sexual partners of treated patients should be treated simultaneously if the organism has been found to be present, in order to prevent reinfection of the partner. The decision as to whether to treat an symptomatic male partner who has negative culture or one for whom no culture has been attempted is an individual one. In making this decision, it should be noted that there is evidence that a woman may become reinfected if her consort is not treated. Also, since there can be considerable difficulty in isolating the organism from the asymptomatic male carrier, negative smears and cultures cannot be relied upon in this regard. In any event, the consort should be treated with metronidazole in cases of reinfection. • In the treatment of acute intestinal amoebiasis (amoebic dysentery) and amoebic liver abscess. In amoebic liver abscess, metronidazole therapy does not obviate the need for aspiration or drainage of pus. Metronidazole is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria. Indicated surgical procedures should be performed in conjunction with metronidazole therapy. In a mixed aerobic and anaerobic infection, antimicrobials appropriate for the treatment of the aerobic infection should be used in addition to metronidazole. In the treatment of most serious anaerobic infections, intravenous metronidazole is usually administered initially. This may be followed by oral therapy at the discretion of the physician.

		Intra-abdominal infections, including peritonitis, intra-abdominal abscess, and liver abscess caused by *Bacteroides* species including the *B. fragilis* group (*B. fragilis, B. distasonis, B. ovatus, B.thetaiotaomicron, B. vulgatus*), *Clostridium* species, *Eubacterium* species, *Peptococcus niger* or *Peptostreptococcus* species. Skin and skin structure infections caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus niger* , *Peptostreptococcus* species, or *Fusobacterium* species. Gynaecologic infections, including endometritis, endomyometritis, tubo-ovarian abscess, and postsurgical vaginal cuff infection, caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus niger* , or *Peptostreptococcus* species. Bacterial septicaemia caused by Bacteroides species including the *B. fragilis* group or *Clostridium* species. Bone and joint infections (as adjunctive therapy) caused by *Bacteroides* species including the *B. fragilis* group. Central nervous system (CNS) infections, including meningitis and brain abscess, caused by *Bacteroides* species including the *B. fragilis* group. Endocarditis caused by *Bacteroides* species including the *B. fragilis* group.
BRU08020016P	Anikef Sterile 750mg	• Respiratory tract infections, e.g. acute and chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess and postoperative chest infections. • Ear, nose and throat infections, e.g. sinusitis, tonsillitis and pharyngitis. • Urinary tract infections, e.g. acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria. • Bone and joint infections e.g. osteomyelitis and septic arthritis. • Obstetric and gynaecological infections, pelvic inflammatory diseases. • Gonorrhoea particularly when penicillin is unsuitable. • Other infections including septicaemia and meningitis. • Prophylaxis against infection in abdominal, pelvic, orthopaedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk from infection.

BRU08020017P	Bicafar Sterile 1g	Cefoperazone is indicated for the treatment of the following infections when caused by susceptible organisms: Respiratory tract infections (upper and lower); urinary-tract infections (upper and lower); peritonitis, cholecystitis, cholangitis and other intra-abdominal infections; septicaemia, skin and soft tissue infections; infections of bone and joints; pelvic inflammatory disease, endometritis, gonorrhoea, and other infections of the genital tract. Prophylaxis: (Cefoperazone sodium may be indicated in the prophylaxis of postoperative infection in patients undergoing abdominal and gynaelogical surgery, cardiovascular and orthopaedic surgery). Combination Therapy: Because of the broad-spectrum of activity of Cefoperazone, most infections can be treated adequately with this antibiotic alone. However, Cefoperazone may be used concomitantly with other antibiotics if such combinations are indicated. If an aminoglycoside is used, renal function should be monitored during the course of therapy.
BRU08020018P	Betamox Granules 125mg/5ml	Amoxycillin indicated for the treatment of the following infections due to susceptible strains of sensitive organisms. Note: Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. However, in emergency cases where the causative organism has not been identified, therapy with amoxicillin may be useful. Clinical judgement will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results. **Skin and Skin structure**: *Staphlyococcus* , non-penicillinase producing; *Streptococcus; E. coli* . **Respiratory (Acute and Chronic)**: *H. influenzae, Streptococcus; S. pneumoniae; staphylococcus,* non-penicillinase-producing; *E. coli* . **Genitourinary Tract (Complicated and uncomplicated, Acute and Chronic)**: *E. coli, P. mirabilis* and *S. faecalis* . **Gonorrhoea**: *N. gonorrhoea* (non-penicillinase producing). **Prophylaxis of endocarditis**: Amoxycillin may be used for the prophylaxis of bacterial endocarditis in individuals at particular risk, such as those with prosthetic heart valve or those who have previously had endocarditis.

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BRU08020019P	Betamox Granules 250mg/5ml	Amoxycillin indicated for the treatment of the following infections due to susceptible strains of sensitive organisms. Note: Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. However, in emergency cases where the causative organism has not been identified, therapy with amoxicillin may be useful. Clinical judgement will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results. **Skin and Skin structure**: *Staphlyococcus* , non-penicillinase producing; *Streptococcus; E. coli* . **Respiratory (Acute and Chronic)**: *H. influenzae, Streptococcus; S. pneumoniae; staphylococcus,* non-penicillinase-producing; *E. coli* . **Genitourinary Tract (Complicated and uncomplicated, Acute and Chronic)**: *E. coli, P. mirabilis* and *S. faecalis* . **Gonorrhoea**: *N. gonorrhoea* (non-penicillinase producing). **Prophylaxis of endocarditis**: Amoxycillin may be used for the prophylaxis of bacterial endocarditis in individuals at particular risk, such as those with prosthetic heart valve or those who have previously had endocarditis.
BRU08020020P	Diprivan 10mg/ml (1%) Emulsion For Injection Or Infusion (20ml Ampoule)	Diprivan is a short-acting intravenous anaesthetic agent suitable for induction and maintenance of general anaesthesia. Diprivan may also be used for sedation of ventilated adult patients receiving intensive care. Diprivan may also be used for conscious sedation for surgical and diagnostic procedures.

BRU08030023P	Augmentin Tablet 625mg	*AUGMENTIN* is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other beta-lactam antibiotics. *AUGMENTIN* should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. *AUGMENTIN* oral presentations are indicated for short-term treatment of bacterial infections at the following sites: *Upper respiratory tract infections (including ENT)* e.g. tonsillitis, sinusitis, otitis media. *Lower respiratory tract infections* e.g. acute exacerbation of chronic bronchitis, lobar and bronchopneumonia. *Genito-urinary tract infections* e.g. cystitis, urethritis, pyelonephritis. *Skin and soft tissue infections* e.g. boils, abscesses, cellulitis, wound infections. *Bone and joint infections* e.g. osteomyelitis. *Dental infections* e.g. dentoalveolar abscess *Other infections* e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis. Susceptibility to *AUGMENTIN* will vary with geography and time (see *Pharmacological Properties, Pharmacodynamics* for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.

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BRU08030024P	Augmentin Suspension 228mg/5ml	*AUGMENTIN* should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. *AUGMENTIN* suspension (228mg/5ml and 457mg/5ml), for twice daily oral dosing, is indicated for short term treatment of bacterial infections at the following sites when amoxicillin resistant beta-lactamase producing strains are suspected as the cause. In other situations, amoxicillin alone should be considered. *Upper respiratory tract infections (including ENT)* e.g. recurrent tonsillitis, sinusitis, otitis media. *Lower respiratory tract infections* e.g. acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. *Urinary tract infections* e.g. cystitis, urethritis, pyelonephritis *Skin and soft tissue infections* e.g. cellulitis, animal bites. *Dental infections* e.g. severe dental abscess with spreading cellulitis. Susceptibility to *AUGMENTIN* will vary with geography and time (see *Pharmacological Properties, Pharmacodynamic* s for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary. Mixed infections caused by amoxicillin-susceptible organisms in conjunction with *AUGMENTIN* susceptible beta-lactamase-producing organisms may be treated with *AUGMENTIN* suspension 228mg/5ml and 457mg/5ml. These infections should not require the addition of another antibiotic resistant to beta-lactamases.

BRU08030025P	Augmentin Suspension 457mg/5ml	*AUGMENTIN* should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. *AUGMENTIN* suspension (228mg/5ml and 457mg/5ml), for twice daily oral dosing, is indicated for short term treatment of bacterial infections at the following sites when amoxicillin resistant beta-lactamase producing strains are suspected as the cause. In other situations, amoxicillin alone should be considered. *Upper respiratory tract infections (including ENT)* e.g. recurrent tonsillitis, sinusitis, otitis media. *Lower respiratory tract infections* e.g. acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. *Urinary tract infections* e.g. cystitis, urethritis, pyelonephritis *Skin and soft tissue infections* e.g. cellulitis, animal bites. *Dental infections* e.g. severe dental abscess with spreading cellulitis. Susceptibility to *AUGMENTIN* will vary with geography and time (see *Pharmacological Properties, Pharmacodynamic* s for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary. Mixed infections caused by amoxicillin-susceptible organisms in conjunction with *AUGMENTIN* susceptible beta-lactamase-producing organisms may be treated with *AUGMENTIN* suspension 228mg/5ml and 457mg/5ml. These infections should not require the addition of another antibiotic resistant to beta-lactamases.
BRU08030027P	Foban Cream	Skin lesions primarily or secondarily infected with Staphylococcus or Streptococcus.

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BRU08030030P	Garasent 80mg Injection (2ml Amp)	Gentamicin is effective in treating many gram-negative infections and should be considered for treatment of the following conditions, when caused by susceptible organisms: urinary tract infections, bacteraemia, respiratory tract infections, infected wounds, burns complicated by sepsis.
BRU08030031P	Retrovir IV For Infusion 1%	*RETROVIR* I.V. for infusion is indicated for the short-term management of serious manifestations of Human Immunodeficiency Virus (HIV) infection in patients with Acquired Immune Deficiency Syndrome (AIDS), who are unable to take *RETROVIR* oral formulations. *RETROVIR* is indicated for use in HIV-positive pregnant women (over 14 weeks of gestation) and their newborn infants, as it has been shown to reduce the rate of maternal-foetal transmission of HIV (see *Pregnancy and Lactation*).

BRU08030034P	Zinacef Injection 750mg	*ZINACEF* is a bactericidal cephalosporin antibiotic which is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for the treatment of infections before the infecting organism has been identified or when caused by sensitive bacteria. Susceptibility to *ZINACEF* will vary with geography and time and local susceptibility data should be consulted where available (*see Pharmacological properties, Pharmacodynamics*). Indications include: – respiratory tract infections for example, acute exacerbation of chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess and post-operative chest infections – ear, nose and throat infections for example, sinusitis, tonsillitis, pharyngitis and otitis media – urinary tract infections for example, acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria – soft-tissue infections for example, cellulitis, erysipelas and wound infections – bone and joint infections for example, osteomyelitis and septic arthritis – obstetric and gynaecological infections, pelvic inflammatory diseases – gonorrhoea particularly when penicillin is unsuitable – other infections including septicaemia, meningitis and peritonitis – prophylaxis against infection in abdominal, pelvic, orthopaedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk from infection. Usually *ZINACEF* will be effective alone, but when appropriate it may be used in combination with an aminoglycoside antibiotic, or in conjunction with metronidazole (orally or by suppository or injection), especially for prophylaxis in colonic or gynaecological surgery. Where appropriate *ZINACEF* is effective when used prior to oral therapy with *ZINNAT* (cefuroxime axetil) in the treatment of pneumonia and acute exacerbations of chronic bronchitis.

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BRU08030037P	Zinnat Tablet 250mg	*ZINNAT* is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most β (beta)-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for the treatment of infections caused by susceptible bacteria. Susceptibility to *ZINNAT* will vary with geography and time, and it should be used in accordance with local official antibiotic prescribing guidelines and local susceptibility data. Indications include: – upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis – lower respiratory tract infections for example, pneumonia, acute exacerbations of chronic obstructive pulmonary disease – genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis – skin and soft tissue infections for example, furunculosis, pyoderma and impetigo – gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis Cefuroxime is also available as the sodium salt (*ZINACEF*) for parenteral administration. This permits the use of sequential therapy with the same antibiotic, when a change from parenteral to oral therapy is clinically indicated. Where appropriate *ZINNAT* is effective when used following initial parenteral *ZINACEF* (cefuroxime sodium) in the treatment of pneumonia and acute exacerbations of chronic obstructive pulmonary disease.
BRU08040040P	Retrovir Oral Solution	*RETROVIR* is indicated in combination with other anti-retroviral agents for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and children. *RETROVIR* is indicated for use in HIV-positive pregnant women and their newborn infants as it has been shown to reduce the rate of maternal-foetal transmission of HIV (see *Pregnancy and Lactation*).

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BRU08040041P	Zeffix Tablet 100mg	Indicated in the treatment of patient 16 years of age with chronic hepatitis B and evidence of hepatitis B virus (HBV) replication.
BRU08040043P	Zoraxin Suspension 200mg/5ml	Herpes Simplex virus infections of the skin and mucous membranes, including initial and recurrent genital herpes. Suppression (prevention of recurrences) of recurrent herpes simplex infections, in immunocompetent patients. Prophylaxis of herpes in immunocompromised patients. Herpes Zoster (shingles) infections. Early treatment of shingles with Aciclovir has a beneficial effect on pain and can reduce the incidence of post-herpetic neuralgia (zoster-associated pain).
BRU08040045P	Apalin Solution For Injection 500mg	1. Short-term management of serious infections due to susceptible strains of gram negative bacteria (see below for susceptible strains). 2. Treatment of staphylococcal infections: the use of Amikacin in the treatment of staphylococcal infection should be restricted to second line of defence rather than initial therapy and should be confined to patients suffering from severe infection caused by susceptible strains of staphylococcus who have failed to respond or who are allergic to other available antibiotics. 3. Treatment of neonatal sepsis when sensitivity testing indicates that other aminoglycosides cannot be used. In certain severe infections such as neonatal sepsis, concomitant therapy with a penicillin-type drug may be indicated because of the possibility of infections due to gram-positive organisms such as streptococci pneumococci. Clinical studies have shown Amikacin to be effective in the following infections when due to susceptible organisms; bacteraemia, septicaemia, neonatal sepsis, serious infections of the respiratory tract, bones and joints, and recurrent urinary tract infections. **Antibacterial activity**: Amikacin is active, in-vitro, against the following organisms (refer to PI).

BRU08040049P	Diflucan IV Infusion 2mg/ml (50ml)	Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. 1. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g., pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. 2. Systemic candidiasis, including candidemia, disseminated candidiasis and other forms of invasive candidal infections. These include infections of the peritoneum, endocardium, eye, and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 3. Mucosal candidiasis. These include oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of oropharyngeal candidiasis in patients with AIDS. 4. Genital candidiasis. Vaginal candidiasis, acute or recurrent, and prophylaxis to reduce the incidence of recurrent vaginal candidiasis (three or more episodes a year). Candidal balanitis. 5. Prevention of fungal infections in patients with malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy. 6. Dermatomycosis, including tinea pedis, tinea corporis, tinea cruris, tinea versicolor, and dermal *Candida* infections.

BRU08040050P	Sulperazon IM/IV 1g	*Monotherapy* Sulbactam/cefoperazone is indicated for the treatment of the following infections when caused by susceptible organisms: Respiratory Tract Infections (Upper and Lower) Urinary Tract Infections (Upper and Lower) Peritonitis, Cholecystitis, Cholangitis, and Other Intra-abdominal Infections Septicemia Meningitis Skin and Soft Tissue Infections Bone and Joint Infections Pelvic Inflammatory Disease, Endometritis, Gonorrhea, and Other Infections of the Genital Tract *Combination Therapy* Because of the broad spectrum of activity of sulbactam/cefoperazone, most infections can be treated adequately with this antibiotic alone. However, sulbactam/cefoperazone may be used concomitantly with other antibiotics if such combinations are indicated. If an aminoglycoside is used (see section 6.2 **Incompatibilities** - *Aminoglycosides*), renal function should be monitored during the course of therapy (see section 4.2 **Posology and Method of Administration** - *Use in Renal Dysfunction*).
BRU08040052P	Becarin Cream 2%	Treatment of fungal infections of skin and nails including cutaneous candidiasis, tinea corporis, tinea cruris, tinea pedis and tinea versicolor (pityriasis versicolor).
BRU08050053P	Pharmaniaga Aciclovir Tablet 400mg	Treatment and prophylaxis of herpes genitalis, treatment of herpes zoster, herpes simplex and varicella (chicken-pox).

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BRU08050054P	Pharmaniaga Cephalexin Capsule 250mg	Cephalexin is used to treat septicaemia, bone and joint infections, including burn wound infections and urinary tract infections caused by susceptible bacterial organisms. They are not effective in treating meningitis. Cephalexin is used as a possible alternative to the penicillins for staphylococcus and nonenterococcal streptococcal infections including pneumonia, bone and joint infection and bacterial endocarditis.
BRU08050060P	Unocef Injection 500mg (Vial)	Ceftriaxone is indicated for the treatment of the following infections when caused by pathogens sensitive to Ceftriaxone, e.g.: **Sepsis;** **Meningitis;** **Disseminated Lyme borreliosis** (early and late stages of the disease); **Abdominal infections** (peritonitis, infections of the biliary and gastrointestinal tracts); **Infections of the bones, joints, soft tissue, skin and of wounds;** **Infections in patients with impaired defence mechanisms;** **Renal and urinary tract infections;** **Respiratory tract infections**, particularly pneumonia, and ear, nose and throat infections; **Genital infections**, including gonorrhoea; And **perioperative prophylaxis** of infections.

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BRU08050061P	Unocef Injection 1000mg (Vial)	Ceftriaxone is indicated for the treatment of the following infections when caused by pathogens sensitive to Ceftriaxone, e.g.: **Sepsis;** **Meningitis;** **Disseminated Lyme borreliosis** (early and late stages of the disease); **Abdominal infections** (peritonitis, infections of the biliary and gastrointestinal tracts); **Infections of the bones, joints, soft tissue, skin and of wounds;** **Infections in patients with impaired defence mechanisms;** **Renal and urinary tract infections;** **Respiratory tract infections**, particularly pneumonia, and ear, nose and throat infections; **Genital infections**, including gonorrhoea; And **perioperative prophylaxis** of infections.
BRU08050066P	Beagenta Eye/Ear Drops	Beagenta eye/ear drops are indicated in the treatment of the following conditions:- ***Eye*** : Blepharitis, blepharoconjunctivitis, conjunctivitis, dacryocystitis, keratitis, keratconjunctivitis and acute meibomianitis caused by coagulase-negative and positive staphylococci, *Pseudomonas aeruginosa* , indole-positive and negative *Proteus species, Escherichia Coli, klebsiella pneumonia, Haemophilus influenzae, H. aegyptius, Enterobacter aerogenes, Moraxella lacunata* and *Neisseria species* . ***Ear*** : Mastoidectomy cavity infections, chronic suppurative otitis media, subcute purulent otitis media with tympanic membrane perforation and external otitis.

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BRU08050068P	Krisovin Tablet 500mg	Griseofulvin is administered by mouth in the treatment of infections caused by various species of Epidermophyton, Microsporum, and Trichophyton. It is generally given for such infections that involve the scalp, hair, nails and skin and which do not respond to topical treatment such as Tinea barbae, Tinea capitis, Tinea corporis, Tinea cruris, Tinea Pedis and Tinea unguium. Infections of the soles of the feet, the palms of the hands and toenails respond slowly.
BRU08050070P	Betacin Eye Ear Drop	Betacin eye/ear drops are indicated in the treatment of the following conditions: - ***Eye*** : Corticosteroid-responsive allergic and inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, corneal injuries, superficial punctuate keratitis, vernal keratoconjuctivitis and as an adjunct in the treatment of superficial ocular infections caused by susceptible organisms. Betacin eye/ear drops are indicated in the tropical treatment of bacterial blepharitis, blepharoconjunctivitis, bacterial conjunctivitis, bacterial keratitis and bacterial keratoconjunctivitis. ***Ear*** : Allergic otitis externa, infective otitis and other corticosteroid-responsive disorders of the external auditory meatus. Betacin eye/ear drops are indicated in the treatment of external ear canal infections caused by susceptible organisms.
BRU08050071P	Foban Ointment	Skin lesions primarily or secondarily infected with *Staphylococcus* or *Streptococcus* .
BRU08050072P	Fobancort Cream	Inflammatory dermatoses, psoriasis, where bacterial infection caused by Staphylococcus and Streptococcus are present or likely to occur.
BRU08050073P	Dezor Cream	Topical treatment of tinea corporis, tinea cruris, tinea pedis, pityriasis versicolor and cutaneous candidiasis.

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BRU08050074P	Dezor Shampoo	Treatment and prophylaxis of infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is involved, such as pityriasis versicolor (localized), serborrhoeic dermatitis and pityriasis capitis (dandruff).
BRU08060075P	Genta-Dex Eye Drops	Genta-Dex eye drops is indicated for the treatment of allergic and inflammatory conditions of the eye where there is superficial bacterial infection of the conjunctiva, cornea (without epithelial defect) and margin of eye lid. This includes conjunctivitis, keratitis and keratoconjunctivitis, corneal ulcers, blepharitis and blepharoconjunctivitis, acute meibomianitis and dacryocystitis. **N/B:** "To ensure that fungal infection has been eliminated before use of preparation."
BRU08060078P	Beapen VK Granules 125mg	Phenoxymethylpenicillin is used in the treatment and prophylaxis of infections caused by susceptible organisms, especially streptococci. It is used only for the treatment of mild to moderate infections and not for chronic, severe, or deep-seated infections. Specific indications for Phenoxymethylpenicillin include otitis media, pharyngitis or tonsilitis, primary and secondary prophylaxis of rheumatic fever, skin infections. Other indications include bacterial exarcebations of bronchitis, prophylaxis of diphtheria and bacterial endocarditis, erysipelas, gingivitis, scarlet fever and sinusitis.

BRU08060079P	Enoxin Tablet 500mg	Consideration should be given to official guidance on the appropriate use of antibacterial agents. **Uncomplicated and complicated infections caused by ciprofloxacin susceptible pathogens**. • Infections of respiratory tract: Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E.coli, Pseudomonas, Haemophilus, Moraxella catarrhalis, Legionella and Staphylococcus. • Infections of the middle ear (otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by Gram-negative organisms including Pseudomonas aeruginosa or by staphylococci. •Infections of the eyes • Infections of the kidneys and/or the efferent urinary tract. • Infections of the genital organs, including adnexitis, gonorrhea, prostatitis • Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or of the biliary tract, peritonitis) • Infections of the skin and soft tissue • Infections of the bones and joints • Sepsis • Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or have neutropenia) • Selective intestinal decontamination in immunosuppressed patients Prophylaxis of invasive infections due to Neisseria meningitidis. <u>Children and adolescents</u> Ciprofloxacin may be used in children for the second- and third-line treatment of complicated urinary tract infections and pyelonephritis due to Escherichia coli (age range applied in clinical studies: 1 – 17 years) and for the treatment of broncho-pulmonary infections of cystic fibrosis associated with Pseudomonas aeruginosa (age range applied in clinical studies: 5 – 17 years). Treatment should only be initiated after careful benefits/risk evaluation, due to possible adverse events related to joints and/or surrounding tissues.

		The clinical trials in children were performed in the indications listed above. For other indications clinical experience is limited. Inhalational anthrax (post-exposure) in adults and in children: To reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis.
BRU08060081P	Betagen Eye/Ear Drops	Betagen eye/ear drops are indicated in the treatment of the following conditions: **Eye**: Corticosteroids-responsive allergic and inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, corneal injuries, superficial punctuate keratitis, vernal keratoconjunctivitis and as adjunct in the treatment of superficial ocular infections caused by susceptible organisms. Topical treatment of blepharitis, blepharoconjunctivitis, conjunctivitis, keratitis, keratoconjunctivitis and acute meibomianitis. **Ear**: Allergic otitis externa, infective otitis and other corticosteroid-responsive disorders of the external auditory meatus. Betagen eye/ear drops are indicated in the treatment of mastoidectomy cavity infections, chronic suppurative otitis media, subacute purulent otitis media with tympanic membrane perforation and external otitis.
BRU08060083P	Eryson Granules 200mg/5ml	Bronchitis, enteritis, venereal diseases, diphtheria, Legionella infections, pertussis, pneumonia, sinusitis. Prophylaxis of surgical infections, endocarditis, pharyngitis, perinatal streptococcal infections, rheumatic fever. Alternative to tetracyclines in Lyme disease, chlamydial & rickettsial infections, severe acne. Otitis media, erythrasma, listeriosis, diphtheria, primary syphilis in patients allergy to penicillin.
BRU08060084P	Eryson Granules 400	Bronchitis, enteritis, venereal diseases, diphtheria, Legionella infections, pertussis, pneumonia, sinusitis. Prophylaxis of surgical infections, endocarditis, pharyngitis, perinatal streptococcal infections, rheumatic fever. Alternative to tetracyclines in Lyme disease, chlamydial & rickettsial infections, severe acne.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08060085P	Neo Cream 0.5% (w/w)	For skin infections, infected wounds and burns due to susceptible organisms. It is also used in surgical prophylaxis.
BRU08060086P	Foban Hydro Cream	Inflammatory dermatoses, including dermatitis, seborrhoeic dermatitis, allergic infantile dermatitis, eczema and acne where bacterial infection is present or likely to occur.
BRU08060087P	Foban Hydro Ointment	Inflammatory dermatoses, including dermatitis, seborrhoeic dermatitis, allergic infantile dermatitis, eczema and acne where bacterial infection is present or likely to occur.
BRU08060088P	Arava Tablet 10mg	Treatment of active rheumatoid arthritis in adult patients to improve physical function. Regarding use in patients recently pre-treated with DMARDs which are toxic for the liver (hepatotoxic) or for the blood (haematotoxic) and patients for whom substitution with another DMARD is planned. Active psoriatic arthritis.
BRU08060089P	Arava Tablet 20mg	Treatment of active rheumatoid arthritis in adult patients to improve physical function. Regarding use in patients recently pre-treated with DMARDs which are toxic for the liver (hepatotoxic) or for the blood (haematotoxic) and patients for whom substitution with another DMARD is planned. Active psoriatic arthritis.

BRU08070090P	Zinnat Suspension 125mg/5ml	*ZINNAT* is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most β (beta)-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for the treatment of infections caused by susceptible bacteria. Susceptibility to *ZINNAT* will vary with geography and time, and it should be used in accordance with local official antibiotic prescribing guidelines and local susceptibility data (See *Pharmacological properties, Pharmacodynamics*). **Indications include:** – upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis – lower respiratory tract infections for example, pneumonia, acute exacerbations of chronic pulmonary disease – genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis – skin and soft tissue infections for example, furunculosis, pyoderma and impetigo – gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis
BRU08070091P	Metronol 0.5% w/v Injection	Metronidazole 0.5% w/v Injection is indicated: (a) For treatment of anaerobic infections in patients (adults and children) for whom oral administration is not possible. (b) The prophylaxis of postoperative infections due to sensitive anaerobic bacteria particularly species of Bacteroides and anaerobic Streptococci, during abdominal, gynaecological gastrointestinal or colorectal surgery which carries a high risk of occurrence of this type of infection. The solution may also be used in combination with an antibiotic active against aerobic bacteria. (c) The treatment of severe intraabdominal and gynaecological infections in which sensitive anaerobic bacteria particularly Bacteriodes and anaerobic Streptococci have been identified or are suspected to be the cause **Note**: Metronidazole is inactive against aerobic or facultative anaerobic bacteria.

BRU08070092P	Eryson Tablet 250	Erythromycin has been used in the treatment of bronchitis, severe campylobacter enteritis, chancroid, gonorrhoea, diphtheria, erythrasma, legionnaire's disease and other legionella infections, neonatal conjunctivitis, pertusis, sinusitis, pneumonia (mycoplasma, streptococcal and atypical). Erythromycin is used as an alternative to penicillin in penicillin-allergic patients with various conditions including anthrax, the prophylaxis of endocarditis, leptospirosis, listeriosis, otitis media (usually with a sulphonamide such as sulphafurazole), pharyngitis, the prevention of perinatal streptococcal infections, rheumatic fever and infections in splenectomised patients, syphilis and patients in the early stages of Lyme disease, erythromycin may be employed as an alternative to a tetracycline. It is also used as an alternative to the tetracyclines in patients with chlamydial infections, Q fever, trench fever and turalaemia. Both oral and topical erythromycin may be employed in severe acne.
BRU08070094P	Ecocort Cream	Ecocort cream in all its dosages as indicated for the treatment of dermatomycoses complicated by inflammatory and/or pruritic manifestations of skin disorders.
BRU08070096P	Betamox Capsule 250mg	Amoxycillin indicated for the treatment of the following infections due to susceptible strains of sensitive organisms. Note: Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. However, in emergency cases where the causative organism has not been identified, therapy with amoxicillin may be useful. Clinical judgement will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results. **Skin and Skin structure**: Staphlyococcus, non-penicillinase producing; Streptococcus; *E. coli* . **Respiratory (Acute and Chronic)**: H. Influenzae, Streptococcus; S. pneumoniae; staphylococcus, non-penicillinase-producing; *E. coli* . **Genitourinary Tract (Complicated and uncomplicated, Acute and Chronic)**: *E. coli, P. mirabilis and S. faecalis* . **Gonorrhoea**: *N. gonorrhoea* (non-penicillinase producing). **Prophylaxis of endocarditis**: Amoxycillin may be used for the prophylaxis of bacterial endocarditis in individuals at particular risk, such as those with prosthetic heart valve or those who have previously had endocarditis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08070097P	Aprovel Tablet 300mg	Treatment of essential hypertension. Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300mg/day) in patients with type 2 diabetes and hypertension. In this population, Aprovel® reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).
BRU08070099P	Atacand Tablet 8mg	Treatment of hypertension. Treatment of patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction < 40%) as add-on therapy to ACE inhibitors or when ACE inhibitors are not tolerated.
BRU08070100P	Atacand Tablet 16mg	Treatment of hypertension. Treatment of patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction < 40%) as add-on therapy to ACE inhibitors or when ACE inhibitors are not tolerated.
BRU08080104P	Beavate Cream 0.1%	Beavate cream is indicated for the treatment of mild to moderate atopic dermatitis, contact dermatitis, mild mummular dermatitis, seborrheic, facial and dermatitis of the intertriginous areas; other mild to moderate inflammatory dermatoses and other forms of dermatitis; intertrigo, facial and intertriginous linchen planus, discoid lupus erythematous, polymorphous light eruption; anogenital pruritus, pruritus senilis, psoriasis, and for treatment during the inflammatory phase of xerosis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08080106P	Candazole Cream 1% w/w	Topical treatment of tinea pedis, tinea cruris, tinea corporis due to Trichophytes rubrum, Trichophyton mentagrophytes, Episermorphyton floccosum, and Microsporum canis; tinea versicolor due to Malassezia furfur; erythrasma candidiasis due to Candida albicans including cutaneous candidiasis, paronychia, external genital candidiasis and candidal balantis.
BRU08080107P	HOE Gentamicin Cream 0.1% w/w	Treatment of impetigo, erythema and other localised primary bacterial skin infection with a gram-negative component and also for secondary bacterial infections complicating other pre-existing dermatoses.
BRU08080109P	Unasyn Tablet 375mg	Sultamicillin is indicated for infections caused by susceptible micro-organisms. Typical indications are upper respiratory tract infections including sinustitis, otitis media and tonsillitis; lower respiratory tract infections including bacterial pneumonia and bronchitis; urinary tract infections and pyelonephritis; skin and soft tissue infections and gonococcal infections. Sultamicillin may also be indicated in patients requiring sulbactam/ ampicillin therapy following initial treatment with sulbactam/ampicillin IM/IV.

BRU08080115P	Vaxcel Cefuroxime-750mg Injection	*Respiratory tract infections* : Acute and chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess amd post-operative chest infection. *Ear, nose and throat infections:* Sinusitis, tonsillitis and pharyngitis. *Urinary tract infections* : Acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria. *Soft-tissue infections* : Cellulitis, erysipelas, peritonitis and wound infections. *Bone and Joint infections* : Osteomyelitis and septic arthritis. *Obstetric and gynaelogical infections* : Pelvic inflammatory diseases. *Gonorrhoea:* Particularly when penicillin is unsuitable. *Other infection* : Septicaemia and meningitis. *Prophylaxis* : Against infection in abdominal, pevic, orthopaedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk from infection.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08080116P	Vaxcel Ceftriaxone 1g Injection	Infections caused by pathogen sensitive of Ceftriaxone; - Sepsis; - Meningitis; - Disseminated Lyme borreliosis (early and late stages of the disease); - Abdominal infections (peritonitis, infections of the biliary and gastrointestinal tracts); - Infections of the bones, joints, soft tissue, skin and of wounds; - Infections in patients with impaired defence mechanisms; - Renal and urinary tract infections; - Respiratory tract infections, particularly pneumonia, and ear, nose and throat infections; - Genital infections, including gonorrhoea. - Perioperative prophylaxis of infections.
BRU08080117P	Axcel Fusidic Acid-B Cream	Inflammatory dermatoses where bacterial infection is present or likely to occur, i.e. atopic eczema, discoid eczema, stasis eczema, seborrhoeic dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis, discoid lupus erythematosus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08090118P	Verorab Injection	VERORAB is indicated for pre-exposure and post-exposure prophylaxis of rabies in all age groups. Verorab should be used according to official recommendations. Pre-exposure prophylaxis should be offered to subjects at high risk of contamination by the rabies virus. All those at permanent risk, such as the personnel of diagnostic, research or production laboratories working on the rabies virus, should be vaccinated. Vaccination is also recommended for the following categories: • chiropterologists and people regularly exposed to the bat rabies virus. • exposed professionals (veterinary personnel, laboratory personnel handling equipment that is contaminated or likely to be contaminated, slaughterhouse butchers, pound personnel, naturalists, taxidermists, gamekeepers, forest rangers, slaughterhouse personnel). • adults and children living in or travelling to enzootic areas.
BRU08090119P	Decocort Cream	Superficial fungal infection accompanied by inflammation, eczematous rash superinfected by fungus and/or gram positive bacteria.
BRU08090120P	Fobancort Ointment	Inflammatory dermatoses, psoriasis, where bacterial infection caused by Staphylococcus and Streptococcus are present or likely to occur.
BRU08090121P	Candacort Cream	Topical treatment of tinea pedis, tinea cruris, tinea corporis due to Trichophytes canis, tinea versicolor due to Malassezia furfur; and for cutaneous or external genital candidiasis due to Candida albicans when these dermal infections are accompanied by pronounced inflammatory symptoms. Thus Candacort is particularly indicated for the initial stages of treatment. Once the inflammatory symptoms have disappeared, treatment may be continued with Candazole* Cream, if preferred.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08090124P; BRU08090124PS2	Ciprobay® 200 Infusion Solution	Uncomplicated and complicated infections caused by ciprofloxacin sensitive pathogens: Infections of the respiratory tract In the treatment of outpatients with pneumonia due to Pneumococcus. Ciprofloxacin should not be used as first choice of drug. Ciprofloxacin can be regarded as an advisable treatment for Pneumonias caused by *Klebsiella, Enterobacter, Proteus, E.Coli, Pseudomonas, Haemophilus, Branhamella, Legionella* , and *Staphylococcus.* Infections of the middle ear (otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by gram negative organisms including *Pseudomonas* or by *Staphylococcus.* Infections of the eyes. Infections of the kidneys and/or the efferent urinary tract. Infections of the genital organs, including adnexitis, gonorrhoea, prostatitis. Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or of the biliary tract, peritonitis). Infections of the skin. Infections of bones and joints. Sepsis. Infections or imminent risk infection (prophylaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or have neutropenia). Selective intestinal decontamination in immunosuppressed patients.

BRU08090126P	Axcel Fusidic Acid Cream	Skin Infection caused by Staphylococci and other susceptible or Fusidic-sensitive organisms.
BRU08090127P	Axcel Fusidic Acid Ointment	Skin infection caused by Staphylococci, Streptococci, and other susceptible or sodium fusidate-sensitive organisms.

BRU08090128P	Vaxcel Ceftazidime-1g Injection	Ceftazidime is a bactericidal cephalosporin antibiotic which is resistant to most beta-lactamases and is active against a wide range of Gram-positive and Gram-negative bacteria and indicated for the treatment of single infections and for mixed infections caused by two or more susceptible organisms. It may be used for injections caused by organisms' resistant to other antibiotics including aminoglycosides and many cephalosphorins. <u>*Severe infections*</u> : For example, septicaemia, bacteraemia, peritonitis, meningitis, infection in immunosuppressed patients with haematological or solid malignancies, and in patients in intensive care units with specific problems e.g. infected burns. <u>*Respiratory tract infections*</u> : For example, pneumonia, broncho-pneumonia, infected pleurisy, empyema, lung abscess, infected bronchiectasis and in lung infections in patient with cystic fibrosis. <u>*Ear, nose and throat infections*</u> : For example, otitis media, malignant otitis externa, mastoiditis, sinusitis and other severe ear and throat infections. <u>*Urinary tract infections*</u> : For example, acute and chronic pyelonephritis, pyelitis, prostatitis, cystitis, urethritis (bacterial only), renal abscess and infections associated with bladder and renal stones. <u>*Skin and tissues infections*</u> : For example, erysipelas, abscesses, cellulitis, infected burns and wounds, mastitis, skin ulcers. <u>*Gastrointestinal biliary and abdominal infections*</u> : For example, cholangitis, cholecystitis, empyema of gall bladder, intra-abdominal abscesses, peritonitis, diverticulitis, post-partum and pelvic inflammatory conditions.

		<u>*Bone and joints infections*</u> : For example, osteitis, osteomyelitis, septic arthritis, infected bursitis. <u>*Dialysis*</u> : Infections associated with haemo- and peritoneal dialysis and with continuous ambulatory peritoneal dialysis (CAPD).
BRU08090129P	Axcel Miconazole Cream	Miconazole is used topically in the management of superficial candidiasis and fungal skin infections, such as: mucocutaneous candidiasis, dermatophytosis and pityriasis versicolor.
BRU08100134P	Decozol Cream	For treatment of tinea pedis (athlete's foot), tinea cruris and tinea corporis caused by Trichophyton rubrum, Trichophyton mentagrophytes and Epidermophyton floccosum, in the treatment of cutaneous candidiasis (moniliasis) and in the treatment of tinea versicolor.
BRU08100135P	Betamox Capsule 500mg	Amoxycillin indicated for the treatment of the following infections due to susceptible strains of sensitive organisms. Note: Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. However, in emergency cases where the causative organism has not been identified, therapy with amoxicillin may be useful. Clinical judgement will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results. **Skin and Skin structure**: Staphlyococcus, non-penicillinase producing; Streptococcus; *E. coli* . **Respiratory (Acute and Chronic)**: H. Influenzae, Streptococcus; S. pneumoniae; staphylococcus, non-penicillinase-producing; *E. coli* . **Genitourinary Tract (Complicated and uncomplicated, Acute and Chronic)**: *E. coli, P. mirabilis and S. faecalis* . **Gonorrhoea**: *N. gonorrhoea* (non-penicillinase producing). **Prophylaxis of endocarditis**: Amoxycillin may be used for the prophylaxis of bacterial endocarditis in individuals at particular risk, such as those with prosthetic heart valve or those who have previously had endocarditis.
BRU08100137P	Neo Deca Eye/Ear Drop	Acute steroid responsive inflammatory and allergic conditions with accompanying bacterial infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08100142P	Candazole Lotion	Topical fungal treatment of tinea corporis, tinea cruris, tinea pedis, tinea versicolor and cutaneous candidiasis.
BRU08100146NP	Silfazine Cream	As an adjunct for the prevention and treatment of wound sepsis in patients with second and third-degree burns.
BRU08110150P	Avaxim 160U Suspension For Injection In A Prefilled Syringe	This medicinal product is recommended for the prevention of infection caused by hepatitis A virus in adolescents from 16 years of age and in adults. Vaccination against viral hepatitis A is recommended for subjects at risks of exposure to hepatitis A virus including: • Non-immunised adolescents from 16 years of age and adults travelling in endemic areas, • Adults at risk of contamination through their work: nursery personnel, personnel in residential institutions and homes for handicapped children and young people, sewage and water treatment personnel, food industry and catering personnel, • Adolescents from 16 years of age and adults exposed to specific risk: haemophilia, multiple transfusion, IV drug dependency, homosexual practices. • Adolescents from 16 years of age and adults chronically infected by Hepatitis B virus. It does not protect against infection due to other types of hepatitis virus or to other known pathogens of the liver.
BRU08110151P	Aprovel 150mg Tablet	Treatment of essential hypertension. Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300mg/day) in patients with type 2 diabetes and hypertension. In this population, Aprovel® reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08110152P	Zovirax IV For Infusion 250mg	*ZOVIRAX* i.v. for infusion is indicated for the treatment of herpes simplex infections. *ZOVIRAX* i.v. for infusion is indicated for the prophylaxis of herpes simplex infections in immune-compromised patients. *ZOVIRAX* i.v. for infusion is indicated in the treatment of varicella zoster infections. *ZOVIRAX* i.v. for infusion is indicated for the treatment of herpes simplex infections in the neonate.
BRU08110153P	Axcel Acyclovir Cream 5% w/w	Treatment of herpes simplex virus infection of the skin including genital herpes and herpes labialis.
BRU08110154P	Axcel Erythromycin ES Tablet 400mg	Indicated in the treatment of infections caused by susceptible strains of designated organisms in the diseases listed below: upper and lower respiratory tract infections that are caused by *Streptococcus pyogenes* and *Streptococcus pneumoniae* . Pertussis (whooping cough) caused by *Bordetella pertussis* . Skin and soft tissue infections caused by *Streptococcus pyogenes* and *Streptococcus aureus* . Otitis media, erythrasma, listeriosis, dipheteria, primary syphilis in patients allergy to penicillin, prophylaxis of endocarditis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08110155P	Axcel Cephalexin-500 Capsule	Treatment of infections caused by susceptible bacteria: - Respiratory tract infections: acute and chronic bronchitis and infected bronchietasis. - Ear, nose and throat infections: otitis media, mastoiditis, sinusitis, follicular tonsillitis and pharyngitis. - Urinary tract infections: acute and chronic pyelonephritis, cystitis and prostatitis. - Prophylaxis of recurrent urinary tract infection. Gynaecological and obstetric infections. - Skin, soft tissue and bone infections. - Gonorrhoea (when Penicillin is not suitable) - Dental procedures: treatment of dental infections. As prophylaxis treatment for patients with heart disease undergoing dental treatment as an alternative to penicillin.
BRU08110156P	Axcel Erythromycin ES-200 Suspension	Indicated in the treatment of infections caused by susceptible strains of designated organisms in the diseases listed below: - Upper and lower respiratory tract infections that caused by *Streptococcus pyogenes* and *Streptococcus pneumoniae* . - Pertussis (whooping cough) caused by *Bordetella pertussis* . - Skin and soft tissue infections caused by *Streptococcus pyogenes* and *Streptococcus aureus* . - Otitis media, erythrasma, listeriosis, diphetheria, primary syphilis in patients allergy to penicillin, prophylaxis of endocarditis.
BRU08110159P	SW Miconazole Cream 2% w/w	For topical application in the treatment of tinea pedis, tinea cruris and tinea corporis caused by Trichophyton rubrum, Trichophyton mentagrophytes and Epidermophyton floccosum, in the treatment of cutaneous candidiasis and in the treatment of tinea versicolor.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08110162P	Cordarone Tablet 200mg	Cordarone® is indicated only for the treatment of severe rhythm disorders, not responding to therapy or when other treatments cannot be used: • Atrial rhythm disorders (conversion of fibrillation of flutter, and maintenance of sinus rhythm following conversion) • Nodal rhythm disorders • Ventricular rhythm disorders (life-threatening ventricular premature contractions, ventricular tachycardia salves, prevention of ventricular tachycardia attacks or ventricular fibrillation episodes) • Rhythm disorders associated with Wolff-Parkinson-White syndrome In view of its pharmaceutical properties, amiodarone is indicated in the above rhythm disorders especially when they are associated with an underlying heart disease (coronary insufficiency, heart failure).
BRU08110163P	CoAprovel 150/12.5mg Film-Coated Tablet	Treatment of essential hypertension. This fixed dose combination is indicated in patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.
BRU08120167P	Axcel Cephalexin 250mg Capsule	Treatment of infections caused by susceptible bacteria. Respiratory tract infections: acute and chronic bronchitis and infected bronchiectasis. Ear, nose and throat infections: otitis media, mastoiditis, sinusitis, follicular tonsillitis and pharyngitis. Urinary tract infections: acute and chronic pyelonephritis, cystitis and prostatitis. Prophylaxis of recurrent urinary tract infection: Gynaecological and obstetric infections. Skin, soft tissue and bone infections. Gonorrhoea (when penicillin is not suitable). Dental procedures: treatment of dental infections. As prophylaxis treatment for patients with heart disease undergoing dental treatment as an alternative to penicillin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08120168P	Axcel Cephalexin-125 Suspension	Treatment of infections caused by susceptible bacteria; - Respiratory Tract Infections: acute and chronic bronchitis and infected bronchiectasis. - Ear, nose and throat infections; otitis media, mastoiditis, sinusitis, follicular tonsillitis and pharyngitis. - Urinary Tract Infections: acute and chronic pyclonephritis, cystitis and prostitis. - Prophylaxis of recurrent urinary tract infection. - Gynaecological and obstetric infections. - Skin, soft tissue and bone infections. - Gonorrhea (when Penicillin is not suitable). - Dental procedures: treatment of dental infections. As prophylaxis treatment for patients with heart disease undergoing dental treatment as an alternative to penicillin.
BRU08120169P	Oxacil Capsule 250	Cloxacillin is used in the treatment of infections due to staphylococci-resistant to benzylpenicillin; it is also used for mixed streptococcal and staphylococcal infections when the staphylococcal are penicillin resistant. The following infections are indicated: Respiratory tract infection, Ear, Nose and Throat infection, Infected wounds, Septicaemia, Endocarditis, Staphylococcal enterocolitis. Osteomylitis. CLOXACILLIN is sometimes given with ampicillin for infection due to Beta-lactamase producing Gram-negative organisms since it may inhibit the destruction of ampicillin.
BRU08120170P	Hysone Cream 1% (w/w)	For relief of symptoms of acute and chronic skin dermatoses, e.g. Eczema, contact dermatitis psoriasis.
BRU08120173P	Ventolin Respirator Solution	VENTOLIN Respirator Solution is indicated for the treatment of acute severe asthma (status asthmaticus) and for routine management of chronic bronchospasm–unresponsive to conventional therapy.
BRU08120177P	Beprosalic Lotion	For the relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses which include psoriasis, chronic atopic dermatitis, neurodermatitis and sebarrhoeic dermatitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU08120180P	Zithromax Film-Coated Tablet 250mg	Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx; however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, azithromycin is indicated for the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated for the treatment of chancroid due to *Haemophilus ducreyi* and uncomplicated genital infections due to non-multiresistant *Neisseria gonorrhoeae* ; concurrent infection with *Treponema pallidum* should be excluded.
BRU09010181P	Unasyn IM/IV 0.75g	Sulbactam sodium/ampicillin sodium IM/IV is indicated for infections caused by susceptible microorganisms. Typical indications are upper and lower respiratory tract infections including sinusitis, otitis media and epiglottitis; bacterial pneumonias; urinary tract infections and pyelonephritis; intra-abdominal infections including peritonitis, cholecystitis, endometritis and pelvic cellulitis; bacterial septicemia; skin, soft tissue, bone and joint infections and gonococcal infections. Sulbactam sodium/ampicillin sodium IM/IV may also be administered peri-operatively to reduce the incidence of post-operative wound infections in patients undergoing abdominal or pelvic surgery, in which peritoneal contamination may be present. In termination of pregnancy or cesarean section, sulbactam sodium/ampicillin sodium IM/IV may be used prophylactically to reduce post-operative sepsis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09010182P	Unasyn IM/IV 3.0g	Sulbactam sodium/ampicillin sodium IM/IV is indicated for infections caused by susceptible microorganisms. Typical indications are upper and lower respiratory tract infections including sinusitis, otitis media and epiglottitis; bacterial pneumonias; urinary tract infections and pyelonephritis; intra-abdominal infections including peritonitis, cholecystitis, endometritis and pelvic cellulitis; bacterial septicemia; skin, soft tissue, bone and joint infections and gonococcal infections. Sulbactam sodium/ampicillin sodium IM/IV may also be administered peri-operatively to reduce the incidence of post-operative wound infections in patients undergoing abdominal or pelvic surgery, in which peritoneal contamination may be present. In termination of pregnancy or cesarean section, sulbactam sodium/ampicillin sodium IM/IV may be used prophylactically to reduce post-operative sepsis.
BRU09010183P	Vaxcel Ceftriaxone-500mg Injection	Infections caused by pathogen sensitive of Ceftriaxone; - Sepsis; - Meningitis; - Disseminated Lyme borreliosis (early and late stages of the disease); - Abdominal infections (peritonitis, infections of the biliary and gastrointestinal tracts); - Infections of the bones, joints, soft tissue, skin and of wounds; - Infections in patients with impaired defence mechanisms; - Renal and urinary tract infections; - Respiratory tract infections, particularly pneumonia, and ear, nose and throat infections; - Genital infections, including gonorrhea. - Perioperative prophylaxis of infections.

BRU09010186P	Plavix Tablet 75mg	***Secondary prevention of atherothrombotic events*** Clopidogrel is indicated in: • Adult patients suffering from myocardial infarction (from a few days until less than 35 days), ischemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. • Adult patients suffering from acute coronary syndrome: − Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA). - ST segment elevation acute myocardial infarction, in combination with ASA in patients undergoing percutaneous coronary intervention (including patients undergoing a stent placement) or medically treated patients eligible for thrombolytic/fibrinolytic therapy. ***In patients with moderate to high-risk Transient Ischemic Attack (TIA) or minor Ischemic Stroke (IS)*** Clopidogrel in combination with ASA is indicated in: - Adult patients with moderate to high-risk TIA (ABCD2[1] score ≥4) or minor IS (NIHSS[2] ≤3) within 24 hours of either the TIA or IS event. ***Prevention of atherothrombotic and thromboembolic events in atrial fibrillation*** In adult patients with atrial fibrillation who have at least one risk factor for vascular events, are not suitable for treatment with Vitamin K antagonists (VKA) and who have a low bleeding risk, clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09010187P	Symbicort Turbuhaler 160/4.5mcg Dose	**Asthma** Symbicort Turbuhaler is indicated for the treatment of asthma, to achieve overall asthma control, including the relief of symptoms and the reduction of the risk of exacerbations (see Section Posology and Method of Administration). **Note**: Symbicort (80/4.5 micrograms/inhalation) is not appropriate in patients with severe asthma. **Chronic Obstructive Pulmonary Disease (COPD)** Symbicort Turbuhaler is indicated in adults, aged 18 years and older, for the symptomatic treatment of patients with COPD with FEV1 < 70% predicted normal (post bronchodilator) and an exacerbation history despite regular bronchodilator therapy.
BRU09010188P	CoAprovel 300/12.5mg Film-Coated Tablet	Treatment of essential hypertension. This fixed dose combination is indicated in patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.
BRU09020207P	Beprosalic Ointment	For the relief of the inflammatory manifestation of hyperkeratotic and dry corticosteroid-responsive dermatoses such as: psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.
BRU09020208P	Beprogel Topical Solution	Suppression of skin diseases in which inflammation is a prominent feature, e.g. eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, dermatitis venenata, seborrhoeic dermatitis, neurodermatitis, psoriasis and intertrigo.
BRU09020209P	Cloderm Scalp Application	Psoriasis and recalcitrant eczemas of the scalp. Clobetasol is a highly-active topical corticosteroid which is indicated for use in short courses for conditions which do not respond satisfactorily to less active steroids.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09030213P	3TC Tablet 150mg	*3TC* , in combination with other anti-retroviral agents, is indicated for the treatment of HIV infected adults and children.
BRU09030214P	3TC Oral Solution 10mg/ml	*3TC,* in combination with other anti-retroviral agents, is indicated for the treatment of HIV infected adults and children.
BRU09030216P	Cordarone Injection 150mg/3ml	Serious rhythm disturbances when the oral route is not appropriate, namely: - Atrial arrhythmia, with rapid ventricular rhythm; - Wolf-Parkinson-White syndrome tachycardia; - Documented symptomatic and incapacitating ventricular arrhythmia. Cordarone® intravenous is to be used where a rapid response required or where oral administration is not possible.
BRU09030217PS1; BRU09030217PS2	Vastarel MR 35mg Tablet	Prophylactic treatment of episodes of angina pectoris. Adjuvant symptomatic treatment of vertigo and tinnitus. Adjuvant treatment of the decline in visual acuity and visual field disturbances presumably of vascular origin.
BRU09030219P	Cataflam 1.5% Oral Drops Suspension	Short-term treatment in the following acute conditions: - Post-traumatic and post-operative pain, inflammation and swelling, e.g. following dental or orthopaedic surgery. - As an adjuvant in several painful inflammatory infections of the ear, nose or thorat, e.g. pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09030223P	Crestor 20mg Tablet	Crestor (rosuvastatin calcium) is indicated as an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL cholesterol, ApoB, the total cholesterol: HDL-cholesterol ratio and triglycerides and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of Cardiovascular Events. In adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers such as an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease, Crestor is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, MI, unstable angina, or arterial revascularization) Crestor is indicated as an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia). Primary hypercholesterolaemia (Type IIa including heterozygous familial hypercholesterolaemia and severe non-familial hypercholesterolaemia) Combined (mixed) dyslipidemia (Type IIb) Homozygous familial hypercholesterolaemia where Crestor is used either alone or as an adjunct to diet and other lipid lowering treatment such as apheresis. Crestor is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels. Pediatric Patients 10 to 17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH): Adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesteroleamia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09030224P	Beprosone Ointment	Suppression of skin diseases in which inflammation is a prominent feature, e.g. eczema, infantile eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, neurodermatitis, psoriasis and intertrigo.
BRU09030225P	Beprosone Cream	Suppression of skin diseases in which inflammation is a prominent feature, e.g. eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, dermatitis venenata, seborrhoeic dermatitis, neurodermatitis, psoriasis and intertrigo.
BRU09030227P	Pocin H Ear Drop	Pocin H ear drops are indicated in the treatment of external ear canal infections and mastoidectomy cavity infections caused by susceptible organisms.
BRU09030228P	U-Closone Cream	All types of eczema and dermatitis, including atopic eczema, photodermatitis, otitis externa, primary irritant and allergic dermatitis, prurigo nodularis, seborrheic dermatitis and insect bite reactions. Maintenance between courses of more potent topical steroids in more resistant dermatoses.
BRU09040230P	Axcel Cefuroxime-250 Capsule	Lower respiratory tract infection, e.g. acute and chronic bronchitis and pneumonia. Upper respiratory tract infection e.g. ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis. Genitourinary tract infections, e.g. Pylonephritis, cystitis and urethritis. Skin and soft tissue infection e.g. Furunculosis, pyoderma and impetigo. Gonorrhoea, acute uncomplicated gonococcal urethritis and cervicitis.

BRU09040232P0.5gV; BRU09040232P0.5gS	Stamaril Vaccine	STAMARIL is indicated for active immunization against yellow fever in persons: • travelling to, passing through or living in an area where there is a persisting or periodical risk of yellow fever transmission • travelling to any country that requires an International Certificate of Vaccination for entry (which may or may not depend on the previous itinerary), • handling potentially infectious materials (e.g. laboratory personnel). See sections 4.2, 4.3 and 4.4 regarding the minimum age for vaccination of children under special circumstances and guidance for vaccination of other specific patient populations. See the regular updates related to obligations and recommendations for yellow fever vaccination on the dedicated site of the World Health Organisation (WHO) or on the official sites of local health authorities. In order to comply with vaccine regulations and to be officially recognised, yellow fever vaccines must be administered by a qualified and trained health professional in an approved WHO vaccination centre and registered on an International Certificate of Vaccination. The validity period of this Certificate is established according to International Health Regulations (IHR) recommendations, and starts 10 days after primary vaccination and immediately after revaccination.
BRU09040233P	Voltaren Suppository 25mg	Treatment of: • Inflammatory and degenerative forms of rheumatism; rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteo-arthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism. • Acute attacks of gout. • Painful post-traumatic and post-operative inflammation and swelling. • Primary dysmenorrhoea.

BRU09040234P	Tidact Capsule 150mg	Serious infections caused by susceptible anaerobic bacteria or strains of streptococci, pneumococci and staphylococci. Anaerobes: Serious respiratory tract infections such as empyema, anaerobic pneumonitis and lung abscess, serious skin and soft tissue infections; septicemia, intra-abdominal infections such as peritonitis and intra-abdominal abscess (typically resulting from anaerobic organisms' resident in the normal gastrointestinal tract); infections of the female pelvis and genital tract such as endometritis, non-gonococcal tubo-ovarian abscess, pelvic cellulitis and post-surgical vaginal cuff infection. Streptococci: Serious respiratory tract infections, serious skin and soft tissue infections. Staphylococci: Serious respiratory tract infections, serious skin and soft tissue infections. Pneumococci: Serious respiratory tract infections.
BRU09040235P	Voltaren 75mg/3ml Solution For Injection	**Intramuscular injection** Treatment of: • Exacerbations of inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism. • Acute attacks of gout. • Renal colic and biliary colic. • Post-traumatic and post-operative pain, inflammation and swelling. **Intravenous infusion** Treatment or prevention of post-operative pain in a hospital setting.

		A. FOR INTRAMUSCULAR ADMINISTRATION When oral therapy is not feasible and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, the intramuscular use of DEPO-MEDROL is indicated as follows: 1. ENDOCRINE DISORDERS Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance). Acute adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice, mineralocorticoid supplementation may be necessary, particularly when synthetic analogs are used). • Congenital adrenal hyperplasia • Hypercalcemia associated with cancer • Nonsuppurative thyroiditis

2. RHEUMATIC DISORDERS

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

• Post-traumatic osteoarthritis
• Epicondylitis
• Synovitis of osteoarthritis
• Acute nonspecific tenosynovitis
• Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
• Psoriatic arthritis
• Acute gouty arthritis
• Ankylosing spondylitis
• Acute and subacute bursitis

3. COLLAGEN DISEASES

During an exacerbation or as maintenance therapy in selected cases of:

• Systemic lupus erythematosus
• Systemic dermatomyositis (polymyositis)
• Acute rheumatic carditis

4. DERMATOLOGIC DISEASES

• Pemphigus
• Bullous dermatitis herpetiformis
• Severe erythema multiforme (Stevens-Johnson syndrome)
• Exfoliative dermatitis
• Mycosis fungoides

BRU09040237P	Depo-Medrol Sterile Aqueous Suspension 40mg/ml	5. ALLERGIC STATES Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in: • Chronic asthmatic respiratory disorders • Drug hypersensitivity reactions • Contact dermatitis • Urticarial transfusion reactions • Atopic dermatitis • Acute non-infectious laryngeal edema (epinephrine is the drug of first choice) • Serum sickness 6. OPHTHALMIC DISEASES Severe acute and chronic allergic and inflammatory processes involving the eye, such as: • Herpes zoster ophthalmicus • Iritis, iridocyclitis • Chorioretinitis • Diffuse posterior uveitis • Optic neuritis 7. GASTROINTESTINAL DISEASES To tide the patient over a critical period of the disease in: • Ulcerative colitis (systemic therapy) • Crohn's disease (systemic therapy)

8. RESPIRATORY DISEASES

• Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate anti-tuberculous chemotherapy
• Symptomatic sarcoidosis
• Berylliosis
• Loeffler's syndrome not manageable by other means
• Aspiration pneumonitis

9. HEMATOLOGICAL DISORDERS

• Acquired (autoimmune) hemolytic anemia
• Erythroblastopenia (RBC anemia)
• Secondary thrombocytopenia in adults
• Congenital (erythroid) hypoplastic anemia

10. NEOPLASTIC DISEASES

For palliative management of:
• Leukemias and lymphomas in adults
• Acute leukemia in children

11. EDEMATOUS STATES

To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

12. MISCELLANEOUS

• Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate anti-tuberculous chemotherapy
• Trichinosis with neurologic or myocardial involvement

		B. FOR INTRA-SYNOVIAL OR SOFT TISSUE ADMINISTRATION (including peri-articular and intrabursal) DEPO-MEDROL is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: • Synovitis of osteoarthritis • Epicondylitis • Rheumatoid arthritis • Acute and subacute bursitis • Post-traumatic osteoarthritis • Acute gouty arthritis **C. FOR INTRALESIONAL ADMINISTRATION** DEPO-MEDROL is indicated for intralesional use in the following conditions: • Keloids • Localized hypertrophic, infiltrated, inflammatory lesions of: Lichen planus, psoriatic plaques, granuloma annulare and lichen simplex chronicus (circumscribed neurodermatitis) • Discoid lupus erythematosus • Alopecia areata DEPO-MEDROL may also be useful in cystic tumors or an aponeurosis or tendon (ganglia). **D. FOR INTRARECTAL INSTILLATION** • Ulcerative colitis

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09040241P	Celebrex Capsule 200mg	For the management of acute pain in adults and for the treatment of primary dysmenorrhoea. Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. Relief of signs and symptoms of ankylosing spondylitis. For the management of low back.
BRU09040242P	Voltaren® SR Tablet 100mg	• Inflammatory and degenerative form of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis; • Painful syndromes of the vertebral column; • Non-articular rheumatism; • Painful post-traumatic and post-operative inflammation and welling; • Primary dysmenorrhoea.
BRU09040243P	T3 Mycin Gel	Indicated for the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea and pseudomembranous colitis, the physician should consider whether other agents are more appropriate.
BRU09040244P	Cloderm Cream	For short-term treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroids – responsive dermatoses.
BRU09040245NP	YSP Bisacodyl Suppositories 10mg	i) Constipation. ii) Bowel preparation for radiological procedures and surgery.
BRU09040246P	U-Closone Ointment	All types of eczema and dermatitis, including atopic eczema, photodermatitis, otitis externa, primary irritant and allergic dermatitis, prurigo nodularis, sebarrhoeic dermatitis and insect bite reactions. Maintenance between courses of more potent topical steroids in more resistant dermatoses.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09040247P	Nexium® IV 40mg	Nexium for injection and infusion is indicated for □ Gastric antisecretory treatment when the oral route is not possible, such as: o gastroesophageal reflux disease in patients with esophagitis and/or severe symptoms of reflux. o healing of gastric ulcers associate with NSAID therapy. o prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk. □ Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.
BRU09050249P	Vastarel 20mg Tablet	Trimetazidine is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies.
BRU09050250P	Coversyl Plus Tablet	Essential hypertension. Treatment should not be initiated with this combination.
BRU09050254P	Benosone Ointment	For the relief of the inflammatory manifestations of corticosteroid-responsive dermatoses e.g. eczema (atopic, infantile, nummular contact dermatitis, seborrhoeic dermatitis, neurodermatitis, solar dermatitis, exfoliative dermatitis, stasis dermatitis, dermatitis due to radiation), intertrigo, otitis externa, psoriasis and anogenital and senile pruritus.
BRU09050256P	H-Cort Ointment 1% w/w	Suppression of skin diseases in which inflammation is a prominent feature, e.g. eczema, infantile eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, neurodermatitis, psoriasis and intertrigo.
BRU09050257P	T3 Mycin Lotion	For the treatment of acne vulgaris.
BRU09050258P	Lobesol Cream	It is used for the short-term relief of the inflammatory and pruritic manifestations of moderate to severe corticosteroid–responsive dermatoses.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09060263P	Voltaren 50mg Tablets	• Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteo-arthritis and spondylarthritis • Painful syndromes of the vertebral column; • Non-articular rheumatism; • Acute attacks of gout; • Painful post-traumatic and postoperative inflammation and swelling; • Primary dysmenorrhoea.
BRU09060264P	Voltaren 12.5mg Suppositories	• Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteo-arthritis and spondylarthritis • Painful syndromes of the vertebral column; • Non-articular rheumatism; • Acute attacks of gout; • Painful post-traumatic and postoperative inflammation and swelling; • Primary dysmenorrhoea.
BRU09060265P	Voltaren 50mg Suppositories	• Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteo-arthritis and spondylarthritis • Painful syndromes of the vertebral column; • Non-articular rheumatism; • Acute attacks of gout; • Painful post-traumatic and postoperative inflammation and swelling; • Primary dysmenorrhoea.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09060266P	Benosone Cream	For the relief of the inflammatory manifestations of corticosteroid-responsive dermatoses e.g. eczema (atopic, infantile, nummular contact dermatitis, seborrhoeic dermatitis, neurodermatitis, solar dermatitis, exfoliative dermatitis, stasis dermatitis, dermatitis due to radiation), intertrigo, otitis externa, psoriasis and anogenital and senile pruritus.
BRU09060268P	SW Betamethasone Cream	It is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, e.g. psoriasis and allergic and inflammatory dermatitis.
BRU09060269P	Zorax Cream	Management of initial herpes genitalis and herpes simplex infections of the skin and mucous membranes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09060270P	Nexium Mups 20mg	Nexium MUPS tablets are indicated for: **Gastroesophageal Reflux Disease (GERD)** - treatment of erosive reflux esophagitis - long-term management of patients with healed esophagitis to prevent relapse - symptomatic treatment of gastroesophageal reflux disease (GERD) **In combination with an appropriate antibacterial therapeutic regimen for the eradication of *Helicobacter pylori* and** - healing of *Helicobacter pylori* associated duodenal ulcer and - prevention of relapse of peptic ulcers in patients with *Helicobacter pylori* associated ulcers **Patients requiring continued NSAID therapy** - healing of gastric ulcers associated with NSAID therapy - prevention of gastric and duodenal ulcers associated with NSAID therapy in patients at risk **Prolonged treatment after i.v. induced prevention of rebleeding of peptic ulcers.** **Treatment of Zollinger Ellison Syndrome**
BRU09060271P	Ebutol-100 Tablet	Treatment of pulmonary tuberculosis.

BRU09060272P	Neurontin Capsule 300mg	***Epilepsy*** Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 3 years and older. Safety and effectiveness for adjunctive therapy in pediatric patients younger than 3 years have not been established. ***Neuropathic pain*** Gabapentin is indicated for the treatment of neuropathic pain which includes diabetic neuropathy, postherpetic neuralgia and trigeminal neuralgia in adults aged 18 years and older. Safety and effectiveness in patients younger than 18 years have not been established.
BRU09060274P	Relenza® Rotadisks 5mg	**Treatment** Zanamivir is indicated for treatment of both influenza A and B in adults and children (aged 5 years and older). Treatment should commence as soon as possible but no later than forty-eight hours after the onset of the initial symptoms of infection (see Precautions for Use). **Prophylaxis** Zanamivir is indicated for prophylaxis of both influenza A and B in adults and children (aged 5 years and older). Vaccination remains the primary method of preventing and controlling influenza. Relenza is indicated for prophylaxis of infection due to influenza A and B viruses in circumstances where prophylaxis of healthy young adults is justified, such as a pandemic with a strain that is not included in the annual vaccine or when vaccine is unavailable. It is not recommended for routine prophylaxis against influenza infection.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09070275P	Unasyn IM/IV 1.5g	Sulbactam sodium/ampicillin sodium IM/IV is indicated for infections caused by susceptible microorganisms. Typical indications are upper and lower respiratory tract infections including sinusitis, otitis media and epiglottitis; bacterial pneumonias; urinary tract infections and pyelonephritis; intra-abdominal infections including peritonitis, cholecystitis, endometritis and pelvic cellulitis; bacterial septicemia; skin, soft tissue, bone and joint infections and gonococcal infections. Sulbactam sodium/ampicillin sodium IM/IV may also be administered peri-operatively to reduce the incidence of post-operative wound infections in patients undergoing abdominal or pelvic surgery, in which peritoneal contamination may be present. In termination of pregnancy or cesarean section, sulbactam sodium/ampicillin sodium IM/IV may be used prophylactically to reduce post-operative sepsis.
BRU09070279P	Salazopyrin® EN-Tabs	*Ulcerative colitis* In the treatment of mild to moderate ulcerative colitis and as adjunctive therapy in severe ulcerative colitis. For maintenance of remission in ulcerative colitis. *Chrohn's disease* In the treatment of active Crohn's disease, especially in patients with colonic involvement. *Rheumatoid arthritis*

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09070280P	Zyloric® 100mg Tablet	Allopurinol is indicated for reducing urate/uric acid formation in conditions where urate/uric acid deposition has already occurred (e.g. gouty arthritis, skin tophi, nephrolithiasis) or is a predictable clinical risk (e.g. treatment of malignancy potentially leading to acute uric acid nephropathy). The main clinical conditions where urate/uric acid deposition may occur are: • idiopathic gout; • uric acid lithiasis; • acute uric acid nephropathy; • neoplastic disease and myeloproliferative disease with high cell turnover rates, in which high urate levels occur either spontaneously, or after cytotoxic therapy; • certain enzyme disorders which lead to overproduction of urate, for example; − Hypoxanthine guanine phosphoribosyltransferase including Lesch-Nyhan syndrome; − glucose-6-phosphatase including glycogen storage disease; − phosphoribosylpyrophosphate synthetase; − phosphoribosylpyrophosphate amidotransferase; − adenine phosphoribosyltransferase; Allopurinol is indicated for the management of 2, 8-dihydroxyadenine (2, 8-DHA) renal stones related to deficient activity of adenine phosphoribosyltransferase. Allopurinol is indicated for the management of recurrent mixed calcium oxalate renal stones in the presence of hyperuricosuria, when fluid, dietary and similar measures have failed.
BRU09070281P	Orrepaste 0.1% w/w	Adjunctive treatment for temporary relief of symptoms associated with oral inflammatory lesions and ulcerative lesions resulting from trauma.
BRU09070282P	SW Hydrocortisone Cream 1% w/w	It is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09070283P	Xanax™ 0.25mg Tablet	Alprazolam is indicated for the treatment of: **● Anxiety states (anxiety neuroses)** Symptoms which occur in such patients include anxiety, tension, agitation, insomnia, apprehension, irritability and/or autonomic hyperactivity resulting in a variety of somatic complaints. **● Mixed anxiety-depression** Symptoms of both anxiety and depression occur simultaneously in such patients. **● Neurotic or reactive depression** Such patients primarily exhibit a depressed mood or a pervasive loss of interest or pleasure. Symptoms of anxiety, psychomotor agitation and insomnia are usually present. Other characteristics include appetite disturbances, changes in weight, somatic complaints, cognitive disturbances, decreased energy, feeling of worthlessness or guilt, or thoughts of death or suicide. **● Anxiety states, mixed anxiety-depression, or depression associated with other diseases** Such as the chronic phase of alcohol withdrawal and functional or organic disease, particularly certain gastrointestinal, cardiovascular or dermatological disorders. **● Panic related disorders** Alprazolam is indicated in the treatment of panic disorder with or without some phobic avoidance. Alprazolam is also indicated for the blocking or attenuation of panic attacks and phobias in patients who have agoraphobia with panic attacks. The effectiveness of alprazolam in the treatment of anxiety, anxiety associated with depression and neurotic (reactive) depression for long-term use exceeding six months has not been established by systematic clinical trials; however, patients with panic-related disorders have been effectively treated for up to eight months. The physician should periodically reassess the usefulness of the drug for the individual patient.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09070284P	Nexium Mups 40mg	Nexium MUPS tablets are indicated for: **Gastroesophageal Reflux Disease (GERD)** - treatment of erosive reflux esophagitis - long-term management of patients with healed esophagitis to prevent relapse - symptomatic treatment of gastroesophageal reflux disease (GERD) **In combination with an appropriate antibacterial therapeutic regimen for the eradication of *Helicobacter pylori* and** - healing of *Helicobacter pylori* associated duodenal ulcer and - prevention of relapse of peptic ulcers in patients with *Helicobacter pylori* associated ulcers **Patients requiring continued NSAID therapy** - healing of gastric ulcers associated with NSAID therapy - prevention of gastric and duodenal ulcers associated with NSAID therapy in patients at risk **Prolonged treatment after i.v. induced prevention of rebleeding of peptic ulcers.** **Treatment of Zollinger Ellison Syndrome**

BRU09070286P	Xanax™ 0.5mg Tablet	Alprazolam is indicated for the treatment of: **● Anxiety states (anxiety neuroses)** Symptoms which occur in such patients include anxiety, tension, agitation, insomnia, apprehension, irritability and/or autonomic hyperactivity resulting in a variety of somatic complaints. **● Mixed anxiety-depression** Symptoms of both anxiety and depression occur simultaneously in such patients. **● Neurotic or reactive depression** Such patients primarily exhibit a depressed mood or a pervasive loss of interest or pleasure. Symptoms of anxiety, psychomotor agitation and insomnia are usually present. Other characteristics include appetite disturbances, changes in weight, somatic complaints, cognitive disturbances, decreased energy, feeling of worthlessness or guilt, or thoughts of death or suicide. **● Anxiety states, mixed anxiety-depression, or depression associated with other diseases** Such as the chronic phase of alcohol withdrawal and functional or organic disease, particularly certain gastrointestinal, cardiovascular or dermatological disorders. **● Panic related disorders** Alprazolam is indicated in the treatment of panic disorder with or without some phobic avoidance. Alprazolam is also indicated for the blocking or attenuation of panic attacks and phobias in patients who have agoraphobia with panic attacks. The effectiveness of alprazolam in the treatment of anxiety, anxiety associated with depression and neurotic (reactive) depression for long-term use exceeding six months has not been established by systematic clinical trials; however, patients with panic-related disorders have been effectively treated for up to eight months. The physician should periodically reassess the usefulness of the drug for the individual patient.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09070287P	Zolterol S/R Tablet 100mg	Indicated for the chronic therapy of the following conditions: musculoskeletal and joint disorders such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and spondylarthritis; peri-articular disorders such as bursitis and tendinitis; non-articular rheumatism; painful syndromes of the vertebral column; soft tissue disorders such as sprains and strains; and painful post-operative and post-traumatic inflammation and swelling.
BRU09070292P	Clotrimazole Cream 1% w/w	For treatment of candidiasis, tinea and pityriasis versicolor, yeasts, moulds, erythrasma and other fungal infection.
BRU09080296P	Epilim Intravenous 400mg/Vial	The treatment of epileptic patients who would normally be maintained on oral sodium valproate, and for whom oral therapy is temporarily not possible.
BRU09080298P	Ebutol-400 Tablet	It is indicated for the treatment of pulmonary tuberculosis.
BRU09080300PS1; BRU09080300PS2	Diamicron MR Tablet 30mg	Non-insulin dependent diabetes (type 2) in adults, when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose levels.
BRU09080301P	Deltasolone Tablet 5mg	It is indicated for primary or secondary adrenocortical insufficiency, rheumatic disorders, collagen diseases (systemic lupus erythematosus), dermatologic diseases (pemphigus, severe psoriasis, severe seborrheic dermatitis), bronchial asthma, ophthalmic diseases (eye inflammation, herpes zoster ophthalmicus, allergic conjunctivitis), hematologic disorders, neoplastic diseases (leukemias), edematous states and gastrointestinal diseases ulcerative colitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09080302P	Sunprox-275 Tablet	Naproxen Sodium is indicated in the relief of mild to moderate pain and for the treatment of primary dysmenorrheal. It is also indicated for the treatment of the rheumatoid arthritis, osteoarthritis, juvenile arthritis, ankylosing spondylitis, tendinitis and bursitis and acute gout.
BRU09080304P	Prednisolone 1mg Tablet	Prednisolone is a synthetic corticosteroid with predominantly glucocorticoid activity. It allows for a greater margin of safety than more potent agents. It is used for its anti-inflammatory and immuno-suppressant glucocorticoid activity. It is indicated for allergic disorders such as bronchial asthma and allergic skin conditions, blood disorders, including auto-immune haemolytic anaemia and idiopathic thrombocytopenic purpura, selected collagen and rheumatic disorders, connective tissue disorders such as arthritis and system lupus erythematosus, gastrointestinal disorders, hepatic disorders, neuromuscular disorders, selected ocular disorders, renal disorders and severe skin disorders.
BRU09080305NP	Poro Suppository 250mg	For the symptomatic relief of fever and pain (headache, muscle ache) associated with common cold.
BRU09080308P	Atrovent N 20µg/Puff Metered Dose Inhaler	ATROVENT® is indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis, emphysema and asthma.
BRU09080309P	Fenagesic Capsule 250mg	Mefenamic acid is indicated for the treatment of primary dysmenorrhoea and the relief of moderate pain when therapy will not exceed one-week.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09080311P	Carinox Capsule	CARINOX capsules are indicated for the relief of symptoms associated with allergic rhinitis and the common cold including nasal congestion, sneezing, rhinorrhea, pruritus and lacrimation.
BRU09090313P	Typhim Vi Single Dose	Prevention of typhoid fever in adults and in children over 2 years of age, and especially: travellers to endemic areas, migrants, health care professionals and military personnel.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09090314P	Crestor 10mg Tablet	Crestor (rosuvastatin calcium) is indicated as an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL cholesterol, ApoB, the total cholesterol: HDL-cholesterol ratio and triglycerides and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of Cardiovascular Events. In adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers such as an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease, Crestor is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, MI, unstable angina, or arterial revascularization) Crestor is indicated as an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia). Primary hypercholesterolaemia (Type IIa including heterozygous familial hypercholesterolaemia and severe non-familial hypercholesterolaemia) Combined (mixed) dyslipidemia (Type IIb) Homozygous familial hypercholesterolaemia where Crestor is used either alone or as an adjunct to diet and other lipid lowering treatment such as apheresis. Crestor is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels. Pediatric Patients 10 to 17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH): Adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesteroleamia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09090317P	Voltaren® SR 75 Tablet	Treatment of: • Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism. • Painful post-traumatic and post-operative inflammation and swelling; • Primary dysmenorrhoea.
BRU09090322P	Actilyse® Treatment-Set	1. **Thrombolytic treatment in acute myocardial infarction (AMI).** • 90 minutes (accelerated) dose regimen (see section 4.2 Posology and administration): for patients in whom treatment can be started within 6 hours of symptom onset; • 3 hours dose regimen (see section 4.2 Posology and administration): for patients in whom treatment can be started between 6 - 12 hours after symptom onset. ACTILYSE has proven to reduce 30-day-mortality in patients with acute myocardial infarction. 2. **Thrombolytic treatment in acute massive pulmonary embolism with haemodynamic instability (PE).** The diagnosis should be confirmed whenever possible by objective means such as pulmonary angiography or non-invasive procedures such as lung scanning. There are no clinical trials on mortality and late morbidity related to pulmonary embolism. 3. **Thrombolytic treatment of acute ischaemic stroke (AIS).** within 4.5 hours from last known well and after exclusion of intracranial haemorrhage.
BRU09090324P	Trenlin SR Tablet 400mg	Pentoxifylline is used in the treatment of peripheral occlusive arterial disease and arteriovenous disorders (e.g. intermittent claudication or rest pain) and trophic disturbances (e.g. gangrene and leg ulcers). It is also used in cerebrovascular disorders (sequel to cerebral arteriosclerosis such as difficulties in concentration, vertigo, impairment of memory).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09090325NP	Paratab Tablet 500mg	Paracetamol is usually used in the relief of fever, colds and flu, earaches, headaches and teething. It is also useful as an analgesic and antipyretic in bacterial or viral infections.
BRU09090327P	Metalyse Injection 10,000 Units	METALYSE® is indicated for the thrombolytic treatment of acute myocardial infarction (AMI). Treatment should be initiated as soon as possible after symptom onset.
BRU09090329P	Exforge Tablet 5mg/80mg	Treatment of essential hypertension. Exforge is indicated in patients whose blood pressure is not adequately controlled by monotherapy. Exforge is indicated for the initial treatment of hypertension. The choice of Exforge for initial treatment should be based on an assessment of the potential benefits and risks.
BRU09100331P	Cloderm Ointment 0.05% w/w	For short-term treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroids – responsive dermatoses.
BRU09100332P	H-Cort Cream	Supression of skin disease in which inflammation is a prominent feature e.g. eczema, infantile eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, neurodermatitis, psoriasis and intertrigo.
BRU09100334P	Prelone Syrup 3mg/5ml	It is indicated for primary or secondary adrenocortical insufficiency, rheumatic disorders, collagen diseases (systemic lupus erythematosus), dermatologic diseases (pemphigus, severe psoriasis, and severe seborrheic dermatitis), ophthalmic diseases (eye inflammation, herpes zoster ophthalmicus, allergic conjunctivitis), hematologic disorders, neoplastic diseases (leukemias), edematous states and gastrointestinal diseases ulcerative colitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09100335P	Ventolin Nebules 2.5mg	Salbutamol is a selective beta$_2$-adrenoceptor agonist. At therapeutic doses it acts on the beta$_2$-adrenoceptors of bronchial muscle, with little or no action on the heart. With its fast onset of action, it is particularly suitable for the management and prevention of attack in asthma. Bronchodilators should not be the only or the main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment as death may occur. Patients with severe asthma have constant symptoms and frequent exacerbations, with limited physical capacity, and PEF values below 60% predicted at baseline with greater than 30% variability, usually not returning entirely to normal after a bronchodilator. These patients will require high dose inhaled (e.g >1mg/day beclomethasone dipropionate) or oral corticosteroid therapy. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision. Routine management of chronic bronchospasm - unresponsive to conventional therapy. Treatment of acute severe asthma (status asthmaticus).
BRU09100336NP	Sunquadin Lozenges	It is indicated in the treatment of infections of the mouth and throat.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09100337P	Zoloft Tablet 50mg	Sertraline is indicated for the treatment of symptoms of depression, including depression accompanied by symptoms of anxiety, in patients with or without a history of mania. Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of depression or recurrence of further depressive episodes. Sertraline is indicated for the treatment of obsessive-compulsive disorder (OCD). Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of OCD. Sertraline is indicated for the treatment of panic disorder, with or without agoraphobia. Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of panic disorder. Sertraline is indicated for the treatment of post-traumatic stress disorder (PTSD). Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of PTSD. Sertraline is indicated for the treatment of social phobia (social anxiety disorder). Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of social phobia.
BRU09100338NP	Uphamol 250 Suspension (Fruity)	Relieves fever, pain, discomforts of teething, headache, toothache, earache, common cold, influenza and post vaccination reactions.

BRU09100339P	Xanax™ 1mg Tablet	Alprazolam is indicated for the treatment of: **● Anxiety states (anxiety neuroses)** Symptoms which occur in such patients include anxiety, tension, agitation, insomnia, apprehension, irritability and/or autonomic hyperactivity resulting in a variety of somatic complaints. **● Mixed anxiety-depression** Symptoms of both anxiety and depression occur simultaneously in such patients. **● Neurotic or reactive depression** Such patients primarily exhibit a depressed mood or a pervasive loss of interest or pleasure. Symptoms of anxiety, psychomotor agitation and insomnia are usually present. Other characteristics include appetite disturbances, changes in weight, somatic complaints, cognitive disturbances, decreased energy, feeling of worthlessness or guilt, or thoughts of death or suicide. **● Anxiety states, mixed anxiety-depression, or depression associated with other diseases** Such as the chronic phase of alcohol withdrawal and functional or organic disease, particularly certain gastrointestinal, cardiovascular or dermatological disorders. **● Panic related disorders** Alprazolam is indicated in the treatment of panic disorder with or without some phobic avoidance. Alprazolam is also indicated for the blocking or attenuation of panic attacks and phobias in patients who have agoraphobia with panic attacks. The effectiveness of alprazolam in the treatment of anxiety, anxiety associated with depression and neurotic (reactive) depression for long-term use exceeding six months has not been established by systematic clinical trials; however, patients with panic-related disorders have been effectively treated for up to eight months. The physician should periodically reassess the usefulness of the drug for the individual patient.
BRU09100340P	Pontalon Capsule	For the relief of mild, moderate pain including muscular, traumatic and dental pain, headache, postoperative and postpartum pain, and dysmenorrhoea.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09100343P	Neurontin 600mg Tablet	***Epilepsy*** Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 3 years and older. Safety and effectiveness for adjunctive therapy in pediatric patients younger than 3 years have not been established (see Section **4.2 Posology and Method of Administration**: ***Epilepsy*** : *Pediatric patients aged 3 to 12 years*). ***Neuropathic pain*** Gabapentin is indicated for the treatment of neuropathic pain which includes diabetic neuropathy, postherpetic neuralgia and trigeminal neuralgia in adults aged 18 years and older. Safety and effectiveness in patients younger than 18 years have not been established.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09100345P	Lipitor™ 40mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD) such as age, smoking, hypertension, low HDL-C, or a family history of early CHD, LIPITOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, LIPITOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: - LDL-C remains ≥190 mg/dL or - LDL-C remains ≥160 mg/dL and • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient
BRU09100346P	Suniton Tablet	Tension headache, dysmenorrhea, muscular pains.
BRU09100347P	SCMC Plus Syrup 250mg/5mL	Reduction of sputum viscosity to facilitate expectoration and evacuation.
BRU09100348NP	Glyprin Tablet	Glyprin is indicated for conditions where modification of platelet behaviour is considered beneficial, including transient ischaemic attacks, secondary prevention of myocardial infarction and for prophylaxis against stroke, vascular occlusion and deep vein thrombosis.
BRU09110350P	Lantus® Solostar® 100 Units/ml	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09110354P	Lipitor™ 10mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD) such as age, smoking, hypertension, low HDL-C, or a family history of early CHD, LIPITOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, LIPITOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: - LDL-C remains ≥190 mg/dL or - LDL-C remains ≥160 mg/dL and • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient
BRU09110359P	Allavin Expectorant	For cough and complications associated with hypersensitivity and allergic manifestation of respiratory tract illness e.g. common cold, flu and bronchitis.
BRU09110361NP	Uphamol 500 Tablet	For relief of pain, headache and fever.
BRU09110362P	Carin Tablet 10mg	Loratadine is indicated for the relief of symptoms with allergic rhinitis e.g. sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. It is also indicated for the relief of signs and symptoms of chronic urticaria and other allergic dermatological disorders.
BRU09120367P	Dilantin 100mg Capsule	Clinical evidence indicates phenytoin is effective in controlling epilepsy, particularly of the generalised tonic-clonic type (grand mal) and psychomotor seizures. It will prevent or greatly decrease the incidence and severity of convulsive seizures in a substantial percentage of cases, and patients exhibit little tendency to become resistant to treatment.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09120369P	Oral Aid Lotion	Oral Aid Lotion is an anaesthetic, antibacterial and anti-inflammatory agent which is used in mouth infection or oral lesions. It heals and relieves pain and discomfort in acute and chronic lesions of the gum, palate, cheek and tongue.
BRU09120375P	Natrilix® SR Tablet	Natrilix SR is indicated in essential hypertension in adults.
BRU09120376NP	Poro Suppository 125mg	For the symptomatic relief of fever and pain (headache, muscle ache) associated with common cold.
BRU09120377P	Vascor 40mg Film-Coated Tablet	Simvastatin is used for primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia or combined (mixed) hyperlipidaemia in patients who have not responded to diet and appropriate measures; to reduce the incidence of clinical coronary events and slow progression of coronary atherosclerosis in patients with coronary heart disease.
BRU09120378P	Chloramine Tablet 4mg	Chlorpheniramine is used for the prophylactic and symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods and sneezing and rhinorrhoea associated with the common cold. It is also indicated for the symptomatic relief of pruritus associated with allergic reactions and of mild, uncomplicated allergic skin manifestations of urticarial and angioedema, in dermatographism, and in urticaria associated with transfusions. It is used as adjunctive therapy to epinephrine and other standard measures for anaphylactic reactions after the acute manifestations have been controlled, and to ameliorate the allergic reactions to blood or plasma.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09120379P	Covastin Film-Coated Tablet 10mg	**Covastin** is used when the response to a saturated fat and cholesterol-restricted diet and other non-pharmacological measures alone has been inadequate. ***Coronary heart disease*** In patients with coronary heart disease and hypercholesterolemia, **Covastin** is indicated to: • Reduce the risk of total mortality by reducing coronary death. • Reduce the risk of non-fatal myocardial infarction. • Reduce the risk for undergoing myocardial revascularization procedures (coronary artery bypass grafting and percutaneous transluminal coronary angioplasty). • Slow the progression of coronary atherosclerosis, including reducing the development of new lesions and new total occlusions. ***Hyperlipidemia*** **Covastin** is indicated as an adjunct to diet for reduction of elevated total-cholesterol, LDL-C, apolipoprotein B (Apo B), and TG in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate. **Covastin** also raises HDL-C and therefore lowers the LDL/HDL and total cholesterol/HDL ratios.
BRU09120380P	Glucoxit Tablet 500mg	Metformin is indicated in non-insulin dependent diabetics mellitus (NIDDM) patients to control hyperglycaemia that cannot be controlled by diet management,exercise or weight reduction. It can be used a monotherapy or as an adjunct to sulfonylureas. Caution and clinical judgement should be used when combining Metformin with maximum doses sulfonylureas for treating non-obese NIDDM patients who clearly are not responding to the sulfonylureas when insulin may be the preferred treatment.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU09120381PS2	Co-Diovan 80/12.5mg Film-Coated Tablets	Treatment of hypertension. Co-Diovan is indicated for the treatment of hypertension in patients whose blood pressure is not adequately controlled by monotherapy. These fixed dose combinations should be used as second-line therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10010384P	Zyloric 300mg Tablet	Allopurinol is indicated for reducing urate/uric acid formation in conditions where urate/uric acid deposition has already occurred (e.g. gouty arthritis, skin tophi, nephrolithiasis) or is a predictable clinical risk (e.g. treatment of malignancy potentially leading to acute uric acid nephropathy). The main clinical conditions where urate/uric acid deposition may occur are: • idiopathic gout; • uric acid lithiasis; • acute uric acid nephropathy; • neoplastic disease and myeloproliferative disease with high cell turnover rates, in which high urate levels occur either spontaneously, or after cytotoxic therapy; • certain enzyme disorders which lead to overproduction of urate, for example; − Hypoxanthine guanine phosphoribosyltransferase including Lesch-Nyhan syndrome; − glucose-6-phosphatase including glycogen storage disease; − phosphoribosylpyrophosphate synthetase; − phosphoribosylpyrophosphate amidotransferase; − adenine phosphoribosyltransferase; Allopurinol is indicated for the management of 2, 8-dihydroxyadenine (2, 8-DHA) renal stones related to deficient activity of adenine phosphoribosyltransferase. Allopurinol is indicated for the management of recurrent mixed calcium oxalate renal stones in the presence of hyperuricosuria, when fluid, dietary and similar measures have failed.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10010386PS2	Atrovent Unit Dose Vial 0.5mg/2ml	ATROVENT® is indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. ATROVENT® is indicated, when used concomitantly with inhaled beta-agonists in the treatment of acute bronchospasm associated with chronic obstructive pulmonary disease including chronic bronchitis and asthma.
BRU10010387NP	Aspirin EC Tablet 100mg	For prophylaxis of myocardial infarction and strokes in susceptible patients by inhibition of platelet aggregation.
BRU10010388P	Exforge Tablet 5mg/160mg	Treatment of essential hypertension. Exforge is indicated in patients whose blood pressure is not adequately controlled by monotherapy. Exforge is indicated for the initial treatment of hypertension. The choice of Exforge for initial treatment should be based on an assessment of the potential benefits and risks.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10010391PS2	Diovan 80mg Tablet	**Hypertension** Treatment of hypertension. **Heart failure** Treatment of heart failure (NYHA class II-IV) in patients receiving usual therapy (such as diuretics, digitalis) who are intolerant to ACE inhibitors. Diovan improves morbidity in these patients, primarily via reduction in hospitalization for heart failure. Diovan also slows the progression of heart failure, improves NYHA functional class, ejection fraction and signs and symptoms of heart failure and improves quality of life versus placebo. **Post-myocardial infarction** Diovan is indicated to improve survival following myocardial infarction in clinically stable patients with signs, symptoms or radiological evidence of left ventricular failure and/or with left ventricular systolic dysfunction.
BRU10010392PS2	Co-Diovan 160/25mg Film-Coated Tablets	Treatment of hypertension. Co-Diovan is indicated for the treatment of hypertension in patients whose blood pressure is not adequately controlled by monotherapy. These fixed dose combinations should be used as second-line therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10010393P	Chloramine Syrup 4mg/5ml	Chlorpheniramine is used for the prophylactic and symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods and sneezing and rhinorrhoea associated with the common cold. It is also indicated for the symptomatic relief of pruritus associated with allergic reactions and of mild, uncomplicated allergic skin manifestations of urticarial and angioedema, in dermatographism, and in urticaria associated with transfusions. It is used as adjunctive therapy to epinephrine and other standard measures for anaphylactic reactions after the acute manifestations have been controlled, and to ameliorate the allergic reactions to blood or plasma.
BRU10010397P	Metformin Tablet 500mg	It is used only in the treatment of maturity on-set diabetes mellitus not responsive to diet alone or diet plus the treatment with a sulphonylurea.
BRU10010399P	Seretide Accuhaler 50/500mcg	**Asthma** *SERETIDE* is indicated in the regular treatment of asthma, including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** SERETIDE is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

		Glucocorticoids should only be considered as a purely symptomatic treatment, unless in case of some endocrine disorders, where they are used as substitution treatment. **ANTI-INFLAMMATORY TREATMENT** **Rheumatic Disorders** (as adjunctive therapy for short-term administration in the management of an acute episode or exacerbation) • post-traumatic osteoarthritis; • synovitis of osteoarthritis; • rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); • acute and subacute bursitis; • epicondylitis; • acute non-specific tenosynovitis; • acute gouty arthritis; • psoriatic arthritis; • ankylosing spondylitis. **Collagen Diseases** (during an exacerbation or as maintenance therapy in selected cases) • systemic lupus erythematosus; • acute rheumatic carditis; • systemic dermatomyositis (polymyositis); • polyarteritis nodosa; • Goodpasture's syndrome.

Dermatologic Diseases

- pemphigus;
- severe erythema multiforme (Stevens-Johnson syndrome);
- exfoliative dermatitis;
- bullous dermatitis herpetiformis;
- severe seborrheic dermatitis;
- severe psoriasis;
- mycosis fungoides;
- urticaria.

Allergic States (to control severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment)

- bronchial asthma;
- contact dermatitis;
- atopic dermatitis;
- serum sickness;
- drug hypersensitivity reactions;
- urticarial transfusion reactions;
- acute non-infectious laryngeal edema (epinephrine is the drug of first choice).

Ophthalmic Diseases (severe acute and chronic allergic and inflammatory processes involving the eye)

- herpes zoster ophthalmicus;
- iritis, iridocyclitis;
- chorioretinitis;
- diffuse posterior uveitis and choroiditis;
- optic neuritis;
- sympathetic ophthalmia.

BRU10020402P	Solu-Medrol Sterile Powder 500mg	**Gastrointestinal Diseases** (to manage critical periods of the disease) • ulcerative colitis (systemic therapy); • Crohn's disease (systemic therapy). **Respiratory Diseases** • symptomatic pulmonary sarcoidosis; • berylliosis; • fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate anti-tuberculous chemotherapy; • Loeffler's syndrome not manageable by other means; • aspiration pneumonitis. **Edematous States** • To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia of the idiopathic type or that due to lupus erythematosus. **IMMUNOSUPPRESSIVE TREATMENT** Organ Transplantation **TREATMENT OF HEMATOLOGICAL AND ONCOLOGICAL DISORDERS** **Hematologic Disorders** • acquired (autoimmune) hemolytic anemia; • idiopathic thrombocytopenia purpura in adults (IV only; IM Administration is contraindicated); • secondary thrombocytopenia in adults; • erythroblastopenia (RBC anemia); • congenital (erythroid) hypoplastic anemia.

Oncological Diseases

For palliative management of:

• leukemias and lymphomas in adults;

• acute leukemia of childhood.

TREATMENT OF SHOCK STATES

Shock secondary to adrenocortical insufficiency or shock unresponsive to conventional therapy when adrenal cortical insufficiency may be present. (Hydrocortisone is generally the drug of choice. When mineralocorticoid activity is undesirable, methylprednisolone may be preferred.)

Hemorrhagic, traumatic and surgical shock unresponsive to standard therapy.

Although there are no well controlled (double-blind placebo) clinical trials, data from experimental animal models indicate that SOLU-MEDROL may be useful in shock states in which standard therapy e.g., fluid replacement has not been effective.

OTHERS

Nervous system

• cerebral edema from tumour – primary or metastatic and/or associated with surgical or radiation therapy or head trauma;

• acute exacerbations of multiple sclerosis;

• acute spinal cord injury. The treatment should begin within 8 hours of injury.

Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate anti-tuberculosis chemotherapy.

		Trichinosis with neurologic or myocardial involvement. **Prevention of nausea and vomiting** associated with cancer chemotherapy. **ENDOCRINE DISORDERS** • primary or secondary adrenocortical insufficiency; • acute adrenocortical insufficiency; • for these indications, the drugs of choice are hydrocortisone or cortisone. Synthetic analogues can be used in certain circumstances if they are combined with mineralocorticoids; • preoperatively and in the event of serious trauma or illness, in patients with known adrenal insufficiency or when adrenocortical reserve is doubtful; • congenital adrenal hyperplasia; • non-suppurative thyroiditis; • hypercalcemia associated with cancer.
BRU10020404P	Imdex 60mg CR Tablet	Prophylactic treatment of angina pectoris.
BRU10020405P	Vascor Tablet 20mg	Simvastatin is used for primary hypercholestrolaemia, heterozygous familial hyperchlolestrolaemia or combined (mixed) hyperlipidaemia in patients who have not responded to diet and appropriate measures; to reduce the incidence of clinical coronary events and slow progression of coronary atherosclerosis in patients with coronary heart disease.
BRU10020406P	Combivent Unit Dose Vials Nebuliser Solution	COMBIVENT® nebuliser solution in unit dose vials are indicated for the management of reversible bronchospasm associated with obstructive airway diseases in patients who require more than a single bronchodilator.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10020407P	Perinace Tablet 4mg	Hypertension: Treatment of hypertension. Heart failure: Treatment of symptomatic heart failure. Stable coronary artery disease: Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation.
BRU10020409PS2	Diovan® 160mg Tablet	**Hypertension** Treatment of hypertension. **Heart failure** Treatment of heart failure (NYHA class II-IV) in patients receiving usual therapy (such as diuretics, digitalis) who are intolerant to ACE inhibitors. Diovan improves morbidity in these patients, primarily via reduction in hospitalization for heart failure. Diovan also slows the progression of heart failure, improves NYHA functional class, ejection fraction and signs and symptoms of heart failure and improves quality of life versus placebo. **Post-myocardial infarction** Diovan is indicated to improve survival following myocardial infarction in clinically stable patients with signs, symptoms or radiological evidence of left ventricular failure and/or with left ventricular systolic dysfunction.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10020411P	Decondine Syrup	It is indicated in nasal and respiratory congestion, common cold, acute sinusitis, and allergic rhinitis.
BRU10020412P	Seretide Accuhaler 50/100mcg	**Asthma** *SERETIDE* is indicated in the regular treatment of asthma, including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** *SERETIDE* is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU10020413P	Optizoline Eye Drops	A conjunctival decongestant for the relief of burning, itching, excessive tears and redness due to conjunctival allergies.
BRU10020414P	Sunadine Syrup	Loratadine is indicated for the relief of nasal as well as non-nasal symptoms of seasonal allergic rhinitis, chronic urticaria and other allergic dermatological disorders.

BRU10020416P	Lipitor 20mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD) such as age, smoking, hypertension, low HDL-C, or a family history of early CHD, LIPITOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, LIPITOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: - LDL-C remains ≥190 mg/dL or - LDL-C remains ≥160 mg/dL and • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient
BRU10020421P	Xatral XL Tablet 10mg	• Treatment of the functional symptoms of benign prostatic hypertrophy. • Adjuvant treatment to a catheter in acute urinary retention related to benign prostatic hypertrophy.
BRU10030426P	Aromasin 25mg Tablet	Exemestane is indicated for the adjuvant treatment of post-menopausal women with estrogen receptor positive early breast cancer who have received two to three years of tamoxifen and are switched to Exemestane for completion of a total of five consecutive years of adjuvant hormonal therapy. Exemestane is indicated for the second-line treatment of advanced breast cancer (ABC) in women with natural or induced post-menopausal status whose disease has progressed following anti-estrogen therapy alone. Exemestane is also indicated for the third-line treatment in post-menopausal woman with ABC whose disease has progressed following multiple hormonal therapies. Efficacy has not been demonstrated in patients with estrogen receptor negative status.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10030427P	Omesec Capsule 20mg	Omeprazole is used in the treatment of gastro-oesophageal reflux disease; duodenal ulcer, benign gastric ulcer and Zollinger-Ellison Syndrome. It is combined with antibacterial agents in dual or triple therapy regimen for the elimination of Helicobacter Pylori infection in patients with duodenal ulcer.
BRU10030429P	Polarax 2mg Tablet	Dexchlorpheniramine is indicated for the symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjuctivities, mild, uncomplicated allergic skin manifestations of urticaria and angiodema, amelioration of allergic reactions to blood or plasma and dermographism, They are also indicated as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.
BRU10030430P	Pharmorubicin CS 50mg/25ml	Pharmorubicin has produced responses in a wide spectrum of neoplastic diseases, and is indicated for the treatment of: • Breast cancer • Gastric cancer • Ovarian cancer • Small cell lung cancer • Lymphoma (non-Hodgkin's lymphoma) • Advanced/metastatic soft tissue sarcoma • Superficial bladder cancer (Tis; Ta) In bladder cancer, Pharmorubicin is also indicated in the prophylaxis of recurrence after transurethral resection of stage T1 papillary cancers and stage Ta multifocal papillary cancers (Grade 2 and 3).
BRU10030433P	Terramycin Ophthalmic Ointment	Terramycin with Polymyxin B Ophthalmic Ointment is indicated in the treatment of superficial ocular infections involving the conjunctiva and/or cornea due to susceptible microorganisms.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10030435P	Adriamycin CS Injection 50mg/25ml	ADRIAMYCIN has been used successfully to produce regression in neoplastic conditions such as: acute leukaemia, Wilms' tumour, neuroblastoma, soft tissue and bone sarcomas, breast carcinoma, lymphomas of both Hodgkin's and non-Hodgkin's type, bronchogenic (lung) carcinoma, thyroid carcinoma, hepatomas, ovarian carcinoma, etc. The main antitumour activities are listed in Table 1. ADRIAMYCIN is also indicated by intravesical administration in the primary management of non-metastatic carcinoma of the bladder (Tis, T_1, T_2).
BRU10030439P	Prozine Syrup 5mg/5ml	In addition to its antihistaminic action, which is of marked potency and prolonged duration, it also provides antiemetic as well as sedative actions. Promethazine HCl is useful in the management of the following conditions: a) Dermographism b) Vasomotor rhinitis c) Perennial and seasonal allergic rhinitis d) Antiemetic therapy in postoperative patients e) Preoperative, post-operative or obstetric sedation f) Amelioration of allergic reactions to blood or plasma g) Active and prophylactic treatment of motion sickness h) Allergic conjunctivitis due to inhalant allergens and foods i) Mild, uncomplicated allergic skin manifestation of urticaria and angioedema j) Prevention and control of nausea and vomiting associated with certain types of anaesthesia and surgery k) Sedation in both children and adults as well as relief of apprehension and production of light sleep from which the patient can be easily aroused
BRU10040444NP	Cartril-S 500mg Capsule	As adjuvant therapy in osteoarthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10040445P	Seretide Accuhaler 50/250mcg	**Asthma** *SERETIDE* is indicated in the regular treatment of asthma, including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** *SERETIDE* is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU10040453P	Temodal Capsule 20mg	Temodal capsules are indicated for the treatment of patients with: • Newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as adjuvant treatment. • Malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.
BRU10040454NP	Colimix™ Syrup	Relieves infant colic, flatulence (wind) and abdominal discomfort due to entrapped gas.
BRU10040455P	Xepanicol® Eye Drops 0.5%	Treatment of bacterial conjunctivitis and other superficial ocular infections caused by organisms susceptible to chloramphenicol.
BRU10040457PS2	Co-Diovan 160/12.5mg Film-Coated Tablets	Treatment of hypertension.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10040459P	Atenolol 50mg Tablet	Treatment of hypertension, angina pectoris, myocardial infarction and cardiac arrhythmias.
BRU10040460P	Bromhexine Tablet 8mg	It is indicated in bronchitis and other respiratory conditions as an aid to expectoration.
BRU10050466NP	Uphamol 250 Suspension 250mg/5ml (Orange)	Relieves fever, pain, discomforts of teething, headache, toothache, earache, common cold, influenza and post vaccination reactions.

		Remicade is indicated for: **Rheumatoid arthritis** Remicade is a "Disease-Controlling Anti-Rheumatic Therapy" (DCART) indicated for: □ the reduction of signs and symptoms □ prevention of structural joint damage (erosions and joint space narrowing) □ improvement in physical function in patients with active disease despite treatment with methotrexate (MTX), and patients with active disease not previously treated with MTX. **Ankylosing spondylitis** Remicade is indicated for: □ reduction of signs and symptoms □ improvement in physical function □ improvement in quality life in patients with active disease. **Psoriatic arthritis** Remicade is indicated for: □ the reduction of signs and symptoms of arthritis □ improvement in physical function □ reduction in psoriasis as measured by PASI (an index which combines symptom evaluation and body surface area) in patients with active psoriatic arthritis. **Psoriasis** Remicade is indicated for treatment of moderate to severe plague psioriasis in adults who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

BRU10050468P	Remicade Powder For Concentrate For Solution For Infusion 100mg/Vial	**Crohn's disease** Remicade is indicated for treatment of moderate to severe Crohn's disease for: □ reduction of signs and symptoms □ induction and maintenance of clinical remission □ induction of mucosal healing □ improvement in quality of life in patients who have an inadequate response to conventional therapies. Remicade therapy enables patients to reduce or eliminate corticosteroid use. **Paediatric Crohn's disease** Remicade is indicated for the treatment of severe, active Crohn's disease, in paediatric patients aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. Remicade has been studied only in combination with conventional immunosuppressive therapy. **Fistulizing Crohn's disease** Remicade is indicated for: □ reduction in the number of draining enterocutaneous and rectovaginal fistulae and maintenance of fistula closure □ reduction of signs and symptoms in patients with fistulizing Crohn's disease.

		Ulcerative colitis Remicade is indicated for: □ reducing signs and symptoms □ inducing and maintaining clinical remission □ inducing mucosal healing □ eliminating corticosteroids used in patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. **Paediatric ulcerative colitis** Remicade is indicated for treatment of severely active ulcerative colitis, in children and adolescents aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.
BRU10050470P	Pristinex Cream 2% w/w	Ketoconazole cream is indicated for the topical treatment of tinea corporis (ringworm of the body), tinea cruris (jock itch), tinea pedis (athlete's foot), tinea (pityriasis) versicolor (white spots), cutaneous candidiasis and seborrheic dermatitis.

BRU10050471P	Zyvox Infusion Bag 600mg/300ml	Linezolid formulations are indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms. Linezolid is active against Gram-positive bacteria only. Linezolid has no clinical activity against Gram-negative pathogens. Specific Gram-negative therapy is required if a concomitant Gram-negative pathogen is documented or suspected. **Vancomycin-Resistant *Enterococcus faecium* infections**, including cases with concurrent bacteremia. **Nosocomial pneumonia** caused by *Staphylococcal aureus* (methicillin-susceptible and -resistant strains), or *Streptococcus pneumonia* (penicillin-susceptible strains). Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. **Complicated skin and skin structure infections** including diabetic foot infections, without concomitant osteomyelitis caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant strains), *Streptococcus pyogenes* , or *Streptococcus agalactiae* . ZYVOX has not been studied in the treatment of decubitus ulcers. Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. **Uncomplicated skin and skin structure infections** caused by *Staphylococcus aureus* (methicillin-susceptible only) or *Streptococcus pyogenes* . **Community-acquired pneumonia** caused by *Streptococcus pneumonia* (penicillin-susceptible strains only), including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible strains only). Due to concerns about inappropriate use of antibiotics leading to an increase in resistant organisms, prescribers should carefully consider alternatives before initiating treatment with linezolid in the outpatient setting. Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to linezolid. Therapy may be instituted empirically while awaiting the results of these tests. Once these results become available, antimicrobial therapy should be adjusted accordingly.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10050474P	Provinace Tablet 4mg	- Hypertension: Treatment of hypertension. - Heart Failure: Treatment of symptomatic heart failure. - Stable coronary artery disease: Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation.

BRU10050476P	Dalacin C Capsule 150mg	Clindamycin has been shown to be effective in the treatment of the following infections when caused by susceptible anaerobic bacteria; susceptible strains of gram positive aerobic bacteria such as streptococci, staphylococci and pneumococci; and susceptible strains of *Chlamydia trachomatis* . (a) Upper respiratory infections including tonsillitis, pharyngitis, sinusitis, otitis media and scarlet fever. (b) Lower respiratory infections including bronchitis, pneumonia, empyema and lung abscess. (c) Skin and soft tissue infections including acne, furuncles, cellulitis, impetigo, abscesses, and wound infections, specific skin and soft tissue infections caused by susceptible organisms like erysipelas and paroanychia (panaritium). (d) Bone and joint infections including osteomyelitis and septic arthritis. (e) Gynaecological infections including endometritis, cellulitis, vaginal cuff infection and tubo-ovarian abscess, salpingitis, and pelvic inflammatory disease when given in conjunction with an antibiotic of appropriate gram negative spectrum. In cases of cervicitis due to *Chlamydia trachomatis* , single drug therapy with clindamycin has been shown to be effective in eradicating the organism. (f) Intra-abdominal infections including peritonitis and abdominal abscess when given in conjunction with an antibiotic of appropriate gram negative aerobic spectrum. (g) Septicaemia and endocarditis – The effectiveness of clindamycin in the treatment of selected cases of endocarditis has been documented when clindamycin is determined to be bactericidal to the infecting organism by in vitro testing of appropriate achievable serum concentrations. (h) Dental infections such as periodontal abscess and periodontitis. (i) Toxoplasmic encephalitis in patients with AIDS. In patients who are intolerant to conventional treatment, clindamycin in combination with pyrimethamine has been shown to be efficacious. (j) *Pneumocystis carinii* pneumonia in patients with AIDS. In patients who are intolerant to, or do not respond adequately to conventional treatment, clindamycin may be used in combination with primaquine.

		Clindamycin phosphate, when used concurrently with an aminoglycoside antibiotic such as gentamicin or tobramycin, has been shown to be effective in preventing peritonitis or intra-abdominal abscess after bowel perforation and bacterial contamination secondary to trauma. Limited data from uncontrolled studies using a variety of doses suggest that clindamycin, either orally or parenterally at a dose of 20mg/kg/d for a minimum of 5 days, is useful alternative therapy when used alone or in combination with quinine or amodiaquine, for the treatment of multi-resistant Plasmodium falciparum infection In-vitro susceptibility to clindamycin has been shown for the following organisms: *B. melaninogenicu* , *B. disiens* , *B. bivius* , *Peptosterptococcus spp.* , *G. vaginalis* , *M. mulieris* , *M. curtisii* , and *Mycoplasma hominis* .
BRU10050479P	Cozaar 100mg Film-Coated Tablet	**Hypertension** COZAAR is indicated for the treatment of hypertension. **Hypertensive Patients with Left Ventricular Hypertrophy** COZAAR is indicated for the reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy (see RACE). **Renal Protection in Type 2 Diabetic Patients with Proteinuria** COZAAR is indicated to delay the progression of renal disease as measured by a reduction in the incidence of doubling of serum creatinine and end stage renal disease (need for dialysis or renal transplantation), and to reduce proteinuria.
BRU10060485P	Allersin-F Tablet 4mg	It is indicated in allergic conditions responsive to anti-histamines.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10060491P	Diatrol Tablet 2mg	Loperamide HCl is indicated for the control and symptomatic relief of acute, nonspecific diarrhea and of chronic diarrhea associated with inflammatory bowel disease. In patients with ileostomy it can be used to reduce the number and volume of stool and to harden their consistency.
BRU10060494P	Norvasc Tablet 5mg	*Hypertension* Amlodipine is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent (other than amlodipine) may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme (ACE) inhibitor. *Chronic Stable Angina* Amlodipine is indicated for the first-line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta-blockers.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10060495P	Epilim 200mg/5ml Syrup	Treatment of generalized or partial epilepsy, particularly with the following patterns of seizures: - absence - myoclonic - tonic-clonic - atonic - mixed As well as, for partial epilepsy: - simple or complex seizures - secondary generalized seizures - specific syndromes (West, Lennox-Gastaut) Treatment and prevention of mania associated with bipolar disorder.
BRU10060496P	Stilnox 10mg Film-Coated Tablet	Indications are limited to treatment of severe sleep disorders in adults with: • Transient insomnia • Short-term insomnia
BRU10060497P	Hyosun Syrup	It is indicated for gastro-intestinal spasm and hypermotility, post-operative vomiting, spasm of the urinary tract, delayed relaxation of the lower uterine segment and painful menstruation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10060498P	Nalol Tablet 40mg	a) Management of hypertension. b) Control of cardiac arrhythmias. c) Long term prophylaxis after recovery from acute myocardial infarction. d) Prophylaxis of common migraine headache. e) Management of pheochromocytoma, after primary treatment with an alpha-adrenergic blocking agent. f) Management of angina pectoris.
BRU10060499P	Exelon Capsule 1.5mg	Treatment of patients with mild to moderately severe dementia of the Alzheimer type, also termed probable Alzheimer's Disease or Alzheimer's Disease. Treatment of patients with mild to moderately severe dementia associated with Parkinson's disease.

BRU10060502P	Zyvox Film-Coated Tablet 600mg	Linezolid formulations are indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms. Linezolid is active against Gram-positive bacteria only. Linezolid has no clinical activity against Gram-negative pathogens. Specific Gram-negative therapy is required if a concomitant Gram negative pathogen is documented or suspected. **Vancomycin-Resistant *Enterococcus faecium* infections**, including cases with concurrent bacteremia. **Nosocomial pneumonia** caused by *Staphyloccous aureus* (methicillin-susceptible and –resistant strains), or *Streptococcus pneumonia* (penicillin-susceptible strains). Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. **Complicated skin and skin structure infections including diabetic foot infections, without concomitant osteomyelitis** caused by *Staphylococcus aureus* (methicillin-susceptible and –resistant strains), *Streptococcus pyrogenes* , or *Streptococcus agalactiae* . Zyvox has not been studied in the treatment of decubitus ulcers. Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. **Uncomplicated skin and skin structure infections** caused by *Staphylococus aureues* (methicillin-susceptible only) or *Streptococcus pyrogenes* . **Community-acquired pneumonia** caused by *Streptococcus pneumonia* (penicillin- susceptible strains only), including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible strains only). Due to concerns about inappropriate use of antibiotics leading to an increase in resistant organisms, prescribers should carefully consider alternatives before initiating treatment with linezolid in the outpatient setting. Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to linezolid. Therapy may be instituted empirically while awaiting the results of these tests. Once these results become available, antimicrobial therapy should be adjusted accordingly.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10060504P	Sifrol Tablet 0.125mg	Sifrol® is indicated in the treatment of signs and symptoms of advanced idiopathic Parkinson's disease. It may be used as monotherapy or in combination with levodopa. Sifrol® is indicated for the symptomatic treatment of idiopathic Restless Legs Syndrome.
BRU10060505P	Myfortic Gastro-Resistant Tablet 180mg	Myfortic is indicated in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in adult patients receiving allogeneic renal transplant.
BRU10070508P	Norvasc Tablet 10mg	*Hypertension* Amlodipine is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent (other than amlodipine) may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme (ACE) inhibitor. *Chronic Stable Angina* Amlodipine is indicated for the first-line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta-blockers.
BRU10070509P	Pseudorine Tablet 60mg	It is indicated for the symptomatic relief of nasal and bronchial congestion in conditions such as common cold, acute bronchitis and allergic asthma.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10070510P	Laxodyl Tablet 5mg	Treatment of acute and chronic constipation, for bowel retraining, for evacuation of the colon before radiological examination of the abdomen, or endoscopy, and before or after surgical operations.
BRU10070511P	Decondine Tablet	It is indicated in nasal and respiratory congestion, common cold, acute sinusitis, and allergic rhinitis.
BRU10070512P	SW Metoclopramide Tablet 10mg	In adults, metoclopramide will be indicated for prevention of nausea and vomiting associated with chemotherapy and radiotherapy with low and minimal emetogenicity; the symptomatic treatment of acute migraine induced nausea and vomiting; the adjunct treatment of gastroparesis, the management of dyspepsia and gastroesophagel reflux disorder when other treatment options are unsuitable; and as adjuvant to surgical and radiological procedures.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10070513PS2	Desferal 500mg	**Therapeutic** Monotherapy iron chealation treatment for chronic iron overload, e.g. • Transfusional haemosiderosis, as seen in thalassaemia major, sideroblastic anaemia, auto-immune haemolytic anaemia, and other chronic anaemias. • Idiopathic (primary) haemochromatosis in patients in whom concomitant disorders (e.g. severe anaemia, cardiac disease, hypoproteinaemia) preclude phlebotomy. • Iron overload associated with porphyria cutanea tarda in patients unable to tolerate phlebotomy. Treatment for acute iron poisoning. Treatment for chronic aluminium overload in patients with end-stage renal failure (under maintenance dialysis) with • Aluminium-related bone disease, • Dialysis encephalopathy or • Aluminium-related anaemia. **Diagnostic** Diagnosis of iron or aluminium overload.
BRU10070515P	Zaricort Cream	Zaricort Cream is used for the topical treatment of fungal infections where inflammation of the skin is also present such as those of tinea pedis (athlete's foot), tinea versicolor (white spot), tinea corporis (ringworm) and candidiasis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10070516P	Singulair® Tablet 10mg	SINGULAIR is indicated in adult and pediatric patients 1 year of age and older for the prophylaxis and chronic treatment of asthma, including the prevention of day- and nighttime symptoms, the treatment of aspirin-sensitive asthmatic patients, and the prevention of exercise-induced bronchoconstriction. SINGULAIR is indicated for the relief of daytime and nighttime symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older, and perennial allergic rhinitis in adults and pediatric patients 1 year of age and older). Because the benefits of SINGULAIR may not outweigh the risk of neuropsychiatric symptoms in patients with allergic rhinitis, reserve use for patients who have an inadequate response or intolerance to alternative therapies.
BRU10070518P	Lanoxin Injection 0.5mg/2ml	**Cardiac Failure** Lanoxin is indicated in the management of chronic cardiac failure where the dominant problem is systolic dysfunction. Its therapeutic benefit is greatest in those patients with ventricular dilatation. Lanoxin is specifically indicated where cardiac failure is accompanied by atrial fibrillation. **Supraventricular Arrhythmias** Lanoxin is indicated in the management of certain supraventricular arrhythmias, particularly atrial flutter and fibrillation.
BRU10070519P	Zithromax IV 500mg	Azithromycin IV is indicated for the treatment of community-acquired pneumonia (CAP) caused by susceptible organisms, including *Legionella pneumophila* , in patients who require initial IV therapy. Azithromycin IV is indicated for the treatment of pelvic inflammatory diseases (PID) caused by susceptible organisms (*Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma hominis*) in patients who require initial IV therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10070521P	Epilim Chrono 500mg Scored Film-Coated Tablet	Treatment of generalized or partial epilepsy, particularly with the following patterns of seizures: - Absence - Myoclonic - Tonic-clonic - Atonic - Mixed As well as, for partial epilepsy: - Simple or complex seizures - Secondary generalized seizures - Specific syndromes (West, Lennox-Gastaut) Treatment and prevention of mania associated with bipoloar disorders.
BRU10080523P	Exforge 10/160mg Film-Coated Tablet	Treatment of essential hypertension. Exforge is indicated in patients whose blood pressure is not adequately controlled by monotherapy. Exforge is indicated for the initial treatment of hypertension. The choice of Exforge for initial treatment should be based on an assessment of the potential benefits and risks.

BRU10080530P	Ritalin 10mg Tablet	Ritalin 10 tablets and Ritalin LA capsules are indicated for the treatment of ADHD. Ritalin 10 tablets are also indicated for the treatment of narcolepsy. **Attention-Deficit Hyperactivity Disorder (ADHD)** ADHD was previously known as attention-deficit disorder. Other terms used to describe this behavioural syndrome include: minimal brain dysfunction in children, hyperkinetic child syndrome, minimal brain damage, minimal cerebral dysfunction, minor cerebral dysfunction and psycho-organic syndrome of children. Ritalin 10 / Ritalin LA are indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational and social) for patients with this syndrome. Stimulants are not intended for use in the patient who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. **Special Diagnostic Considerations for ADHD in children** The aetiology of this syndrome is unknown and there is no single diagnostic test. Adequate diagnosis requires the use, not only of medical, but also of psychological, educational and social resources. Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, moderate to severe hyperactivity, minor neurological signs and an abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics. Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in children who exhibit symptoms secondary to environmental factors (e.g. child abuse in particular) or primary psychiatric disorders. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medicine will depend upon the physician’s assessment of the chronicity and severity of the child's symptoms.

		Continuation of Treatment in Adolescent and Special Diagnostic Considerations for ADHD in adults There is limited information to guide clinicians about how long older adolescents should continue to receive treatment with drugs for attention deficit hyperactivity disorder (ADHD). The decision should be based on the extent to which symptoms of ADHD and social functioning have improved to a point that medication is no longer needed. If older adolescents have been largely symptoms-free for a year and are functioning well, a trial without medication is warranted. This should be undertaken at times of low stress such as during holidays or in a period when a school routine is well established. ADHD needs to be considered in adults who present with longstanding symptoms suggestive of ADHD (inattention, impulsivity, disorganization) that appear to have started in childhood and are persisting into adult life. Further, people with personality disorder and/or problems with drug use accompanied by a significant level of impulsivity and inattention should be referred for evaluation by a psychiatrist with the training and skills required to assess and treat ADHD. This expertise is necessary due to the overlap of ADHD symptoms with anxiety, mood and personality disorders. **Narcolepsy (Ritalin only)** The symptoms include daytime sleepiness, inappropriate sleep episodes and rapidly occurring loss of voluntary muscle tone. Ritalin 10 is effective for symptoms of sleepiness but not for loss of voluntary muscle tone.
BRU10080532P	Prostin VR Paediatric® Sterile Solution 500mcg/ml	Indicated for palliative, not definitive, therapy to temporarily maintain the patency of the ductus arteriosus until corrective or palliative surgery can be performed in neonates who have congenital heart defects and who depend upon the patent ductus for survival. Such congenital heart defects include pulmonary artesia, pulmonary stenosis, tricuspid artesia, tetralogy of fallot, interruption of the aortic arch, coarctation of the aorta, or transposition of the great vessels with or without other defects.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10080533P	Lioresal 10mg Tablet	Spasticity of the skeletal muscles in multiple sclerosis. Spastic conditions occurring in spinal cord diseases of infectious, degenerative, traumatic, neoplastic, or unknown origin e.g. spastic spinal paralysis, amyotrophic lateral sclerosis, syringomyelia, transverse myelitis, traumatic paraplegia or paraparesis, and compression of the spinal cord; muscle spasticity of cerebral origin, especially where due to infantile cerebral palsy. In spasticity due to cerebrovascular accident or degenerative or neoplastic brain disease, Lioresal is less suitable owing to the likelihood of intolerance, but it may be tried if administered cautiously.
BRU10080534PS2	Fosamax Tablet 70mg	FOSAMAX is indicated for the treatment of osteoporosis in postmenopausal women. For the treatment of osteoporosis, FOSAMAX reduces the incidence of fractures, including those of the hip and spine (vertebral compression fractures). FOSAMAX is indicated for the treatment of osteoporosis in men.
BRU10090540P	Cozaar Tablet 50mg	**Hypertension** COZAAR is indicated for the treatment of hypertension. **Hypertensive Patients with Left Ventricular Hypertrophy** COZAAR is indicated for the reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy (see RACE). **Renal Protection in Type 2 Diabetic Patients with Proteinuria** COZAAR is indicated to delay the progression of renal disease as measured by a reduction in the incidence of doubling of serum creatinine and end stage renal disease (need for dialysis or renal transplantation), and to reduce proteinuria.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10090541P	Lanoxin Paediatric/Geriatric Elixir	**Cardiac Failure** Digoxin is indicated in the management of chronic cardiac failure where the dominant problem is systolic dysfunction. Its therapeutic benefit is greatest in those patients with ventricular dilatation. Digoxin is specifically indicated where cardiac failure is accompanied by atrial fibrillation. **Supraventricular Arrhythmias** Digoxin is indicated in the management of certain supraventricular arrhythmias, particularly chronic atrial flutter and fibrillation.
BRU10090542PS2	Singulair Oral Granules 4mg	SINGULAIR is indicated in adult and pediatric patients 1 year of age and older for the prophylaxis and chronic treatment of asthma, including the prevention of day- and nighttime symptoms, the treatment of aspirin-sensitive asthmatic patients, and the prevention of exercise-induced bronchoconstriction. SINGULAIR is indicated for the relief of daytime and nighttime symptoms of allergic rhinitis (seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older, and perennial allergic rhinitis in adults and pediatric patients 1 year of age and older). Because the benefits of SINGULAIR may not outweigh the risk of neuropsychiatric symptoms in patients with allergic rhinitis, reserve use for patients who have an inadequate response or intolerance to alternative therapies.
BRU10090549P	Livial 2.5mg Tablet	Treatment of oestrogen deficiency symptoms in postmenopausal women, more than one year after menopause. For all women the decision to prescribe tibolone should be based on assessment of the individual patient's overall risks and particularly in the over 60's, should include consideration of the risk of stroke.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10090551P	Zoladex LA Depot Injection 10.8mg	Prostate cancer: Zoladex LA 10.8 mg is indicated in the management of prostate cancer suitable for hormonal manipulation. Premenopausal Breast cancer: Zoladex LA 10.8mg is indicated in the management of estrogen-receptor-positive breast cancer in premenopausal women. Endometriosis: In the management of endometriosis, Zoladex LA 10.8mg alleviates symptoms, including pain, and reduces the size and number of endometrial lesions.
BRU10090554P	Proscar® Tablets 5mg	• PROSCAR is indicated for the treatment and control of benign prostatic hyperplasia (BPH) and for the prevention of urologic events as it: - May reduce the risk of acute urinary retention - May reduce the risk of surgery including transurethral resection of the prostate (TURP) and prostatectomy. • PROSCAR causes regression of the enlarged prostate, improves urinary flow and improves the symptoms associated with BPH. Patients with an enlarged prostate are the appropriate candidates for therapy with PROSCAR.
BRU10090555PS1	Elomet Cream 0.1%	Elomet Cream 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.
BRU10100556P	Myfortic Gastro-Resistant Tablet 360mg	Indicated in combination with ciclosporin and corticosteroid for the prophylaxis of acute transplant rejection in adult patients receiving allogeneic renal transplant.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10100559P	Exelon® Capsule 3mg	Treatment of patients with mild to moderately severe dementia of the Alzheimer type, also termed probable Alzheimer's Disease or Alzheimer's Disease.
BRU10100562P	Exelon® Patch 10	Treatment of patients with mild to moderately severe dementia of the Alzheimer type, also termed probable Alzheimer's Disease or Alzheimer's Disease. Treatment of patients with mild to moderately severe dementia associated with Parkinson's disease. Treatment of patients with severe dementia of the Alzheimer's type.
BRU10100563P	Exelon® Patch 5	Treatment of patients with mild to moderately severe dementia of the Alzheimer type, also termed probable Alzheimer's Disease or Alzheimer's Disease. Treatment of patients with mild to moderately severe dementia associated with Parkinson's disease. Treatment of patients with severe dementia of the Alzheimer's type.

BRU10100564P	ATGAM® Sterile Solution 50mg/mL (5mL Amp)	**1.1 Renal Allograft Rejection** ATGAM is indicated for the management of allograft rejection in renal transplant patients; when administered with conventional therapy at the time of rejection, it increases the frequency of resolution of the acute rejection episode [*see Clinical Studies (13.1)*]. The drug has also been administered as an adjunct to other immunosuppressive therapy to delay the onset of the first rejection episode. Data accumulated to date have not consistently demonstrated improvement in functional graft survival associated with therapy to delay the onset of the first rejection episode. **1.2 Aplastic Anemia** ATGAM is indicated for the treatment of moderate to severe aplastic anemia in patients who are unsuitable for bone marrow transplantation [*see Clinical Studies (13.2)*]. The usefulness of ATGAM has not been demonstrated in patients with aplastic anemia who are suitable candidates for bone marrow transplantation or in patients with aplastic anemia secondary to neoplastic disease, storage disease, myelofibrosis, Fanconi's syndrome, or in patients known to have been exposed to myelotoxic agents or radiation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10100565PS1; BRU10100565PS2	Ezetrol 10mg Tablet	***Primary Hypercholesterolemia*** EZETROL, administered with an HMG-CoA reductase inhibitor (statin) or alone, is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C) and apolipoprotein B (Apo B) in patients with primary (heterozygous familial and non-familial) hypercholesterolemia. EZETROL, administered in combination with fenofibrate, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with mixed hyperlipidemia. ***Homozygous Familial Hypercholesterolemia (HoFH)*** EZETROL, administered with atorvastatin or simvastatin, is indicated for the reduction of elevated total-C and LDL-C levels in patients with HoFH, as an adjunct to other lipid-lowering treatments (eg. LDL apheresis) or if such treatments are unavailable. ***Homozygous Sitosterolemia (Phytosterolemia)*** EZETROL is indicated as adjunctive therapy to diet for the reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolemia.
BRU10100567P	Sun-Glizide Tablet 80mg	Non Insulin Dependent Diabetes Mellitus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10100568P	Zithromax Powder For Oral Suspension 200mg/5ml	Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx; however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, azithromycin is indicated for the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated for the treatment of chancroid due to *Haemophilus ducreyi* and uncomplicated genital infections due to non-multiresistant *Neisseria gonorrhoeae* ; concurrent infection with *Treponema pallidum* should be excluded.
BRU10100569P	Fosamax Plus 70/2800mcg Tablets	FOSAMAX PLUS is indicated for: • Treatment of osteoporosis in postmenopausal women where vitamin D supplementation is recommended. FOSAMAX PLUS reduces the incidence of fractures, including those of the hip and spine (vertebral compression fractures). • Treatment of osteoporosis in men where Vitamin D supplementation is required.
BRU10100571P	Arimidex 1mg Tablet	Adjuvant treatment of post-menopausal women with hormone receptor positive early breast cancer. Treatment of advanced breast cancer in post-menopausal women. Efficacy has not been demonstrated in oestrogen receptor negative patients unless they had a previous positive clinical response to Tamoxifen.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10100572NP	Casprin Enteric Microencapsulated Capsule 100mg	In the treatment of acute myocardial infarction (heart attack), for prevention of heart attack in certain high-risk group patients and for prevention of stroke after transient ischemic attack (TIA).
BRU10100573P	Pontalon Film Coated Tablet 500mg	For the relief of mild to moderate pain including muscular, traumatic and dental pain, headache, postoperative and postpartum pain, and dysmenorrhoea.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10100576P	Albutein® Solution For Infusion 25%	Albutein® 25% is indicated: a. For treatment of hypovolemic shock. b. As an adjunct in hemodialysis for patients undergoing long-term dialysis or for those patients who are fluid-overloaded and cannot tolerate substantial volumes of salt solution for therapy of shock or hypotension. c. In cardiopulmonary bypass procedures; however, the optimum regimen of fluids has not been established. Conditions in which Albutein® 25% MAY BE indicated: - Adult respiratory distress syndrome (ARDS). - Major injury or surgery resulting in increased albumin loss or inadequate synthesis. - Acute nephrosis not responding to cyclophosphamide or steroid therapy. Steroid therapy may increase edema which may respond to combined therapy of albumin with a diuretic. - Acute liver failure or ascites where the therapeutic use is regulated by the individual circumstances. Unless the pathologic condition responsible for hypoalbuminemia can be corrected, administration of albumin can afford only symptomatic relief. There is NO valid reason for the use of albumin as an intravenous nutrient. Pediatric Use: Albutein® 25% is indicated in conjunction with exchange transfusion in the treatment of neonatal hyperbilirubinemia. The pediatric use of Albutein® 25% has not been clinically evaluated. Therefore, physicians should weigh the risks and benefits of the use of Albutein® 25% in the pediatric population.
BRU10100578P	Axol Liquid 3mg/ml	Mucolytic agent used in the treatment of respiratory tract disorders associated with viscid mucus.

BRU10110581PS2; BRU10110581PS2R2	Januvia™ Tablet 50mg	**1.1 Monotherapy** JANUVIA is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. **1.2 Combination with Metformin** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin as initial therapy or when the single agent alone, with diet and exercise, does not provide adequate glycemic control. **1.3 Combination with a Sulfonylurea** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with a sulfonylurea when treatment with the single agent alone, with diet and exercise, does not provide adequate glycemic control. **1.4 Combination with a PPARγ agonist** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with a PPARγ agonist (e.g., thiazolidinediones) when the single agent alone, with diet and exercise, does not provide adequate glycemic control. **1.5 Combination with Metformin and a Sulfonylurea** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin and a sulfonylurea when dual therapy with these agents, with diet and exercise, does not provide adequate glycemic control. **1.6 Combination with Insulin** JANUVIA is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycemic control.

		1.7 Important Limitations of Use JANUVIA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. JANUVIA has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUVIA. *[See Warnings and Precautions (5.1).]*
BRU10110587P; BRU10110587PS2	Metoclopramide Syrup 5mg/5ml	Adult population Metoclopramide is indicated in adults for: - Prevention of delayed chemotherapy induced nausea and vomiting (CINV). - Prevention of radiotherapy induced nausea and vomiting (RINV). - Symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting. Paediatric population Metoclopramide is indicated in children (aged 1-18 years) for: - Prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second line option.
BRU10110588NP	Suntacid Tablet	It is indicated in the relief of the symptoms of peptic ulcer and other problems related to acid hypersecretion.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10110590P	Zoladex Depot 3.6mg/Dose	i) Prostate cancer: Zoladex 3.6 mg is indicated in the management of prostate cancer suitable for hormonal manipulation. ii) Breast cancer: Zoladex 3.6 mg is indicated in the management of breast cancer in premenopausal and perimenopausal women suitable for hormonal manipulation. iii) Endometriosis: In the management of endometriosis, Zoladex 3.6 mg alleviates symptoms, including pain, and reduces the size and number of endometrial lesions. iv) Endometrial thinning: Zoladex 3.6 mg is indicated for the prethinning of the uterine endometrium prior to endometrial ablation or resection. v) Uterine fibroids: In conjunction with iron therapy in the haematological improvement of anaemic patients with fibroids, prior to surgery. vi) Assisted reproduction: Pituitary downregulation in preparation for superovulation.
BRU10110591P	Voren Enteric Coated Tablet 25mg	Inflammatory and degenerative forms of rheumatism; rheumatoid arthritis; ankylosing spondylitis and osteoarthritis. Non-articular rheumatism, post-traumatic inflammation and swelling.
BRU10110592P	Oroxine Tablet 50mcg	Hypothyroidism.
BRU10110593P	Voren Enteric Coated Tablet 50mg	Inflammatory and degenerative forms of rheumatism; rheumatoid arthritis; ankylosing spondylitis and osteoarthritis. Non-articular rheumatism, post-traumatic inflammation and swelling.

BRU10120599PS2; BRU10120599PS2R2	Januvia™ Tablet 25mg	**1.1 Monotherapy** JANUVIA is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. **1.2 Combination with Metformin** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin as initial therapy or when the single agent alone, with diet and exercise, does not provide adequate glycemic control. **1.3 Combination with a Sulfonylurea** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with a sulfonylurea when treatment with the single agent alone, with diet and exercise, does not provide adequate glycemic control. **1.4 Combination with a PPARγ agonist** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with a PPARγ agonist (e.g., thiazolidinediones) when the single agent alone, with diet and exercise, does not provide adequate glycemic control. **1.5 Combination with Metformin and a Sulfonylurea** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin and a sulfonylurea when dual therapy with these agents, with diet and exercise, does not provide adequate glycemic control. **1.6 Combination with Insulin** JANUVIA is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycemic control.

		1.7 Important Limitations of Use JANUVIA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. JANUVIA has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUVIA. *[See Warnings and Precautions (5.1).]*
BRU10120602P	Orgalutran 0.25mg/0.5ml Solution For Injection	The prevention of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH) for assisted reproduction techniques (ART). In clinical trials Orgalutran was used with recombinant follicle stimulating hormone (FSH).
BRU10120604P	ClariClear Nasal Spray 0.05%	Clariclear® Nasal Spray is indicated for symptomatic relief of nasal and nasal pharyngeal congestion due to the common cold, sinusitis, hay fever or other upper respiratory allergies.
BRU10120607P	YSP Allopurinol Tablet 300mg	Allopurinol is indicated for the main clinical manifestations of urate/uric acid deposition. It is also indicated for the management of 2,8-dihydroxyadenine (2,8-DHA) renal stone and recurrent mixed calcium oxalate renal stones.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU10120612P	Flixonase Aqueous Nasal Spray 0.05%	Indicated for the prophylaxis and treatment of seasonal allergic rhinitis including hay fever, and perennial rhinitis. In patients with allergic rhinitis fluticasone propionate aqueous nasal spray is also indicated for the management of associated sinus pain and pressure.
BRU10120613PS1; BRU10120613PS2	Esmeron® Injection 50mg/5ml (10mg/ml)	Esmeron is indicated as an adjunct to general anaesthesia to facilitate endotracheal intubation, to provide skeletal muscle relaxation and to facilitate mechanical ventilation in adults, children and infants from one month of age. Esmeron is also indicated as an adjunct in the intensive care unit (ICU) to facilitate mechanical ventilation as part of Rapid Sequence Induction, however, this has not been studied in infants and children.
BRU10120617P	IRESSA™ Tablet 250mg	IRESSA is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK.

BRU11010619PS2; BRU11010619PS2R2	Januvia™ Tablet 100mg	**1.1 Monotherapy** JANUVIA is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. **1.2 Combination with Metformin** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin as initial therapy or when the single agent alone, with diet and exercise, does not provide adequate glycemic control. **1.3 Combination with a Sulfonylurea** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with a sulfonylurea when treatment with the single agent alone, with diet and exercise, does not provide adequate glycemic control. **1.4 Combination with a PPARγ agonist** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with a PPARγ agonist (e.g., thiazolidinediones) when the single agent alone, with diet and exercise, does not provide adequate glycemic control. **1.5 Combination with Metformin and a Sulfonylurea** JANUVIA is indicated in patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin and a sulfonylurea when dual therapy with these agents, with diet and exercise, does not provide adequate glycemic control. **1.6 Combination with Insulin** JANUVIA is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycemic control.

		1.7 Important Limitations of Use JANUVIA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. JANUVIA has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUVIA.
BRU11010621P	Femara® 2.5mg Tablets	(i) Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. (ii) Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown oestrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy). (iii) First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer. (iv) Treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antioestrogens. (v) Pre-operative therapy in postmenopausal women with localised hormone receptor positive breast cancer, to allow subsequent breast-conserving surgery in women not originally considered candidates for this type of surgery. Subsequent treatment after surgery should be in accordance with standard of care.
BRU11010624P	Elomet Ointment 0.1%	Elomet Ointment 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11010627P	Tegretol CR 200 Tablet	• Epilepsy - Complex or simple partial seizures (with or without loss of consciousness) with or without secondary generalization. - Generalized tonic-clonic seizures. Mixed forms of seizures. Tegretol is suitable for both monotherapy and combination therapy. Tegretol is usually not effective in absences (petit mal) and myoclonic seizures. • Acute mania and maintenance treatment of bipolar affective disorders to prevent or attenuate recurrence. • Alcohol-withdrawal syndrome. • Idiopathic trigeminal neuralgia and trigeminal neuralgia due to multiple sclerosis (either typical or atypical). Idiopathic glossopharyngeal neuralgia.
BRU11010628P	Oxy-Nase Paediatric Nasal Spray 0.025%	It is indicated for the relief of nasal congestion.
BRU11010629P	Trandate™ Tablets 100mg	Tablet is indicated for: • Mild, moderate or severe hypertension. • Hypertension in pregnancy. • Angina pectoris with coexisting hypertension.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11010631P	Tegretol® CR 400mg Film-Coated Tablet	• Epilepsy - Complex or simple partial seizures (with or without loss of consciousness) with or without secondary generalization. - Generalized tonic-clonic seizures. Mixed forms of seizures. Tegretol is suitable for both monotherapy and combination therapy. Tegretol is usually not effective in absences (petit mal) and myoclonic seizures. • Acute mania and maintenance treatment of bipolar affective disorders to prevent or attenuate recurrence. • Alcohol-withdrawal syndrome. • Idiopathic trigeminal neuralgia and trigeminal neuralgia due to multiple sclerosis (either typical or atypical). Idiopathic glossopharyngeal neuralgia.
BRU11010636NP	YSP Bisacodyl Suppositories 5mg	1. Constipation. 2. Bowel preparation for radiological procedures and surgery.

BRU11010637P	Engerix-B 20 Adult Dose Suspension For Injection	***Engerix-B*** is indicated for active immunisation against HBV infection caused by all known subtypes in subjects of all ages considered at risk of exposure to HBV. It can be expected that hepatitis D will also be prevented by immunisation with ***Engerix-B*** as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection. Immunisation against hepatitis B is expected in the long term to reduce not only the incidence of this disease, but also its chronic complications such as chronic active hepatitis B and hepatitis B associated cirrhosis. In areas of **low prevalence** of hepatitis B, immunisation is particularly recommended for those belonging to groups identified at increased risk of infection (see below), however, universal immunisation of all infants and adolescents will contribute to the control of hepatitis B on a population basis. In areas of **intermediate and high prevalence** of hepatitis B, with most of the population at risk of acquiring the HBV, the best strategy is to provide universal immunisation of neonates, infants, children and adolescents, as well as adults belonging to groups at increased risk of infection. The WHO, the US Immunisation Practices Advisory Committee (ACIP) and the American Academy of Paediatrics advocate that the vaccination of new-borns and/or the vaccination of adolescents is the optimal strategy for the control of hepatitis B in all countries. Groups identified at increased risk of infection: health care personnel, patients frequently receiving blood products, personnel and residents of institutions, persons at increased risk due to their sexual behaviour, illicit users of addictive injectable drugs, travellers to areas with a high endemicity of HBV, infants born of mothers who are HBV carriers, persons originating from areas with a high endemicity of HBV, patients with sickle-cell anaemia, patients who are candidates for organ transplantation, household contacts of any of the above groups and of patients with acute or chronic HBV infection, subjects with chronic liver disease (CLD) or at risk of developing CLD (e.g. Hepatitis C virus carriers, persons who abuse alcohol), others (police personnel, fire brigade personnel, armed forces personnel and anybody who through their work or personal lifestyle may be exposed to HBV).

BRU11010638P	Havrix Junior 720	**Havrix™** is indicated for active immunization against hepatitis A virus (HAV) infection in subjects at risk of exposure to HAV. **Havrix™** will not prevent hepatitis infection caused by other agents such as hepatitis B virus, hepatitis C virus, hepatitis E virus or other pathogens known to infect the liver. In areas of low to intermediate prevalence of hepatitis A, immunization with **Havrix™** is particularly recommended in subjects who are, or will be, at increased risk of infection such as: Travellers. Persons travelling to areas where the prevalence of hepatitis A is high. These areas include Africa, Asia, the Mediterranean basin, the Middle East, Central and South America. Armed Forces. Armed Forces personnel who travel to higher endemicity areas or to areas where hygiene is poor have an increased risk of HAV infection. Active immunization is indicated for these individuals. Persons for whom hepatitis A is an occupational hazard or for whom there is an increased risk of transmission. These include employees in day-care centres, nursing, medical and paramedical personnel in hospitals and institutions, especially gastroenterology and paediatric units, sewage workers, food handlers, among others. Person at increased risk due to their sexual behaviour. Homosexuals, persons with multiple sexual partners. Haemophiliacs. Abusers of Injectable Drugs. Contact of Infected Persons. Since virus shedding of infected persons may occur for a prolonged period, active immunization of close contacts is recommended. Persons who require protection as part of hepatitis A outbreak control or because of regionally elevated morbidity. Specific population groups known to have higher incidence of hepatitis A. For example, American Indians, Eskimos, recognized community-wide HAV epidemics. Subject with chronic liver disease or who are at risk of developing chronic liver disease (e.g. Hepatitis B (HB) and Hepatitis C (HC) chronic carriers and alcohol abusers). In areas of intermediate to high prevalence of hepatitis A (e.g. Africa, Asia, the Mediterranean basin, the Middle East, Central and South America) susceptible individuals should be considered for active immunization. These children and adolescents especially in high socio-economic groups and urban areas.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11010639P	Hiberix	***Hiberix™*** is indicated for active immunisation of all infants from the age of 6 weeks against disease caused by Hib. ***Hiberix™*** does not protect against disease due to other types of H. influenzae nor against meningitis caused by other organisms.
BRU11020644P	Tegretol® 200mg Tablet	• Epilepsy - Complex or simple partial seizures (with or without loss of consciousness) with or without secondary generalization. - Generalized tonic-clonic seizures. Mixed forms of seizures. Tegretol is suitable for both monotherapy and combination therapy. Tegretol is usually not effective in absences (petit mal) and myoclonic seizures. • Acute mania and maintenance treatment of bipolar affective disorders to prevent or attenuate recurrence. • Alcohol-withdrawal syndrome. • Idiopathic trigeminal neuralgia and trigeminal neuralgia due to multiple sclerosis (either typical or atypical). Idiopathic glossopharyngeal neuralgia.
BRU11020645P	Oroxine™ Tablet 100mcg	Hypothyroidism.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11020647P	Tegretol® 2% Syrup	• Epilepsy - Complex or simple partial seizures (with or without loss of consciousness) with or without secondary generalization. - Generalized tonic-clonic seizures. Mixed forms of seizures. Tegretol is suitable for both monotherapy and combination therapy. Tegretol is usually not effective in absences (petit mal) and myoclonic seizures. • Acute mania and maintenance treatment of bipolar affective disorders to prevent or attenuate recurrence. • Alcohol-withdrawal syndrome. • Idiopathic trigeminal neuralgia and trigeminal neuralgia due to multiple sclerosis (either typical or atypical). Idiopathic glossopharyngeal neuralgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11020648P	Glivec® 100mg Film-Coated Tablet	• Glivec is indicated for the treatment of adult and pediatric patients with newly diagnosed chronic myeloid leukemia (CML) as well as for the treatment of adult and pediatric patients with CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. • adult patients with unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST). • adjuvant treatment of adult patients following resection of GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. • adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy. • adult patients with relapsed or refractory Ph+ ALL as monotherapy. • adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements. • adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) with F1P1L1-PDGFRα rearrangement. • adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP). • adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown. The effectiveness of Glivec is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and ASM and on objective response rates in GIST and DFSP, and on recurrence-free survival in adjuvant GIST (see section PHARMACODYNAMICS). The experience with Glivec in patients with MDS/MPD associated with PDGFR gene re-arrangements is very limited. Except in newly diagnosed chronic phase CML, there are no controlled trials demonstrating a clinical benefit or increased survival in diseases.
BRU11030660P	Oxy-Nase® Nasal Spray 0.05% w/v	It is indicated for the relief of nasal congestion.

BRU11030669PS2; BRU11030669PS3	Caelyx 2mg/ml Concentrate For Infusion	**Breast Cancer** CAELYX®, as monotherapy, is indicated for the treatment of metastatic breast cancer. **Ovarian Cancer** CAELYX® is indicated for the treatment of advanced ovarian cancer in women who have failed a first-line platinum based chemotherapy regimen. **Multiple Myeloma** CAELYX® is indicated in combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and have not previously received bortezomib. Patients should have already undergone or are unsuitable for bone marrow transplant. **AIDS-related Kaposi's Sarcoma** CAELYX® is also indicated for AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (<200 CD4 lymphocytes/mm^3) and extensive mucocutaneous or visceral disease. CAELYX® may be used as first-line systemic chemotherapy, or as second line chemotherapy in AIDS-KS patients with disease that has progressed with, or in patients intolerant to, prior combination systemic chemotherapy comprising at least two of the following agents: a vinca alkaloid, bleomycin and standard doxorubicin (or other anthracyclines).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11030670P	Alkeran Tablet 2mg	ALKERAN tablets are indicated in the treatment of: multiple myeloma; advanced ovarian adenocarcinoma; ALKERAN tablets may be used in the treatment of: breast carcinoma: ALKERAN either alone or in combination with other drugs has a significant therapeutic effect in a proportion of patients suffering from advanced breast cancer; polycythaemia rubra vera: ALKERAN is effective in the treatment of a proportion of patients suffering from polycythaemia vera.
BRU11030672P	Avodart Soft Gelatin Capsules	**Monotherapy** *AVODART* is indicated for the treatment and control of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for BPH-related surgery. **Combination With Alpha-Blocker** *AVODART* in combination with the alpha-blocker tamsulosin is indicated for the treatment of symptomatic BPH in men with an enlarged prostate.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11030674P	Arixtra™ 2.5mg/0.5ml Solution For Injection	Prevention of Venous Thromboembolic Events (VTE) in patients undergoing major orthopaedic surgery of the lower limbs such as: • Hip fracture; • Knee replacement surgery • Hip replacement surgery Prevention of Venous Thromboembolic Events (VTE) in patients undergoing abdominal surgery who are at risk of thromboembolic complications. Prevention of Venous Thromboembolic Events (VTE) in medical patients who are at risk of thromboembolic complications due to restricted mobility during acute illness. Treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) in patients for whom an urgent (<120 mins) invasive management (PCI) is not indicated. Treatment of ST segment elevation myocardial infarction (STEMI) in patients who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11040675P	Puregon® 600IU/0.72ml Solution For Injection	In the female Puregon is indicated for the treatment of female infertility in the following clinical situations: • Anovulation (including polycystic ovarian syndrome, PCOS) in women who have been unresponsive to treatment with clomifene citrate. • Controlled ovarian hyperstimulation to induce the development of multiple follicles in medically assisted reproduction programs [e.g., in vitro fertilization/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)]. In the male • Deficient spermatogenesis due to hypogonadotrophic hypogonadism.
BRU11040679P	Trandate Injection 5mg/ml x 5ml	***Injection is indicated for:*** • Severe hypertension, including severe hypertension of pregnancy, when rapid control of blood pressure is essential. • May be used to achieve controlled hypotension during anaesthesia.
BRU11040681P	Oxy-Nase Nasal Drops 0.05%	It is indicated for the relief of nasal congestion.

BRU11040690P	Engerix-B 10 Junior Dose Suspension For Injection	***Engerix-B*** is indicated for active immunisation against HBV infection caused by all known subtypes in subjects of all ages considered at risk of exposure to HBV. It can be expected that hepatitis D will also be prevented by immunisation with ***Engerix-B*** as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection. Immunisation against hepatitis B is expected in the long term to reduce not only the incidence of this disease, but also its chronic complications such as chronic active hepatitis B and hepatitis B associated cirrhosis. In areas of **low prevalence** of hepatitis B, immunisation is particularly recommended for those belonging to groups identified at increased risk of infection (see below), however, universal immunisation of all infants and adolescents will contribute to the control of hepatitis B on a population basis. In areas of **intermediate and high prevalence** of hepatitis B, with most of the population at risk of acquiring the HBV, the best strategy is to provide universal immunisation of neonates, infants, children and adolescents, as well as adults belonging to groups at increased risk of infection. The WHO, the US Immunisation Practices Advisory Committee (ACIP) and the American Academy of Paediatrics advocate that the vaccination of new-borns and/or the vaccination of adolescents is the optimal strategy for the control of hepatitis B in all countries. Groups identified at increased risk of infection: health care personnel, patients frequently receiving blood products, personnel and residents of institutions, persons at increased risk due to their sexual behaviour, illicit users of addictive injectable drugs, travellers to areas with a high endemicity of HBV, infants born of mothers who are HBV carriers, persons originating from areas with a high endemicity of HBV, patients with sickle-cell anaemia, patients who are candidates for organ transplantation, household contacts of any of the above groups and of patients with acute or chronic HBV infection, subjects with chronic liver disease (CLD) or at risk of developing CLD (e.g. Hepatitis C virus carriers, persons who abuse alcohol), others (police personnel, fire brigade personnel, armed forces personnel and anybody who through their work or personal lifestyle may be exposed to HBV).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11040691P	Elosone Cream	Indicated for the relief of inflammatory and pruritic manifestation of corticosteroid responsive dermatoses.
BRU11040695P	Revolade™ Film-Coated Tablet 25mg	Revolade is indicated for the treatment of adult patients with primary immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Revolade is indicated for the treatment of paediatric patients aged 6 years and above with primary immune thrombocytopenia (ITP) lasting 6 months or longer from diagnosis and who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Revolade is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. Revolade is indicated in combination with standard immunosuppressive therapy for the first-line treatment of adult and adolescent patients 12 years and older with severe aplastic anemia. Revolade is indicated in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11040696P	Coversyl® Film-Coated Tablet 10mg	<u>Hypertension</u> Treatment of hypertension. <u>Stable coronary artery disease</u> Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation.
BRU11050699P	Avamys Nasal Spray	**Adults/Adolescents (12 years and older)** Treatment of the nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing) and ocular symptoms (itching/burning, tearing/watering, and redness of the eye) of seasonal allergic rhinitis. Treatment of the nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing) of perennial allergic rhinitis. **Children (2 to 11 years)** Treatment of the nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing) of seasonal and perennial allergic rhinitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11050701P	Depo-Provera Vial 150mg/3ml	Depot-Medroxyprogesterone acetate (DMPA) injectable suspension is indicated for: Contraception Contraception (ovulation suppression) Gynecology Treatment of endometriosis Treatment of menopausal vasomotor symptoms Oncology Adjunctive and/or palliative treatment of recurrent and/or metastatic endometrial or renal carcinoma. Treatment of hormonally-dependent, recurrent breast cancer in post-menopausal women. Long-term Use: Since loss of bone mineral density (BMD) may occur in pre-menopausal women who use DMPA injection long-term (see Sections 4.4. Special Warnings and Precautions for Use - Additional Warnings and Precautions for Specific Use or Formulation, Contraception/Endometriosis - Injectable Formulations, Loss of Bone Mineral Density (BMD) and 5.1. Pharmacodynamic Properties - Clinical Studies, Bone Mineral Density Studies), a risk/benefit assessment, which also takes into consideration the decrease in BMD that occurs during pregnancy and/or lactation, should be considered.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11050706P	Zofran 8mg In 4ml Solution For Injection	**Adults** *ZOFRAN* injection is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. *ZOFRAN* injection is also indicated for the prevention and treatment of post-operative nausea and vomiting. **Paediatric Population** ***Injection and oral formulations*** : *ZOFRAN* is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting; IV injection is recommended for this purpose.
BRU11050710P	Coveram Tablets 5mg/5mg	Coveram is indicated as substitution therapy for treatment of essential hypertension and/or stable coronary artery disease, in patients already controlled with perindopril and amlodipine given concurrently at the same dose level.
BRU11060715P	Oxy-Nase Paediatric Nasal Drop 0.025% w/v	For the relief of nasal congestion.
BRU11060718P	Myleran™ Tablets 2mg	Busulfan is indicated for the palliative treatment of the chronic phase of chronic myeloid leukaemia. Busulfan is effective in producing prolonged remission in polycythaemia vera, particularly in cases with marked thrombocytosis. Busulfan may be useful in selected cases of essential thrombocythaemia and myelofibrosis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11060722P; BRU11060722PR2	Propecia 1mg Tablet	Treatment of men with male pattern hair loss (androgenic alopecia) to increase hair growth and prevent further hair loss. Propecia is not indicated for use in women (see PREGNANCY and studies in women) or children.
BRU11060723P	Seroquel XR Extended-Release Tablets 50mg	Seroquel XR is indicated for the treatment of schizophrenia. Seroquel XR is effective in preventing relapse in stable schizophrenic patients who have been maintained on Seroquel XR. Seroquel XR is indicated for the treatment of moderate to severe manic episodes in the framework of bipolar disorder. Seroquel XR is indicated for the treatment of major depressive episodes in bipolar disorder. Seroquel XR is indicated for the prevention of recurrence in patients with bipolar disorder, in patients whose manic or depressive episode has responded to quetiapine treatment. Seroquel XR is indicated for the maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or divalproex. The efficacy of SEROQUEL XR in bipolar disorder was established, in part, on the basis of extrapolation from the established effectiveness of SEROQUEL. ***Major depressive disorder*** Treatment of recurrent major depressive disorder (MDD) in patients who are intolerant of, or who have an inadequate response to alternative therapies.
BRU11070729P	Priorix Vaccine	Priorix™ is indicated for the active immunisation against measles, mumps and rubella.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11070733P	Zofran 4mg In 2ml Solution For Injection	**Adults** *ZOFRAN* injection is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. *ZOFRAN* injection is also indicated for the prevention and treatment of post-operative nausea and vomiting. **Paediatric Population** ***Injection and oral formulations*** : *ZOFRAN* is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting; IV injection is recommended for this purpose.
BRU11070734P	Syntometrine® Injection 5IU/ml Ampoule	Active management of the third stage of labour (in order to facilitate separation of the placenta and thus reduce blood loss). Prevention and treatment for post-partum haemorrhage associated with uterine atony.
BRU11070735P	Elosone Ointment 0.1% w/w	For the relief of inflammatory and pruritic manifestation of corticosteroid responsive dermatoses.
BRU11070736P	Coveram 5/10mg Tablet	COVERAM is indicated as substitution therapy for treatment of essential hypertension and/or stable coronary artery disease, in patients already controlled with perindopril and amlodipine given concurrently at the same dose level.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11070737P	Zofran™ Tablets 8mg	**Adults** ZOFRAN oral formulations are indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. ZOFRAN is also indicated for the prevention of post-operative nausea and vomiting. **Paediatric Population** ***Oral formulation*** : ZOFRAN is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting.
BRU11070738PS1; BRU11070738PS2	Diamicron® MR 60mg Tablet	Noninsulin-dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose.
BRU11070740P	Tracrium Injection 50mg/5ml	Tracrium is a highly selective, competitive or non-depolarising neuromuscular blocking agent which is used as an adjunct to general anaesthesia to enable tracheal intubation to be performed and to relax skeletal muscles during surgery or controlled ventilation, and to facilitate mechanical ventilation in Intensive Care Unit (ICU) patients.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11070741P	Coralan® Tablet 7.5mg	Symptomatic treatment of chronic stable angina pectoris Ivabradine is indicated for the symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm and heart rate ≥ 70 bpm. Ivabradine is indicated : - in adults unable to tolerate or with a contra-indication to the use of beta-blockers. - or in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose. Treatment of chronic heart failure Ivabradine is indicated in chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥ 75 bpm, in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated.
BRU11080743P	Lanoxin Tablet 250mcg	**<u>Cardiac Failure</u>** Digoxin is indicated in the management of chronic cardiac failure where the dominant problem is systolic dysfunction. Its therapeutic benefit is greatest in those patients with ventricular dilatation. Digoxin is specifically indicated where cardiac failure is accompanied by atrial fibrillation. **<u>Supraventricular Arrhythmias</u>** Digoxin is indicated in the management of certain supraventricular arrhythmias, particularly atrial flutter and fibrillation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11080744P	Lanoxin PG Tablet 0.0625mg	**Cardiac Failure** Digoxin is indicated in the management of chronic cardiac failure where the dominant problem is systolic dysfunction. Its therapeutic benefit is greatest in those patients with ventricular dilatation. Digoxin is specifically indicated where cardiac failure is accompanied by atrial fibrillation. **Supraventricular Arrhythmias** Digoxin is indicated in the management of certain supraventricular arrhythmias, particularly atrial flutter and fibrillation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11080745P	Glivec® 400mg Film-Coated Tablet	• Glivec is indicated for the treatment of adult and pediatric patients with newly diagnosed chronic myeloid leukemia (CML) as well as for the treatment of adult and pediatric patients with CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. • adult patients with unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST). • adjuvant treatment of adult patients following resection of GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. • adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy. • adult patients with relapsed or refractory Ph+ ALL as monotherapy. • adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements. • adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) with F1P1L1-PDGFRα rearrangement. • adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP). • adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown. The effectiveness of Glivec is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and ASM and on objective response rates in GIST and DFSP, and on recurrence-free survival in adjuvant GIST (see section PHARMACODYNAMICS). The experience with Glivec in patients with MDS/MPD associated with PDGFR gene re-arrangements is very limited. Except in newly diagnosed chronic phase CML, there are no controlled trials demonstrating a clinical benefit or increased survival in diseases.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11080749P	Econazine Cream	Indicated for the topical treatment of inflammatory dermatoses where infected by susceptible organisms co-exist e.g. inflammatory fungal infections and infective eczema.
BRU11080751P	Urosin Film Coated Tablet 100mg	Hypertension, angina pectoris.
BRU11080753P	Fukole Capsule 150mg	Treatment and prevention of cryptococcal meningitis and other cryptococcal infections; treatment of vaginal, oropharyngeal and other forms of candidiasis; prevention of fungal infections in immunocompromised patients.
BRU11080758P	Loramide Capsule 2mg	Indicated for the control and symptomatic relief of acute non-specific diarrhea and of chronic diarrhea associated with inflammatory bowel disease.
BRU11090763P	Infanrix Hexa Vaccine	Infanrix Hexa™ is indicated for primary immunisation against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *Haemophilus influenzae* type B in infants from the age of 6 weeks and may be given to infants who received a first dose of Hepatitis B vaccine at birth.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11090764P	Eloxatin 5mg/ml Concentrate For Solution For Infusion (10ml)	Oxaliplatin, in combination with 5-fluorouracil (5FU) and folinic acid (FA), is indicated for: • Adjuvant treatment of stage III (Dukes' C) colon cancer after complete resection of the primary tumor. • Treatment of metastatic colorectal cancer.
BRU11090765P	Eloxatin 5mg/ml Concentrate For Solution For Infusion (20ml)	Oxaliplatin, in combination with 5-fluorouracil (5FU) and folinic acid (FA), is indicated for: • Adjuvant treatment of stage III (Dukes' C) colon cancer after complete resection of the primary tumor. • Treatment of metastatic colorectal cancer.
BRU11090766P	Infanrix-IPV Vaccine	Infanrix™-IPV is indicated for active immunisation in infants from the age of 2 months against diphtheria, tetanus, and pertussis, and poliomyelitis. Infanrix™-IPV is also indicated as a booster dose for children who have previously been immunised with diphtheria, tetanus, pertussis (DTP) and polio antigens.

BRU11090767P	Sandimmun Neoral® Oral Solution 100mg/ml	**Transplantation indications** **Solid organ transplantation** Prevention of graft rejection following kidney, liver, heart, combined heart-lung, lung or pancreas allogeneic transplantations. Treatment of transplant rejection in patients previously receiving other immunosuppressive agents. **Bone marrow transplantation** Prevention of graft rejection following bone marrow transplantation. Prevention or treatment of graft-versus-host disease (GVHD). **Non-transplantation indications** **Endogenous uveitis** Active sight-threatening intermediate or posterior uveitis of non-infectious aetiology in patients where conventional therapy fails, or causes unacceptable side effects. Behçet uveitis with repeated inflammatory attacks involving the retina. **Nephrotic syndrome** Steroid-dependent and steroid-resistant nephrotic syndrome in adults and children, due to glomerular diseases such as minimal change nephropathy, focal and segmental glomerulosclerosis, or membranous glomerulonephritis. Sandimmun Neoral can be used to induce remissions and to maintain them. It can also be used to maintain steroid-induced remission, allowing withdrawal of steroids. **Rheumatoid arthritis** Treatment of severe, active rheumatoid arthritis. **Psoriasis** Treatment of severe psoriasis in patients in whom conventional therapy is ineffective or inappropriate.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11090769P	Hyzaar® Plus Tablet 100/12.5mg	**Hypertension** HYZAAR® / HYZAAR® PLUS / HYZAAR® FORTE is indicated for the treatment of hypertension, for patients in whom combination therapy is appropriate. **Hypertensive Patients with Left Ventricular Hypertrophy** HYZAAR® / HYZAAR® PLUS / HYZAAR® FORTE is a combination of losartan (COZAAR) and hydrochlorothiazide. In patients with hypertension and left ventricular hypertrophy, losartan, often in combination with hydrochlorothiazide, reduces the risk of stroke in hypertensive patients with left ventricular hypertrophy (see RACE).
BRU11090772P	Diabetmin 500mg Film-Coated Tablet	Metformin is used in the treatment of non-insulin-dependent diabetes mellitus (type 2) in adults, not responding to exercise and dietary modification. Diabetmin may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.
BRU11090778P	Hovasc Tablet 5mg	Amlodipine is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme inhibitor. Amlodipine is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic / vasoconstrictive component but where vasospasm / vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta blockers.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11100782P	Gardasil Vaccine	GARDASIL is a vaccine indicated in girls and women aged 9 through 26 years for the prevention of cervical, vulvar and vaginal cancer, premalignant genital lesions (cervical, vulvar and vaginal), HPV infection, cervical adenocarcinoma *in situ* (AIS) and external genital warts (condyloma acuminata) causally related to Human Papillomavirus (HPV) types 6, 11, 16 and 18. GARDASIL is indicated in boys and men 9 through 26 years of age for the prevention of HPV infection caused by HPV types 6, 11, 16 and 18 and genital warts (condyloma acuminata) caused by HPV types 6 and 11. GARDASIL is also indicated in individuals 9 through 26 years of age for the prevention of anal cancer and premalignant lesions due to HPV types 6, 11, 16 and 18.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11100784PS2	Sandostatin® Ampoules 0.1mg/ml	Symptomatic control and reduction of growth hormone (GH) and IGF-1 plasma levels in patients with acrogemaly who are inadequately controlled by surgery or radiotherapy. Sandostatin treatment is also indicated for acromegalic patients unfit or unwilling to undergo surgery, or in the interim period until radiotherapy becomes fully effective. Relief of symptoms associated with functional gastro-entero-pancreatic (GEP) endocrine tumours: • Carcinoid tumours with features of the carcinoid syndrome. • VIPomas. • Glucagonomas. • Gastrinomas / Zollinger-Ellison syndrome, usually in conjuction with proton-pump inhibitors, or H2-antagonist therapy. • Insulinomas, for pre-operative control of hypoglycaemia and for maintenance therapy. • GRFomas. Sandostatin is not an antitumour therapy and is not curative in these patients. Prevention of complications following pancreatic surgery. Emergency management to stop bleeding and to protect from re-bleeding owing to gastro-oesophageal varices in patients with cirrhosis. Sandostatin is to be used in association with specific treatment such as endoscopic sclerotherapy.
BRU11100787P	Coveram Tablet 10mg/5mg	COVERAM is indicated as substitution therapy for treatment of essential hypertension and/or stable coronary artery disease, in patients already controlled with perindopril and amlodipine given concurrently at the same dose level.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11100788P	Coversyl® Film-Coated Tablet 5mg	Hypertension: Treatment of hypertension. Heart Failure: Treatment of symptomatic heart failure. Stable Coronary Artery Disease: Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation.
BRU11100789P	Myonal 50mg Tablet	• Improvement of myotonic conditions caused by the following diseases: - Neck-shoulder-arm syndrome, scapulohumeral periarthritis and low back pain. • Spastic paralysis caused by the following diseases: Cerebrovascular disorders, spastic spinal paralysis, cervical spondylosis, sequelae of surgical trauma (including cerebrospinal tumor), sequelae of trauma (spinal trauma, head injury), amyotrophic lateral sclerosis, infantile cerebral palsy, spinocerebellar degeneration, spinal vascular disorder, subacute myelo-optico neuropathy (SMON) and other encephalomyelopathies.
BRU11100791P	Coveram Tablet 10mg/10mg	COVERAM is indicated as substitution therapy for treatment of essential hypertension and/or stable coronary artery disease, in patients already controlled with perindopril and amlodipine given concurrently at the same dose level.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11100795P	Euthyrox® Tablet 25mcg	• Treatment of benign euthyroid goitre • Prophylaxis of relapse after surgery for euthyroid goitre • Substitution therapy in hypothyroidism • Concomitant therapy during anti-thyroid medicinal treatment of hyperthyroidism • Suppression therapy in thyroid cancer
BRU11100796P	Concor® 2.5mg Tablet	Treatment of hypertension as well as treatment of coronary heart disease (angina pectoris). Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, diuretics and optionally cardiac glycosides.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11110799P	Sandostatin® LAR® Injection 20mg	Treatment of patients with acromegaly: • *who are adequately controlled* on s.c. treatment with Sandostatin, • *in whom* surgery or radiotherapy is inappropriate or ineffective, or in the interim period until radiotherapy becomes fully effective. Treatment of patients with symptoms associated with functional gastro-entero-pancreatic endocrine tumours *in whom symptoms are adequately controlled on s.c. treatment with Sandostatin* : • Carcinoid tumours with features of the carcinoid syndrome • VIPomas • Glucagonomas • Gastrinomas/Zollinger-Ellison syndrome • Insulinomas, for pre-operative control of hypoglycaemia and for maintenance therapy • GRFomas Treatment of patients with advanced neuroendocrine tumours of the midgut; or of unknown primary origin where non-midgut sites of origin have been excluded.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11110800P	Sandostatin® LAR® Injection 30mg	Treatment of patients with acromegaly: • *who are adequately controlled* on s.c. treatment with Sandostatin, • *in whom* surgery or radiotherapy is inappropriate or ineffective, or in the interim period until radiotherapy becomes fully effective. Treatment of patients with symptoms associated with functional gastro-entero-pancreatic endocrine tumours *in whom symptoms are adequately controlled on s.c. treatment with Sandostatin* : • Carcinoid tumours with features of the carcinoid syndrome • VIPomas • Glucagonomas • Gastrinomas/Zollinger-Ellison syndrome • Insulinomas, for pre-operative control of hypoglycaemia and for maintenance therapy • GRFomas Treatment of patients with advanced neuroendocrine tumours of the midgut; or of unknown primary origin where non-midgut sites of origin have been excluded.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11110802P	Gardasil™ Vaccine (Syringe)	GARDASIL is a vaccine indicated in girls and women aged 9 through 26 years for the prevention of cervical, vulvar and vaginal cancer, premalignant genital lesions (cervical, vulvar and vaginal), HPV infection, cervical adenocarcinoma *in situ* (AIS) and external genital warts (condyloma acuminata) causally related to Human Papillomavirus (HPV) types 6, 11, 16 and 18. GARDASIL is indicated in boys and men 9 through 26 years of age for the prevention of HPV infection caused by HPV types 6, 11, 16 and 18 and genital warts (condyloma acuminata) caused by HPV types 6 and 11. GARDASIL is also indicated in individuals 9 through 26 years of age for the prevention of anal cancer and premalignant lesions due to HPV types 6, 11, 16 and 18.
BRU11110803P; BRU11110803PS2	Nexavar® 200mg Film-Coated Tablets	NEXAVAR is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC). NEXAVAR is indicated for the treatment of patients with advanced renal cell carcinoma who have failed prior systemic therapy or are considered unsuitable for such therapy. NEXAVAR is indicated for the treatment of patients with locally advanced or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11110812P	Euthyrox® Tablet 100mcg	• Treatment of benign euthyroid goitre • Prophylaxis of relapse after surgery for euthyroid goitre • Substitution therapy in hypothyroidism • Concomitant therapy during anti-thyroid medicinal treatment of hyperthyroidism • Suppression therapy in thyroid cancer *applies only to tablets of 100 microgram* : • Diagnostic use for thyroid suppression testing
BRU11110814P	YSP Prednisolone 5mg Tablet	For the treatment of bronchial asthma, allergic disease, rheumatoid arthritis, rheumatosis, Still's disease, rheumatoid myocarditis, psoriasis, osteoarthritis, rheumatic myelitis, gouty arthritis, acute and chronic gout and other inflammatory skin disease.
BRU11120818P	Clarityne Syrup Grape 5mg/5mL	Clarityne* products are indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhoea) and itching, as well as ocular itching and burning. Nasal and ocular signs and symptoms are relieved rapidly after oral administration. Clarityne* products are also indicated for relief of symptoms and signs of chronic and other allergic dermatologic disorders.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11120819P0.5gV; BRU11120819P0.5gS	Synflorix Vaccine	Active immunization of infants and children from 6 weeks up to 5 years of age against disease caused by *Streptococcus pneumoniae* vaccine serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F and cross-reactive serotype 19A (including sepsis, meningitis, pneumonia, bacteraemia and acute otitis media) and against acute otitis media caused by Non-Typeable *Haemophilus influenzae* .
BRU11120820P	Ventolin Evohaler	*VENTOLIN* Evohaler provides short-acting (4 to 6 hours) bronchodilation with fast onset (within 5 minutes) in reversible airway obstruction. It is particularly suitable for the relief and prevention of asthma symptoms. *VENTOLIN* Evohaler should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure). *VENTOLIN* Evohaler is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11120822P	Revolade™ Film-Coated Tablets 50mg	Revolade is indicated for the treatment of adult patients with primary immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Revolade is indicated for the treatment of paediatric patients aged 6 years and above with primary immune thrombocytopenia (ITP) lasting 6 months or longer from diagnosis and who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Revolade is indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy. Revolade is indicated in combination with standard immunosuppressive therapy for the first-line treatment of adult and adolescent patients 12 years and older with severe aplastic anemia. Revolade is indicated in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pretreated and are unsuitable for haematopoietic stem cell transplantation.
BRU11120823P	Coversyl® Plus 5mg	Treatment of essential hypertension in adults, Coversyl Plus 5mg/1.25mg film-coated tablet is indicated in patients whose blood pressure is not adequately controlled on perindopril alone.
BRU11120826NP	Arcalion® 200mg Tablet	Symptomatic treatment of all forms of asthenia.
BRU11120827PS2	Methycobal Injection 500mcg/ml	Peripheral neuropathies. Megaloblastic anemia caused by Vitamin B12 deficiency.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11120832P	Clopivid Tablet 75mg	**Secondary prevention of atherothrombotic events** Clopidogrel is indicated in: • Adult patients suffering from myocardial infarction (from a few days until less than 35 days), ischemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. • Adult patients suffering from acute coronary syndrome: - Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA). - ST segment elevation acute myocardial infarction, in combination with ASA in medically treated patients eligible for thrombolytic therapy. **In patients with moderate to high-risk Transient Ischemic Attack (TIA) or minor Ischemic Stroke (IS)** Clopidogrel in combination with ASA is indicated in: • Adult patients with moderate to high-risk TIA (ABCD21 score ≥4) or minor IS (NIHSS2 ≤3) within 24 hours of either the TIA or IS event. **Prevention of atherothrombotic and thromboembolic events in atrial fibrillation** In adult patients with atrial fibrillation who have at least one risk factor for vascular events, are not suitable for treatment with Vitamin K antagonists (VKA) and who have a low bleeding risk, clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11120834P	Hovasc Tablet 10mg	Amlodipine is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme inhibitor. Amlodipine is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic / vasoconstrictive component but where vasospasm / vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta blockers.
BRU11120835P	Indomen Capsule 25mg	Arthritis, rheumatism, arthritis deformans, and other inflammatory conditions.
BRU11120837P	Primacor® 10mg/10ml Injection	PRIMACOR is indicated for the short-term intravenous treatment of patients with acute decompensated heart failure. Patients receiving PRIMACOR should be observed closely with appropriate electrocardiographic equipment. The facility for immediate treatment of potential cardiac events, which may include life threatening ventricular arrhythmias, must be available. The majority of experience with intravenous PRIMACOR has been in patients receiving digoxin and diuretics. There is no experience in controlled trials with infusions of PRIMACOR for periods exceeding 48 hours.
BRU11120838NP	Champs D-Worms 6 Chewable Tablet (Chocolate)	Treatment of single or mixed infestation of intestinal parasites including Roundworm, Whipworm, Pinworm, Threadworm, Hookworm and Tapeworm.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU11120839P	Epilim® 200 Enteric Coated Tablets	Treatment of generalized or partial epilepsy, particularly with the following patterns of seizures: - Absence - Myoclonic - Tonic-clonic - Atonic - Mixed As well as, for partial epilepsy: - Simple or complex seizures - Secondary generalized seizures - Specific syndromes (West, Lennox-Gastaut) Treatment and prevention of mania associated with bipolar disorder.
BRU12010842P	Valdoxan® 25mg Film-Coated Tablet	Valdoxan is indicated for the treatment of: - major depressive episodes in adults. - generalised anxiety disorder (GAD).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12010843P	Zofran Tablet 4mg	**Adults** ZOFRAN oral formulations are indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. ZOFRAN is also indicated for the prevention of post-operative nausea and vomiting. **Paediatric Population** ***Oral formulation*** : ZOFRAN is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting.
BRU12010853P	Concor® 5mg Tablet	Treatment of hypertension as well as treatment of coronary heart disease (angina pectoris). Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, diuretics and optionally cardiac glycosides.
BRU12010855P	Euthyrox® Tablet 50mcg	• Treatment of benign euthyroid goitre • Prophylaxis of relapse after surgery for euthyroid goitre • Substitution therapy in hypothyroidism • Concomitant therapy during anti-thyroid medicinal treatment of hyperthyroidism • Suppression therapy in thyroid cancer
BRU12010856NP	Panadol Children Suspension 250mg/5ml	Panadol Suspension 250mg/5ml adalah diguna untuk melegakan demam, kesakitan akibat selesema, sakit tumbuh gigi dan sakit gigi dan demam selepas vaksinasi.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12020860P	Yucomy Tablet 200mg	1. Ketoconazole Tablets should be used only when other effective antifungal therapy is not available or tolerated and the potential benefits are considered to outweigh the potential risks. 2. Ketoconazole Tablets are indicated for the treatment of the following systemic fungal infections in patients who have failed or who are intolerant to other therapies: blastomycosis, coccidioidomy cosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis 3. Ketoconazole Tablets should not be used for fungal meningitis because it penetrates poorly into the cerebrospinal fluid.
BRU12020864P	Zanidip® Tablet 10mg	ZANIDIP is indicated in adults for the treatment of mild to moderate essential hypertension.
BRU12020870P	Lyrica™ 150mg Capsules	<u>Neuropathic pain</u> Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. <u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised anxiety disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12030874P	Brilinta™ 90mg F/C Tablet	**Acute Coronary Syndrome or a History of Myocardial Infarction** Brilinta, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with Acute Coronary Syndromes (unstable angina, non ST elevation Myocardial Infarction [NSTEMI] or ST elevation Myocardial Infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG). **Acute Ischemic Stroke or Transient Ischemic Attack (TIA)** Brilinta is indicated to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤5) or high-risk transient ischemic attack (TIA). For further information, please refer to section 'Pharmacodynamic properties'.
BRU12030880NP	Aqua Cream	In irritant conditions of the skin, it acts as an emollient to soften or soothe skin.
BRU12030882P	Cancidas Powder For Injection 50mg/Vial	CANCIDAS is indicated in adult and pediatric patients (12 months and older) for: • Empirical therapy for presumed fungal infections (such as *Candida* or *Aspergillus*) in febrile, neutropenic patients, whose fever has failed to respond to broad-spectrum antibiotics. • Treatment of Candidemia and the following *Candida* infections: intra-abdominal abscesses, peritonitis and pleural space infections. CANCIDAS has not been studied in endocarditis, osteomyelitis, and meningitis due to *Candida* . • Treatment of Esophageal Candidiasis • Treatment of Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12040884P	Dilantin Steri Vials 250mg In 5ml	Phenytoin is indicated for the control of status epilepticus of the tonic-clonic (grand mal) type and prevention and treatment of seizures occurring during or following neurosurgery.
BRU12040885P	Jevtana® 60mg Concentrate And Solvent For Solution For Infusion	JEVTANA in combination with prednisone or prednisolone is indicated for the treatment of adult patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing regimen.
BRU12040887NP	Panadol Children Suspension 120mg/5ml	Relieves fever, aches and pain of flu, toothache, discomfort of teething and fever after vaccination.
BRU12040895P	Axcel Lignocaine Sterile Gel 2% w/w	Lignocaine 2% Sterile Gel is indicated as a surface anaesthetic and lubricant for: - The male and female urethra during cystoscopy, catheterisation, exploration by sound and other endourethral procedures. - Nasal and pharyngeal cavities in endoscopic procedures such as gastroscopy and bronchoscopy. - During photoscopy and rectoscopy. - Tracheal intubation. - Symptomatic treatment of pain in connection with cystitis and urethrisis. - To relief pain after circumcision in children.

BRU12050898P	Lamictal Dispersible Tablet 5mg	**EPILEPSY** **• Adults and Adolescents** LAMICTAL is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. **• Children (2 to 12 years of age)** LAMICTAL is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalised seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome (above 3 years of age only). Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti- epileptic drugs (AEDs) may be withdrawn and patients continued on LAMICTAL monotherapy. If LAMICTAL 2 mg Chewable Dispersible Tablet is not available and the calculated dose in children is less than 2.5 mg daily, then LAMICTAL cannot be used. DO NOT attempt to administer partial quantities of the dispersible tablets. **BIPOLAR DISORDER** **• Adults (18 years of age and over)** LAMICTAL is indicated for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes.
BRU12050903NP	Panadol® ActiFast Caplets	Untuk kelegaan demam dan kelegaan sakit daripada ringan hingga sederhana termasuk: sakit kepala, migrain, sakit belakang, sakit muskuloskeletal, sakit senggugut, sakit osteoarthritis, sakit gigi, sakit selepas prosedur pergigian/pencabutan gigi, sakit selepas vaksinasi dan ketidakselesaan akibat selesema dan sakit tekak.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12060908P	Methycobal Tablets 500mcg	Peripheral neuropathies.
BRU12060909P	Lyrica™ 75mg Capsules	<u>Neuropathic pain</u> Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. <u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised anxiety disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.
BRU12060910NP	Panadol® Soluble Tablet 500mg	Panadol® Soluble is used to relieve headache, fever, pain, and discomfort due to cold and flu and pain following dental procedures.
BRU12060912P	Canesten GYN 1 Day Therapy Vaginal Tablet 0.5g	Vaginitis caused by fungi – mostly candida – and/or trichomonads. Super infections caused by Canesten-sensitive bacteria.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12060915NP	Drapolene Cream	For the treatment and prevention of nappy rash redness. For the relief of nappy rash and for use as an adjunct to baby care hygiene for the prevention of nappy rash. For the aftercare of small areas of superficial burns (limited to the epidermis), limited sunburn and the effects of weather.
BRU12070918P	Beclomet Nasal Aqua 50mcg/Dose Nasal Spray	Seasonal and perennial allergic rhinitis. Vasomotor rhinitis. Prevention of recurrence of nasal polyps after surgical removal.
BRU12070920NP	Panadol® Biconvex Film-Coated Tablet 500mg	Untuk kelegaan sakit daripada ringan hingga sederhana termasuk: sakit kepala, migrain, sakit belakang, sakit muskuloskeletal, sakit senggugut, sakit osteoarthritis, sakit gigi, sakit selepas prosedur pergigian / pencabutan gigi, sakit selepas vaksinasi dan ketidakselesaan akibat selesema dan sakit tekak. Untuk melegakan demam.
BRU12070921NP	ENO Ginger Fruit Salt	Indicated for the symptomatic relief of acid indigestion, flatulence and stomach discomfort.
BRU12070922NP	ENO Fruit Salt	Indicated for the symptomatic relief of acid indigestion, flatulence and stomach discomfort.
BRU12070923P	Coversyl Plus 10mg/2.5mg Tablet	Coversyl Plus 10mg/2.5mg is indicated as substitution therapy for treatment of essential hypertension, in patients already controlled with perindopril and indapamide given concurrently at the same dose level.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12070926NP	Bepanthen® Ointment	Bepanthen® Ointment is used for: • Prevention & treatment of nappy (diaper) rash. • Caring & treatment of sore/cracked nipples, for breastfeeding mothers. • Dry, chapped and cracked skin. • Minor skin injuries such as minor burns and wounds.
BRU12090933P; BRU12090933PS2	Xarelto® Film-Coated Tablet 10mg	Prevention of venous thromboembolism (VTE) in patients undergoing total hip replacement or total knee replacement surgery. Xarelto is indicated for the treatment of Deep Vein Thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT, PE in adults. (See section 'Special warnings and precautions for use' for haemodynamically unstable PE patients.)
BRU12090938P; BRU12090938PS2	Glucophage® XR 750mg Extended Release Tablet	o Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with IGT* and/or IFG* who are: ▪ at high risk for developing overt type 2 diabetes mellitus (see section 5.1) and ▪ not suitable for intensive lifestyle modifications. Treatment with Glucophage XR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk (see section 5.1). *IGT: Impaired Glucose Tolerance; IFG: Impaired Fasting Glucose o Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. Glucophage XR may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12090939P	Glucophage® Tablet 500mg	Treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. • In adults, Glucophage film-coated tablets may be used as monotherapy or in combination with other oral anti-diabetic agents or with insulin. • In children from 10 years of age and adolescents, Glucophage film-coated tablets may be used as monotherapy or in combination with insulin. A reduction of diabetic complications has been shown in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after diet failure (see section 5.1).
BRU12100940NP	Dermoplex Calamine Cream	Soothes and relives nappy rashes, pickly heat, minor skin irritations, insect bites and sunburn.
BRU12100942P	Prostin E2™ Vaginal Tablet 3mg	Oxytocic agent. Dinoprostone are indicated for the induction of labour, especially in patients with favourable induction features, when there are no foetal or maternal contraindications.
BRU12100943NP	Dianeal Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution With 2.5% Dextrose	Dianeal Low Calcium peritoneal dialysis solutions are indicated for use in chronic renal failure patients being maintained on peritoneal dialysis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12100944NP	Potassium Chloride Tablet 600mg (Slow Release)	For prevention and treatment of potassium deficiency.
BRU12100945NP	Anucare Suppositories	Uncomplicated haemorrhoids, simple anorectal inflammatory and irritations caused by or associated with proctitis or cryptitis. May be used pro- and post-operation in haemorrhoidectomy and repair of anal fistula as well as after incision of thrombosed or sclerosed anorectal veins.
BRU12100947PS3	Illiadin Decongestant Nasal Drops	Acute cold, paranasal sinusitis, syringitis, otitis media.
BRU12100949P	Lyrica Capsules 50mg	<u>Neuropathic pain</u> Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. <u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised anxiety disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12100951P	Prograf Capsule 0.5mg	Primary immunosuppression in liver and kidney allograft recipients and liver and kidney allograft rejection resistant to conventional immunosuppressive agents.
BRU12110956NP	Vitamin C 100mg Tablet	Vitamin C is used in the treatment and prevention of deficiency.
BRU12110957PS1; BRU12110957PS2	Actrapid® 100IU/ml Solution For Injection	Treatment of diabetes mellitus.
BRU12110958P	Tretinon Cream 0.05%	Topical treatment of acne vulgaris, in which comedones, papules and pustules predominate.
BRU12110960NP	Daflon 500mg Tablet	-Treatment of symptoms related to venolymphatic insufficiency (heavy legs, pain, early morning restless legs). -Treatment of functional symptoms related to acute hemorrhoidal attack.
BRU12110963NP	Polysilic III Suspension	As antacid in dyspepsia, peptic ulcer, gastritis; use in the relief of abdominal distension and treatment of flatulence and oesophageal reflux with heartburn.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12120967P	Cervarix Suspension For Injection	CERVARIX is indicated from 10 to 45 years of age for the prevention of premalignant ano-genital lesions (cervical, vulvar, vaginal and anal) and cervical and anal cancers caused by oncogenic Human Papillomaviruses (HPV) types 16 and 18.
BRU12120968NP	Dianeal Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution With 4.25% Dextrose	Ambuflex Container: Dianeal Low Calcium Peritoneal Dialysis Solutions are indicated for use in chronic renal failure patients being maintained on peritoneal dialysis. Ultrabag Container: Dianeal Low Calcium Peritoneal Dialysis Solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.
BRU12120969NP	ENO Orange	To relieve symptoms of indigestion.

BRU12120970P	Clamentin Film Coated Tablet 625mg	Clamentin are indicated for short-term treatment of bacterial infections at the following sites: - Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media. - Lower respiratory tract infections e.g. acute and chronic bronchitis, lobar and bronchopneumonia. - Genito-urinary tract infection e.g. cystitis, urethritis, pyelonephritis. - Skin and soft tissue infections e.g. boils, abscesses, cellulitis, wound infections. - Bone and joint infections e.g. osteomyelitis. - Dental infections e.g. dentoalveolar abscess. - Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis. <u>Gram positive</u> **Aerobes**: *Enterococcus faecalis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans, *Staphylococcus aureus, *Coagulase negative staphylococci (including Staphylococcus epidermidis), Corynebacterium species, Bacillus anthracis, Listeria monocytogenes.* **Anaerobes**: *Clostridium species, Peptococcus species, Peptostreptococcus.* <u>*Gram negative:*</u> ***Aerobes** : *Haemophilus influenzae, *Escherichia coli, *Proteus mirabilis, *Proteus vulgaris, *Klebsiella species, *Moraxella catarrhalis, *Salmonella species, *Shigella species, Bordetella pertussis, Brucella species, *Neisseria gonorrhoeae, Neisseria meningitidis, Vibrio cholerae, Pasteurella multocida.* ***Anaerobes** : *Bacteroides spp. Including B. fragilis.* **including beta-lactamase producing strains resistant to ampicillin and amoxycillin.*

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12120971P	Survanta® Beractant Intratracheal Suspension	SURVANTA is indicated for prevention and treatment ("rescue") of Respiratory Distress Syndrome (RDS) (hyaline membrane disease) in premature infants. SURVANTA significantly reduces the incidence of RDS, mortality due to RDS and air leak complications.
BRU12120974P	Sutent™ Hard Capsules 12.5mg	**Gastrointestinal Stromal Tumor (GIST)** **SUTENT** is indicated for the treatment of gastrointestinal stromal tumor after disease progression on or intolerance to imatinib mesylate. **Advanced Renal Cell Carcinoma (RCC)** **SUTENT** is indicated for the treatment of advanced renal cell carcinoma. **Pancreatic Neuroendocrine Tumour (pNET)** **SUTENT** is indicated for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults.

BRU12120975PS2	Stelara Solution For Injection In Pre-Filled Syringe 45mg/0.5ml	**Plaque Psoriasis** ***(via subcutaneous administration only)*** STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A). **Psoriatic Arthritis (PsA)** ***(via subcutaneous administration only)*** STELARA alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Crohn's Disease** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies. **Ulcerative Colitis** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU12120976P	Viagra 50mg Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.
BRU12120977P	Viagra 100mg Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.
BRU12120978P	Aerrane (Isoflurane USP) Inhalation Liquid	Volatile halogenated anaesthetic for general inhalation anaesthesia.
BRU12120980NP	Potcit Mixture	This is used in the treatment of inflammatory conditions of the bladder and to prevent crystalluria during treatment with sulphonamides. It may also be used as a potassium supplement.
BRU12120981P	Garbose Tablet 100mg	Additional therapy in association with diet in patients with diabetes mellitus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13010985P	Zanidip® 20mg Tablet	ZANIDIP is indicated in adults for the treatment of mild to moderate essential hypertension.
BRU13010987P	Pontalon Tablet 500mg	For the symptomatic relief of degenerative arthralgia and for the relief of mild to moderate pain, including muscular, traumatic and dental pain, headache, postoperative and post-partum pain and dysmenorrhea.
BRU13010988P	Co-Trimexazole Suspension	The two components of Co-trimexazole interfere with the bacterial synthesis of tetrahydrofolic acid at different points. It is used to treat infections caused by susceptible gram positive and gram negative bacteria. Suitable indications include:- a) Respiratory tract infections, including pneumocystic carinii b) Acute otitis media c) Bacterial dysentery d) Genital tract infections It is also used in prophylaxis regimens, particularly in cases of hypersensitivity to penicillins and in dysentery.
BRU13010993P	FML® Liquifilm Sterile Opthalmic Solution 0.1%	For steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13010996P	Seretide Evohaler Dose Counter 25/125mcg	**Asthma (Reversible Obstructive Airways Disease)** SERETIDE is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** SERETIDE is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU13010997P	Glucophage® Tablet 850mg	Treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. • In adults, Glucophage film-coated tablets may be used as monotherapy or in combination with other oral anti-diabetic agents or with insulin. • In children from 10 years of age and adolescents, Glucophage film-coated tablets may be used as monotherapy or in combination with insulin. A reduction of diabetic complications has been shown in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after diet failure.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13010998PS2	Revlimid® Capsules 5mg	Revlimid® in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
BRU13010999NP	Infusol® NS	• Plasma isotonic fluid replacement • Sodium and chloride depletion • Hypochloremic alkalosis • Vehicle solution for supplementary medication
BRU13021006P	Canesten GYN 6 Day 6-Day-Therapy	Infectious vaginal discharge. Vaginitis due by fungi – mostly Candida – and/or Trichomonas. Super infections with Canesten-sensitive bacteria.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13021008P	Prevenar 13 Suspension For Injection	Active immunization for the prevention of pneumococcal disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F (including invasive disease, pneumonia and acute otitis media) in infants and children from 2 months to 17 years of age. Active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* in adults aged 18 – 49 years old. Active immunization for the prevention of pneumococcal disease caused by *Streptococcus pneumonia* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults aged 50 years and older. This indication is based on immune responses elicited by Prevenar 13 and there have been no controlled trials in adults demonstrating vaccine efficacy.
BRU13021009P	Hemabate Sterile Solution 250mcg/ml	Hemabate Sterile Solution is indicated for aborting pregnancy between the 13th and 20th weeks of gestation as calculated from the first day of the last normal menstrual period and in the following conditions related to second trimester abortion: -Failure of expulsion of the fetus during the course of treatment by another method. -Premature rupture of membranes in intrauterine methods with loss of drug and insufficient or absent uterine activity. -Requirement of a repeat intrauterine instillation of drug for expulsion of the fetus. -Inadvertent or spontaneous rupture of membranes in the presence of a previable fetus and absence of adequate activity for expulsion. -Hemabate is indicated for the treatment of postpartum hemorrhage due to uterine atony which has not responded to conventional methods of management. Prior treatment should include the use of intravenously administered oxytocin, manipulative techniques such as uterine massage and unless contraindicated, intramuscular ergot preparations. Studies have shown that in such cases, the use of Hemabate has resulted in satisfactory control of hemorrhage, although it is unclear whether or not ongoing or delayed effects of previously administered ecbolic agents have contributed to the outcome. In a high proportion of cases, Hemabate used in this manner has resulted in the cessation of life-threatening bleeding and the avoidance of emergency surgical intervention.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13021011NP	Extraneal Peritoneal Dialysis Solution 75g/L	EXTRANEAL is recommended as a once daily replacement for a single Dextrose exchange as part of a CAPD or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for some categories of patients who have lost ultrafiltration on Dextrose solutions, because it can extend time on CAPD therapy in such patients.
BRU13021012P	Afinitor Tablet 10mg	AFINITOR tablets are indicated for the ♦treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole. ♦treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF-targeted therapy. ♦treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors. ♦treatment of adult patients with progressive, well-differentiated (Grade 1 or Grade 2), non-functional neuroendocrine tumors ~~tumours~~ (NET) of gastrointestinal (GI) or lung origin with unresectable, locally advanced or metastatic disease. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors. ♦treatment of adult and pediatric patients, 1 years of age and older, with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not candidates for curative surgical resection. The effectiveness of AFINITOR is based on an analysis of change in SEGA volume (see section CLINICAL STUDIES). Clinical benefit such as improvement in disease-related symptoms or increase in overall survival has not been demonstrated. ♦treatment of adult patients with renal angiomyolipoma (AML) and tuberous sclerosis complex (TSC), not requiring immediate surgery. The effectiveness of AFINITOR in the treatment of renal angiomylipoma is based on an analysis of durable objective responses in patients treated for a median of 8.3 months. Further follow-up of patients is required to determine long-term outcomes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13021013P	Ketovid Cream 2%	Treatment of dermatophyte infections of the skin-tinea corporis, tinea cruris, tinea manus and tinea pedis caused by *Trichophyton rubrum* , *Trichophyton mentagrophytes* , *Microsporum canis* and *Epidermophyton floccosum* as well as in the treatment of cutaneous candidiasis, pityriasis versicolor and seborrhoeic dermatitis.
BRU13021015P	Azopt 10mg/ml Ophthalmic Suspension	AZOPT is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.
BRU13021016P	Rhewlin SR Tablet 100mg	Diclofenac sodium is an orally active non-steroidal anti-inflammatory agent (NSAID) which has analgesic, anti-inflammatory and antipyretic properties. It is used in the treatment of rheumatic arthritis and other rheumatic diseases.
BRU13021017P	Xepa Hydrogen Peroxide Solution 6%	As first aid for minor cuts, wounds and abrasions, to remove dressing from wounds and as mouthwash in the treatment of acute stomatitis and as deodorant gargle. It is also used to remove ear wax.
BRU13021019P; BRU13021019PS2	Stilamin 3000 For Injection 3mg/Ampoule	-Severe acute haemorrhage from oesophageal varices -Severe acute haemorrhage from gastric or duodenal ulcers, or accompanying acute erosive or hemorrhagic gastritis -Adjuvant treatment in pancreatic, biliary and intestinal fistulae -Prophylaxis and treatment of postoperative complications following pancreatic surgery -Adjuvant treatment in diabetic ketoacidosis

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13021020P	Loradine Syrup 1mg/ml	Relief of symptoms associated with allergic rhinitis e.g. sneezing, nasal discharge and itching, as well as ocular itching and burning. Chronic urticaria and other allergic dermatologic disorders.
BRU13021021P	Decozol Oral Gel 2% w/w	Therapeutic and prophylactic treatment of candidiasis of the oropharyngeal cavity and gastrointestinal tract.
BRU13021022P	Rasitol Injection 20mg/2ml	Oedema due to cardiac, hepatic cirrhosis and nephritic syndrome. Treatment of mild to moderate degree of hypertension.
BRU13021023P	Fusate-250 Tablet	Staphylococcal infections e.g. osteomyelitis, septicaemia, endocarditis, cystic fibrosis, pneumonia, cellulitis, surgical and traumatic wound infections.
BRU13021024P	Premarin Vaginal Cream	Premarin (conjugated oestrogens, CE) Vaginal Cream is indicated in the treatment of atrophic vaginitis, dyspareunia and kraurosis vulvas. Estrogens with or without pregestins should not be used for the prevention of cardiovascular disease or dementia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13021026P	Kaletra Film-Coated Tablet 200mg/50mg	Kaletra is indicated in combination with other antiretroviral agents for the treatment of HIV-infection. This indication is based on analyses of plasma HIV RNA levels and CD4 cell counts in a controlled study of Kaletra of 48 weeks duration, and in smaller uncontrolled dose-ranging studies of Kaletra of 72 weeks (for oral solution) and 144-360 weeks (for tablets) duration. At present, there are no results from controlled trials evaluating the effect of Kaletra on clinical progression of HIV. Once daily administration of Kaletra has not been studied in therapy experienced patients.
BRU13021028P	Holoxan For Injection 1g	Holoxan is to be administered exclusively by physicians with experience in oncology. It is indicated in inoperable malignant tumours that are sensitive to ifosfamide, e.g. bronchial carcinoma, ovarian carcinoma, testicular tumours, soft-tissue sarcoma, breast cancer, pancreatic carcinoma, hypernephroma, endometrial carcinoma, malignant lymphomas. Special remark: Should during treatment with Holoxan a cystitis in connection with macro- or microhaematuria appear, Holoxan therapy has to be interrupted until normalization.
BRU13031029NP	Panadol Extend Caplet 665mg	Panadol Extend is a sustained release formulation that provides relief of muscle and joint pain such as backache, pain of osteoarthritis, rheumatic pain and muscular ache and pains. It is also suitable for fever, headache, migraine, period pain, toothache, pain after dental procedures, pain after vaccination, sore throat and the discomfort from colds and influenza.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13031030P	Canesten Clotrimazole Cream 1% w/w	The confirmed indications for Canesten include: 1) All dermatomycoses due to dermatophytes (e.g. Tricophyton species) 2) All dermatomycoses due to yeast (Candida species) 3) Dermatomycoses due to moulds and other fungi 4) Skin diseases showing secondary infection with these fungi Examples of dermatomycoses listed under 1-4: interdigital mycoses (eg. Athlete's foot), paronychias (associated with nail-mycoses), mycoses in skin folds, candida vulvitis, candida balanitis, pityriasis versicolor, erythrasma.
BRU13031035P	Hydralazine Tablets 50mg	Hydralazine is an antihypertensive agent which acts predominantly by causing direct peripheral vasodilatation. Hydralazine tends to improve renal, uterine and cerebral blood flow and its effect on diastolic pressure is greater than its effect on the systolic pressure. It has a more marked effect on the standing than on the supine pressure. It is used for the treatment of moderate to severe hypertension usually in conjunction with a beta-adrenoceptor blocking agent (Beta blocker) and a thiazide diuretic.
BRU13031037P	Tracidol Capsule 50mg	For the management of moderate to severe pain.
BRU13031039NP	Infusol® S3	• Low salt syndrome • Hypochloraemic alkalosis
BRU13031040P	Intril SR 1.5mg Tablets	Indapamide is indicated for the treatment of Essential hypertension.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13031042P	Inox Capsule 100mg	Treatment of the following conditions:- Systemic mycoses: Systemic aspergillosis and candidiasis, cryptococcosis (including cryptococcal meningitis), histoplasmosis, sporotrichosis, paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or typical mycoses. Dermatological/opthalmological: Onychomycosis, pityriasis versicolor, dermatomycosis and oral candidiasis. Gynaecological: Vulvovaginal candidiasis
BRU13031043P	Doxycap Capsule 100mg	• Rickettsial infections, including typhus, Rocky mountain spotted fever and Q fever • Chlamydial infections, including psittacosis, lymphogranuloma venerum, trachoma and inclusion conjunctivitis • Mycoplasmal infections, especially those caused by Mycoplasma pneumonia • Brucellosis and plague (use in association with streptomycin) • Tularaemia, chronic bronchitis, chancroid, granuloma inguinale, urinary tract infections, acne • Malabsorption syndromes such as tropical sprue and Wipple's disease • Cholera, relapsing fever, leptospirosis and early stage of Lyme disease • Balantidiasis, amoebic dysentery (use in association with an amoebicide) • Syphilis, yaws, gonorrhoea, actinomycosis, anthrax, rat bite fever and acute necrotising ulcerative gingivitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13031045P	Recormon Pre-Filled Syringe 2000IU/0.3ml	Recormon is indicated for: - Treatment of anemia associated with chronic renal failure (renal anemia) in patients on dialysis. - Treatment of symptomatic renal anemia in patients not yet undergoing dialysis. - Treatment of symptomatic anemia in adult patients with non-myeloid malignancies receiving chemotherapy. - Increasing the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported increased risk of thromboembolic events. Treatment should only be given to patients with moderate anemia (Hb 10 to 13 g/dl [6.2 to 8.1 mmol/l], no iron deficiency) if blood conserving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females; 5 or more units for males). * Deficiency is defined as an inappropriately low serum erythropoietin level in relation to the degree of anemia.
BRU13031046P	Leukeran Tablet 2mg	Leukeran is indicated in the treatment of Hodgkin's disease; certain forms of non-Hodgkin's lymphoma; Chronic lymphocytic leukaemia; Waldenstrom's macroglobulinaemia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13031047P	Recormon Pre-Filled Syringe 4000IU/0.3ml	Recormon is indicated for: - Treatment of anemia associated with chronic renal failure (renal anemia) in patients on dialysis. - Treatment of symptomatic renal anemia in patients not yet undergoing dialysis. - Treatment of symptomatic anemia in adult patients with non-myeloid malignancies receiving chemotherapy. - Increasing the yield of autologous blood from patients in a predonation programme. Its use in this indication must be balanced against the reported increased risk of thromboembolic events. Treatment should only be given to patients with moderate anemia (Hb 10 to 13 g/dl [6.2 to 8.1 mmol/l], no iron deficiency) if blood conserving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females; 5 or more units for males). * Deficiency is defined as an inappropriately low serum erythropoietin level in relation to the degree of anemia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13031050P; BRU13031050PS2; BRU13031050PS3	Isentress 400mg Tablet	**<u>Adults</u>** ISENTRESS is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients. This indication is based on analyses of plasma HIV-1 RNA levels in three double-blind controlled studies of ISENTRESS. Two of these studies were conducted in clinically advanced, 3-class antiretroviral (NNRTI, NRTI, PI) treatment-experienced adults through 96 weeks and one was conducted in treatment-naïve adults through 240 weeks. The use of other active agents with ISENTRESS is associated with a greater likelihood of treatment response. **<u>Pediatrics</u>** ISENTRESS is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in children and adoloscents 2 years of age and older. This indication is based on the evaluation of safety, tolerability, pharmacokinetic parameters and efficacy of ISENTRESS through at least 24-weeks in a multi-center, open-label, noncomparative study in HIV-1 infected, treatment-experienced children and adoloscents 2 to 18 years of age (see VIId. Clinical Studies) The safety and efficacy of ISENTRESS have not been established in children less than 2 years of age.

BRU13041051P	Taxotere 80mg/4ml Concentrate For Solution For Infusion	<u>Breast Cancer</u>: TAXOTERE (docetaxel) in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with: • operable node-positive breast cancer. • operable node-negative breast cancer. For patients with operable node-negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer (see section *Pharmacodynamic Properties*). TAXOTERE (docetaxel) in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition. TAXOTERE (docetaxel) in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. TAXOTERE (docetaxel) monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer in whom previous therapy has failed. Prior therapy should have included an anthracycline unless clinically contraindicated. <u>Non-Small Cell Lung Cancer</u>: TAXOTERE (docetaxel) is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer even after failure of platinum-based chemotherapy. TAXOTERE (docetaxel) in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer, in patients who have not previously received chemotherapy for this condition. TAXOTERE in combination with carboplatin represents a treatment option to cisplatin-based therapy.

		Ovarian Cancer: TAXOTERE (docetaxel) is indicated for the treatment of metastatic carcinoma of the ovary after failure of first-line or subsequent chemotherapy. Squamous Cell Carcinoma of the Head and Neck: TAXOTERE (docetaxel) is indicated as monotherapy in the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck after failure of a previous chemotherapy regimen. Prostate Cancer: TAXOTERE (docetaxel) in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostatic cancer. Gastric Adenocarcinoma: TAXOTERE (docetaxel) in combination with cisplatin and 5-fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease. Head and Neck Cancer: TAXOTERE (docetaxel) in combination with cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13041055P	Alpranax Tablet 0.5mg	Anxiety States: Symptoms include anxiety, tension, agitation, insomnia, apprehension, irritability and/or autonomic hyperactivity resulting in a variety of somatic complaints. Mixed Anxiety-Depression: Symptoms of both anxiety and depression occur simultaneously. Neurotic or Reactive Depression: Patients show a depressed mood or a pervasive loss of interest or pleasure. Symptoms include anxiety, psychomotor agitation and insomnia. Other characteristics are appetite disturbances, changes in weight, somatic complaints, cognitive disturbances, decreased energy, feeling of worthlessness or guilt or thoughts of death or suicide. Alprazolam should not be used in patients whose primary symptom of depression is psychomotor retardation; with a diagnosis of bipolar depression; with psychotic symptoms. Anxiety states, mixed anxiety-depression or neurotic depression associated with other diseases, e.g. the chronic phase of alcohol withdrawal and functional or organic disease, particularly certain gastrointestinal, cardiovascular or dermatological disorders. Alprazolam is also indicated for the treatment of panic disorder, with or without agoraphobia. The effectiveness of Alprazolam for long-term use exceeding 6 months has not been established. The physician should reassess the usefulness of the drug for the individual patient from time to time.
BRU13041056NP	Liquid Paraffin	When used externally: For occlusive emollient purpose of the skin. Also used as a lubricant. When used orally: Used as an emollient laxative to soften stools.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13041058P	Pegasys Pre-Filled Syringe 180mcg/0.5ml	1) Pegasys is indicated in combination with other medicinal products, for the treatment of chronic hepatitis C (CHC) in patients with compensated liver disease. This includes patients with compensated cirrhosis and patients with HIV disease that is clinically stable (e.g. antiretroviral therapy not required or receiving stable antiretroviral therapy). The optimal way to use Pegasys in patients with chronic hepatitis C is in combination with ribavirin. The combination of Pegasys and ribavirin is indicated in naïve patients and patients who have failed previous treatment with interferon alpha (pegylated or non-pegylated) alone or in combination therapy with ribavirin. Monotherapy is indicated mainly in case of tolerance or contraindication to ribavirin. 2) Chronic Hepatitis B: Pegasys is indicated for the treatment of both HBeAg-positive and HBeAg-negative chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication and liver inflammation.

BRU13041059P	Borymycin Capsule 50mg	Borymycin Capsule is indicated in the treatment of the following infection caused by susceptible strains: Respiratory infections caused by *Mycoplasma pneumonia* ; Psittacosis due to *Chlamydia psittaci* ; Trachoma caused by *Chlamydia trachomatis* , although the infections is not always eliminated, as judged by immunofluorescence; Inclusion conjunctivitis caused by *Chlamydia trachomitis* ; Nongonocccal urethritis in adults caused by *Ureaplasma urealyticum* or *Chlamydia trachomatis* ; Chancroid due to *Haemophilus ducreyi* ; Chlolera caused by *Vibrio chlorae* . Minocycline is indicated for treatment of infections caused by the following gram-negative microorganism, when bacteriologic testing indicates appropriate susceptibility to the drug: *Escherichia coli; Enterobacter aurogenes; Shigella species: Acinetobacter species;* Respiratory tract infections caused by *Haemophilus influenza* ; Respiratory tract and urinary tract infections caused by *Klebsiella species* . Minocycline is indicated for treatment of infection caused by the following gram-positive microorganism, when bacteriologic testing indicates appropriate susceptibility to the drug: Upper respiratory tract infections caused by *Streptococcus pneumoniae* ; Skin and skin structure infections caused by Minocycline-sensitive organism; Uncomplicated urethritis in men due to *Neisseria gonnorheae* and for the treatment of other gonococcal infections when penicillin is contraindicated. Minocycline is an alternative drug in the treatment of the following infections: infections in women caused by *Neisseria gonorrhoea* ; Syphilis caused by *Treponema pallidum* ; Listeriosis due to *Listeria monocytogenes* ; Anthrax caused by *Bacillus anthracis* ; Infections caused by Clostridium species; In severe acne, Minocycline may be used as an adjunct therapy. Oral Minocyline is indicated in the treatment of asymptomatic carriers of *Neisseria meningitidis* to eliminate meningococci from the nasopharynx. It is recommended that prophylactic use of Minocycline be reserved for situations in which the risk of meningococcal meningitis is high. Oral Minocycline also has been used in the treatment of infections caused by *Mycobacterium marinum* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13041060P	Kytril Tablet 1mg	Kytril is indicated for the prevention of nausea and vomiting induced by cytostatic therapy.
BRU13041061NP	Venofer® Solution For Injection 100mg/5ml	Venofer is indicated for the treatment of iron deficiency in the following indications: • Where there is a clinical need for a rapid iron supply • In patients who cannot tolerate oral iron therapy or who are non-compliant • Where oral iron preparations are ineffective (e.g. In active inflammatory bowel disease) Venofer should only be administered where the indication is confirmed by appropriate investigations.
BRU13041062NP	Calamine Cream	Calamine has mild astringent and antipruritic actions and is used as a dusting powder, cream lotion or ointment in a variety of skin conditions although its value is uncertain.
BRU13041063P	Apuzin Tablet 25mg	Hypertension: It may be used alone or in combination with other antihypertensive agents, especially thiazide type diuretics. There is an additive effect on lowering blood pressure when combined Captopril and thiazide are used. Congestive heart failure: For patients who have not responded adequately to treatment with diuretics and digitalis. Following myocardial infarction. Diabetic nephropathy.
BRU13041064P	Lezpain Film-Coated Tablet 135mg	For the symptomatic treatment of abdominal pain and cramps, bowel disturbances and intestinal discomfort related to irritable bowel syndrome.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13041067NP	White Soft Paraffin BP	For treatment of dry skin conditions.
BRU13041068NP	Calamine Lotion 15% w/v	Calamine has mild astringent and antipruritic actions and is used as a dusting powder, cream lotion or ointment in a variety of skin conditions although its value is uncertain.
BRU13061069P	Votrient™ Film-Coated Tablets 200mg	**Renal cell carcinoma (RCC)** Votrient is indicated for the treatment of patients with advanced and/or metastatic renal cell carcinoma (RCC). **Soft tissue sarcoma (STS)** Votrient is indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. The Phase III trial population excluded patients with gastrointestinal stromal tumor (GIST) or adipocytic STS.
BRU13061070PS1; BRU13061070PS2; BRU13061070PS3	NovoMix® 30 FlexPen® Suspension For Injection 100 U/ml	Treatment of patients with diabetes mellitus requiring insulin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13061071P	Duphaston Tablet 10mg	**Progesterone deficiencies** • Treatment of dysmenorrhoea • Treatment of endometriosis • Treatment of secondary amenorrhoea • Treatment of irregular cycles • Treatment of dysfunctional uterine bleeding • Treatment of pre-menstrual syndrome • Treatment of threatened abortion, associated with proven progesterone deficiency • Treatment of habitual abortion, associated with proven progesterone deficiency • Treatment of infertility due to luteal insufficiency • Luteal support as part of an Assisted Reproductive Technology (ART) treatment **Hormone replacement therapy** To counteract the effects of unopposed estrogen on the endometrium in hormone replacement therapy for women with disorders due to the natural or surgical induced menopause with an intact uterus.
BRU13061073P	Prednisolone Tablet 20mg	Prednisolone is a synthetic corticosteroid with predominantly glucocorticoid activity. It allows for a greater margin of safety than more potent agents. It is used for its anti-inflammatory and immune-suppressant glucocorticoid activity. It is indicated for allergic disorders such as bronchial asthma and allergic skin conditions, blood disorders, including auto-immune haemolytic anaemia and idiopathic thrombocytopenic purpurea, selected collagen and rheumatic disorders, connective tissue disorders such as arthritic and systemic lupus erythematosus, gastrointestinal disorders, hepatic disorders, neuromuscular disorders, selected ocular disorders, renal disorders and severe skin disorders.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13061074P	Kytril For Infusion 3mg/3ml	Kytril is indicated for the prevention or treatment of nausea and vomiting induced by cytostatic therapy and for the prevention and treatment of post-operative nausea and vomiting.
BRU13061075P	Minison Tablet 1mg	Prazosin is indicated for the treatment of hypertension.
BRU13061076PS3	Xeloda™ Tablets 500mg	*Breast Cancer:* Xeloda in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. Xeloda is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of a taxane and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. *Colorectal cancer:* Xeloda is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. Xeloda is indicated for the treatment of metastatic colorectal carcinoma. *Gastric Cancer* Xeloda is indicated for first-line treatment of advanced gastric cancer in combination with a platinum-based regimen.
BRU13061079NP	Maltofer® Syrup	Treatment of iron deficiency without anaemia and iron deficiency anaemia. Prophylactic therapy of iron deficiency during pregnancy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13061080P	Noriday® Tablet	Contraception.
BRU13061081P	Keppra 250mg Film-Coated Tablet	Keppra is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. Keppra is indicated as adjunctive therapy: • in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy. • in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy. Keppra Concentrate is an alternative for patients (adults and children from 4 years of age) when oral administration is temporarily not feasible.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13061082P	Keppra 500mg Film-Coated Tablet	Keppra is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. Keppra is indicated as adjunctive therapy: • in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy. • in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy. Keppra Concentrate is an alternative for patients (adults and children from 4 years of age) when oral administration is temporarily not feasible.

BRU13061083PS3; BRU13061083PS4; BRU13061083PS5	Avastin Concentrate For Solution For Infusion 400mg/16ml	***Metastatic carcinoma of the colon or rectum(mCRC)*** Avastin in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum. ***Metastatic Breast Cancer (mBC)*** Avastin in combination with paclitaxel is indicated for the treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer. Avastin in combination with capecitabine is indicated for first-line treatment of patients with HER2-negative metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. Patients who have received taxane and anthracycline-containing regimens in the adjuvant setting within the last 12 months should be excluded from treatment with Avastin in combination with capecitabine. The effectiveness of Avastin in metastatic breast cancer (mBC) is based on an improvement in progression-free survival. Currently, no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Avastin in breast cancer. ***Non-Small Cell Lung Cancer (NSCLC)*** Avastin, in combination with carboplatin and paclitaxel, is indicated for first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic nonsquamous, non-small cell lung cancer. Avastin, in combination with erlotinib, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations. ***Malignant Glioma (WHO Grade IV) - Glioblastoma*** Avastin, as a single agent is indicated for the treatment of patients with glioblastoma after relapse or disease progression following prior therapy.

		The effectiveness of Avastin in glioblastoma is based on an improvement in objective response rate. There are no data demonstrating an improvement in disease-related symptoms or increased survival with Avastin. ***Advanced and/or metastatic Renal Cell Cancer (mRCC)*** Avastin in combination with interferon alfa-2a is indicated for first-line treatment of patients with advance and/or metastatic renal cell cancer. ***Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer*** Avastin, in combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (FIGO stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. Avastin, in combination with carboplatin and gemcitabine or in combination with carboplatin and paclitaxel is indicated for the treatment of patients with recurrent, platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer who have not received prior bevacizumab or other VEGF-targeted angiogenesis inhibitors. Avastin in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin is indicated for the treatment of patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents. ***Cervical Cancer*** Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13061084PS2	Xeloda Tablet 150mg	*Breast Cancer:* Xeloda in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. Xeloda is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of a taxane and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. *Colorectal cancer:* Xeloda is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. Xeloda is indicated for the treatment of metastatic colorectal carcinoma. *Gastric Cancer* Xeloda is indicated for first-line treatment of advanced gastric cancer in combination with a platinum-based regimen.
BRU13061085P	Uripax Film-Coated Tablet 200mg	Symptomatic relief of dysuria, vesical suprapubic pain, nocturia, frequency & incontinence associated with cystitis, prostatitis, urethritis & urethrotrigonitis. Relief of vesico-urethral spasm due to catheterisation, cytoscopy or indwelling catheters & sequelae or surgical intervention of the lower urinary tract.
BRU13061087P	Elonva Solution For Injection 150mcg/0.5ml	Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program.

BRU13061088P	Maxitrol Eye Ointment	MAXITROL® combines two antibiotics, neomycin sulfate and polymyxin B sulfate, offering broad spectrum antibacterial activity with the anti-inflammatory activity of a corticosteroid, dexamethasone, for combating certain microbial infections of the anterior segment of the eye(s). The suspension also contains hypromellose for maximum effectiveness and comfort. MAXITROL® is indicated for ocular inflammation when concurrent use of an antimicrobial is judged necessary.
BRU13061090P	Ciproxol Intravenous Infusion BP 0.2% w/v	Treatment of the following infections caused by organism strains: - **Lower Respiratory Tract Infections** caused by *Escherichia coli, Klebsiella pneumonia, Enterobacter cloacae, Proteus mirabilis* and *pseudomonas aeruginosa* . - **Urinary Tract Infections** caused by E*scherichia coli, Klebsiella pneumonia, Enterobacter cloacae, Proteus mirabilis, Providencia rettgeri, Morganella morganii, Citrobacter freundii, Citrobacter diversu* and *pseudomonas aeruginosa* . - **Skin and Soft Tissue Infections** caused by *Escherichia coli, Klebsiella pneumonia, Enterobacter cloacae, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Morganella morganii, Citrobacter freundii, pseudomonas aeruginosa, Staphylococcus aureus* and *Staphylococcus epidermidis* (methicillin-resistant strains). In the last case, concomitant treatment with another antibiotic is suggested, in order to prevent organism resistance to ciprofloxacin. - **Gastrointestinal Tract Infections** caused by multiresistant gram-negative organisms, in combination with an antibiotic against anaerobes. - **Bone and Joint Infections** caused by *Enterobacter aeruginosa, Serratia marcescens, Pseudomonas aeruginosa* , and *Enterobacter spp.* in general. Other severe / complicated infections, patients with sepsis or neutropenia, Ps. Aeruginosa infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13061091NP	Infusol® W Intravenous Infusion BP	Sterilised water for injection is generally used as diluents for other drugs.
BRU13061092P	Isoket Ampoule 10mg/10ml	Indicated in the treatment of unresponsive left ventricular failure secondary to acute myocardial infarction, unresponsive left ventricular failure of various aetiology and severe or unstable angina pectoris.
BRU13061095NP	Vitamin B1 Tablet	Thiamine is used in the treatment and prevention of thiamine deficiency.
BRU13071100P	Iodosorb Ointment	Iodosorb ointment is indicated for the topical treatment of chronic exuding wounds.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13071101P	Glucophage XR 500mg Extended Release Tablet	o Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with IGT* and/or IFG* who are: ▪ at high risk for developing overt type 2 diabetes mellitus (see section 5.1) and ▪ not suitable for intensive lifestyle modifications. Treatment with Glucophage XR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk (see section 5.1). *IGT: Impaired Glucose Tolerance; IFG: Impaired Fasting Glucose o Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. Glucophage XR may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.
BRU13071108PS2	Revlimid® Capsules 25mg	Revlimid® (lenalidomide) in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
BRU13071109PS2	Revlimid® Capsules 15mg	Revlimid® (lenalidomide) in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
BRU13071111P	Micosten-H Cream	Infections of the skin by dermatophytes or *Candida sp* . in which inflammatory symptoms are prominent. Particularly indicated for the initial stages of treatment may be continued with Micosten-H Cream. May also be used for mycotic infections with bacterial superinfection.

BRU13071114P	Sandimmun Neoral Capsule 25mg	**Transplantation indications** **Solid organ transplantation** Prevention of graft rejection following kidney, liver, heart, combined heart-lung, lung or pancreas allogeneic transplantations. Treatment of transplant rejection in patients previously receiving other immunosuppressive agents. **Bone marrow transplantation** Prevention of graft rejection following bone marrow transplantation. Prevention or treatment of graft-versus-host disease (GVHD). **Non-transplantation indications** **Endogenous uveitis** Active sight-threatening intermediate or posterior uveitis of non-infectious aetiology in patients where conventional therapy fails, or causes unacceptable side effects. Behçet uveitis with repeated inflammatory attacks involving the retina. **Nephrotic syndrome** Steroid-dependent and steroid-resistant nephrotic syndrome in adults and children, due to glomerular diseases such as minimal change nephropathy, focal and segmental glomerulosclerosis, or membranous glomerulonephritis. Sandimmun Neoral can be used to induce remissions and to maintain them. It can also be used to maintain steroid-induced remission, allowing withdrawal of steroids. **Rheumatoid arthritis** Treatment of severe, active rheumatoid arthritis.
		Psoriasis Treatment of severe psoriasis in patients in whom conventional therapy is ineffective or inappropriate.

BRU13081120P	Enbrel® 25mg Solution For Injection In Pre-Filled Syringe	*Rheumatoid arthritis* Treatment of signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis. Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. *Polyarticular juvenile idiopathic arthritis* Treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Enbrel has not been studied in children aged less than 2 years. *Psoriatic arthritis* Enbrel is indicated for reducing signs and symptoms of active arthritis in patients with psoriatic arthritis. Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. *Axial Spondyloarthritis* *Ankylosing spondylitis* Treatment of active ankylosing spondylitis in adults. *Non-radiographic axial spondyloarthritis* Treatment of adults with active* non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs NSAIDs). *Active disease is defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥4. *Plaque psoriasis* Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

		Pediatric plaque psoriasis Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.
BRU13081122P	Requip Tablet 1mg	REQUIP® is indicated for the treatment of idiopathic Parkinsons's disease: • REQUIP may be used alone (without levodopa[L-Dopa]) in the treatment of idiopathic Parkinson's disease; • Addition of REQUIP to levodopa may be used to control "on-off" fluctuations and permit a reduction in the total daily dose of L-Dopa. Treatment of Restless Legs Syndrome: • Ropinirole is indicated for the treatment of idiopathic/primary Restless Legs Syndrome.
BRU13081124P	Heparinol 5000IU/ml	Heparin is indicated for prophylaxis and treatment of thrombo-embolic disorders such as thrombophlebitis, pulmonary embolism, myocardial infarction, arterial embolism and other occlusive vascular disease. It is also used to prevent thrombo-embolic complication from cardiac and vascular surgery, dialysis, frostbite and other perfusion procedures. Heparin is also used as anticoagulant in blood transfusions and for laboratory purposes.
BRU13081125P	Pharmaniaga Pyrazinamide Tablet 500mg	Indicated in combination with other antituberculars, in the treatment of tuberculosis after failure with the primary medications. It is effective only against mycobacteria.
BRU13081127P	Ketovid Shampoo 2% w/w	Treatment and prophylaxis of infections in which the yeast Malassezia (previously called Pityrosporum) is involved, such as pityriasis versicolor (localised), seborrhoeic dermatitis and pityriasis capitis (dandruff).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13081128P	Maxitrol Eye Drops	MAXITROL® combines two antibiotics, neomycin sulfate and polymyxin B sulfate, offering broad spectrum antibacterial activity with the anti-inflammatory activity of a corticosteroid, dexamethasone, for combating certain microbial infections of the anterior segment of the eye(s). The suspension also contains hypromellose for maximum effectiveness and comfort. MAXITROL® is indicated for ocular inflammation when concurrent use of an antimicrobial is judged necessary.
BRU13091130P	Erbitux® 5mg/ml Solution For Infusion	Erbitux is indicated for the treatment of patients with RAS wild-type metastatic colorectal cancer • in combination with irinotecan-based chemotherapy or continuous infusional 5-fluorouracil/folinic acid plus oxiplatin • as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan. Erbitux is indicated in combination with encorafenib, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, who have received prior systemic therapy. Erbitux is indicated for the treatment of patients with squamous cell cancer of the head and neck • in combination with radiation therapy for locally advanced disease • in combination with platinum-based chemotherapy for recurrent and/or metastatic disease.
BRU13091132NP	Beafort Syrup	To enhance energy levels and promote healthy nerves.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13091133P	Clexane 4000 IU (40mg)/0.4ml	Enoxaparin sodium is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prevention of thrombus formation in extracorporeal circulation during hemodialysis. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure , respiratory insufficiency, severe infection or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent Percutaneous Coronary Intervention (PCI).
BRU13091135P	Iodosorb Powder	For the topical treatment of chronic exuding wounds.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13091136P	Anlodin Tablet 10mg	Amlodipine is indicated in the treatment of hypertension and, in most cases, can be used as monotherapy. Patients insufficiently controlled with a single antihypertensive e.g. thiazide diuretic, beta-blockers or angiotensin-converting enzyme inhibitors, may benefit from the addition of amlodipine. Amlodipine can also be used as first line treatment of myocardial treatment of myocardial ischemia, both in cases of fixed obstruction (stable angina), and/or in cases following vasoconstriction or vasospasm (Prinzmetal's angina or variant angina). Amlodipine can therefore be used in cases where the clinical picture suggests a possible vasospastic component even if there is no confirmation of this clinical situation. Amlodipine can used alone or in combination with other anti-angina drugs, in patients suffering from angina who do not respond to nitrates or adequate doses of beta-blockers.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13091138P	Clexane 6000 IU (60mg)/0.6ml	Enoxaparin sodium is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prevention of thrombus formation in extracorporeal circulation during hemodialysis. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure , respiratory insufficiency, severe infection or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent Percutaneous Coronary Intervention (PCI).
BRU13091140P	Camazol Tablet 5mg	It is used for the treatment of thyrotoxicosis, Grave's disease and in the preparation of subtotal thyroidectomy.
BRU13091142NP	Sulbumin 200 Capsule	Symptomatic treatment of all forms of function asthenia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13091143P	Velcade® 3.5 mg For Injection (Sterile Lyophilized Powder)	VELCADE is indicated for the treatment of patients with multiple myeloma. VELCADE is indicated for the treatment of patients with mantle cell lymphoma.
BRU13091144P	Bezamidin Tablet 200mg	Bezamidin Tablet is used with conjunction with dietary and lifestyle modification in the treatment of all types of hyperlipoproteinaemia responsive to drug therapy (types IIa, IIb, III, IV and V). It is also indicated in the treatment of secondary hyperlipidaemias associated with an underlying disorder (e.g. Diabetes mellitus), when treatment of the underlying disorder does not result in adequate control of the hyperlipidaemic state.
BRU13091145NP	A-Bite Cream	For the relief of itch due to mosquitoes and other insects bites.
BRU13101149P	Erycin Film Coated Tablet 250mg	Upper and lower respiratory tract infections, skin and soft tissues infections, ear and oral infections.
BRU13101151NP	ENO Fruit Salt Lemon	Indicated for the symptomatic relief of acid indigestion, flatulence and stomach discomfort.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13101153P	Clexane 2000 IU (20mg)/0.2ml	Enoxaparin sodium is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prevention of thrombus formation in extracorporeal circulation during hemodialysis. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure , respiratory insufficiency, severe infection or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent Percutaneous Coronary Intervention (PCI).
BRU13101154P	Axcel Mefenamic Acid Suspension	Relief of mild to moderate pain including headache, dental pain, postoperative pain and dysmenorrhea; in musculoskeletal and joint disorders such as osteoarthritis and rheumatoid arthritis and in children with fever and juvenile rheumatoid arthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13101155P	Ovidrel Solution For Injection 250mcg/0.5ml In Pre-Filled Pen	Ovidrel® is indicated in the treatment of • Women undergoing superovulation prior to assisted reproductive technologies (ART) such as in vitro fertilisation (IVF): Ovidrel® is administered to trigger final follicular maturation and luteinisation after stimulation of follicular growth, • Anovulatory or oligo-ovulatory women: Ovidrel® is administered to trigger ovulation and luteinisation in anovulatory or oligo-ovulatory patients after stimulation of follicular growth.

BRU13101156P	Sandimmun Neoral Capsule 100mg	**Transplantation indications** **Solid organ transplantation** Prevention of graft rejection following kidney, liver, heart, combined heart-lung, lung or pancreas allogeneic transplantations. Treatment of transplant rejection in patients previously receiving other immunosuppressive agents. **Bone marrow transplantation** Prevention of graft rejection following bone marrow transplantation. Prevention or treatment of graft-versus-host disease (GVHD). **Non-transplantation indications** **Endogenous uveitis** Active sight-threatening intermediate or posterior uveitis of non-infectious aetiology in patients where conventional therapy fails, or causes unacceptable side effects. Behçet uveitis with repeated inflammatory attacks involving the retina. **Nephrotic syndrome** Steroid-dependent and steroid-resistant nephrotic syndrome in adults and children, due to glomerular diseases such as minimal change nephropathy, focal and segmental glomerulosclerosis, or membranous glomerulonephritis. Sandimmun Neoral can be used to induce remissions and to maintain them. It can also be used to maintain steroid-induced remission, allowing withdrawal of steroids. **Rheumatoid arthritis** Treatment of severe, active rheumatoid arthritis. **Psoriasis** Treatment of severe psoriasis in patients in whom conventional therapy is ineffective or inappropriate.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13101158P	Endoxan Tablet 50mg	Endoxan is used within a combination chemotherapy regimen or as monotherapy in • **Leukaemias**: acute or chronic lymphocytic and myelogenous leukaemias • **Malignant lymphomas**: Hodgkin's disease, non-Hodgkin's lymphomas, plasmacytoma • **Metastasizing and non-metastasizing malignant solid tumours**: ovarian cancer, testicular cancer, breast cancer, small cell lung cancer, neuroblastoma, Ewing's sarcoma • **Progressive 'autoimmune diseases**': eg. Rheumatoid arthritis, psoriatic arthropathy, systemic lupus erythematosus, scleroderma, systemic vasculitides (eg. With nephrotic syndrome), certain types of glomerulonephritis (eg. with nephrotic syndrome), myasthenia gravis, autoimmune haemolytic anaemia, cold agglutinin diseases. • **Immunosuppressive treatment in organ transplantations**.
BRU13101159P	CEF-4® Injection 500mg	CEF-4® is used in the treatment of susceptible infections including:- - Lower Respiratory Tract Infections - Urinary Tract Infections - Skin and Soft Tissue Structure Infections - Bacterial Septicemia - Bone and Joint infections - Gynecological infections, including endometritis, pelvic cellulitis and other infections of the female genital tract - Intraabdominal infections - CNS infections - Severe and life-threatening infections

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13101160P	Premarin Tablet 0.625mg	1. Treatment of moderate to severe vasomotor symptoms due to menopause. 2. Prevention and management of osteoporosis associated with estrogen deficiency. When prescribing solely for the prevention of post-menopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and for whom non-estrogen medications are not considered to be appropriate. When prescribing solely for the management of post-menopausal osteoporosis, nonestrogen medications should be first considered. 3. Treatment of vulvar and vaginal atrophy due to menopause. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered. 4. Treatment of hypoestrogenism due to hypogonadism, castration or primary ovarian failure. ERT and HRT should not be initiated or continued to prevent coronary heart disease (see also Cardiovascular risk and section DEMENTIA). The benefits and risks of ERT and HRT must always be carefully weighed, including consideration of the emergence of risks as therapy continues (see SPECIAL WARNINGS). Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman. In the absence of comparable data, the risks of HRT should be assumed to be similar to all estrogens and estrogen/progestin combinations.
BRU13101161PS2	Revlimid® Capsules 10mg	Revlimid® (lenalidomide) in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
BRU13101162P	Pharmaniaga Cephalexin Suspension 125mg	Cephalexin is used to treat septicaemia, bone and joint infections, including burn wound infections and urinary tract infections caused by susceptible bacterial organisms. They are not effective in treating meningitis. Cephalexin is used as a possible alternative to the penicillins for staphylococcus and nonenterococcal streptococcal infections including pneumonia, bone and joint infections, and bacterial endocarditis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13121167P	Copastin Film Coated Tablet 10mg	For unproductive cough induced by common cold, acute and chronic bronchitis.
BRU13121168P	Ucort Cream	For the treatment of all dry ichthyotic, eczematous conditions of the skin, including atopic, infantile, chronic allergic and irritant eczema, asteatotic, hyperkeratotic and lichenified eczema, neurodermatitis and prurigo.
BRU13121169P	Pradaxa® Hard Capsules 150mg	Reduction of the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.
BRU13121170P	Pradaxa® Hard Capsules 110mg	Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery. Reduction of the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13121172NP	Dianeal Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution With 1.5% Dextrose	Ambu-Flex Container: Dianeal Low Calcium Peritoneal Dialysis Solutions are indicated for use in chronic renal failure patients being maintained on peritoneal dialysis. Ultrabag Container: Dianeal Low Calcium Peritoneal Dialysis Solutions in Ultrabag containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.
BRU13121174P	Temodal Capsules 100mg	• Newly diagnosed glioblastoma multiforme concomitantly with radiotherapy & subsequently as monotherapy treatment. • Malignant glioma such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.
BRU13121177P	Cyclogyl® 1% Sterile Ophthalmic Solution	For mydriasis and cycloplegia in diagnostic procedures.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13121178P	Betawin Tablet 50mg	Hypertension: to reduce blood pressure and to reduce the risk of cardiovascular and coronary mortality (including sudden death), and morbidity. Angina pectoris. Disturbances of cardiac rhythm including especially supraventricular tachycardia. Confirmed or suspected myocardial infarction - prevention of cardiac death and reinfarction. Functional heart disorders with palpitations. Migraine prophylaxis. Hyperthyroidism.
BRU13121179P	Imigran FD Tablet 50mg	Sumatriptan fast disintegrating tablets are indicated for the acute relief of migraine attacks with or without aura, including the acute treatment of migraine attacks associated with the menstrual period in women.
BRU13121180P; BRU13121180PS2	Glucovance Tablet 500mg/5mg	Glucovance 500mg/5mg is indicated as second-line therapy when diet, exercise and initial treatment with a sulfonylurea or metformin do not result in adequate glycaemic control in patients with type 2 diabetes.
BRU13121183P	Anarex Tablets	For relief of various types of pain, especially pain due to spasm of voluntary muscle.
BRU13121187NP	B. Braun 10% Glucose Intravenous Infusion B.P.	- Administration of glucose for caloric support - Therapy of hypoglycaemia - Vehicle solution for compatible medicinal products

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU13121192NP	Nutriflex Lipid Peri Emulsion For Infusion	Supply of energy, essential fatty acids, amino acids, electrolytes and fluids during parenteral nutrition for patients with mild to moderately severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated.
BRU14011193PS1	Alimta 500mg Powder For Solution For Infusion	<u>Malignant pleural mesothelioma</u> ALIMTA in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. <u>Non-small cell lung cancer</u> ALIMTA in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. ALIMTA is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. ALIMTA is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. ALIMTA in combination with pembrolizumab and platinum chemotherapy, is indicated for the first line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14011196P	Largo Tablets 100mg	It is used to treat psychotic conditions. It controls excitement, agitation and psychomotor disturbances in schizophrenic patients and reduces the manic phase in manic depressive illness. It is used to control hyperkinetic states and aggression and is used in other psychiatric conditions for the control of anxiety and tension. It may be used as premedication in surgery, reduces analgesic requirements, and has an antiemetic effect.
BRU14011197NP	Axcel Eviline Forte Suspension	Eviline Forte is an antacid / deflatulent for symptomatic treatment of peptic ulcer, dyspepsia of functional or organic origin, heartburn in hiatus hernia or pregnancy, flatulence and abdominal distension, gastension, gastritis oesophagitis and other conditions where hyperacidity or flatulence may be present.
BRU14011198NP	Bepanthen® First Aid Cream	Bepanthen® First Aid is used for the treatment of: • Superficial / minor wounds of any kind when there is a risk of infection: e.g. abrasions, small cuts, scratches, fissures, rhagades, mild burns, sores and ulcers. • Infected skin irritations. • Skin damage & external surgical wounds, in minor surgery.
BRU14011199NP; BRU14011199NPS2	Dextrose 5% And Sodium Chloride 0.9% Injection USP	Dextrose and Sodium Chloride Injection is indicated as a source of water, electrolytes, and calories.
BRU14011200NP	Macgel® Tablet	Hyperacidity, peptic and duodenal ulcer, gastritis, flatulence.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14011203P	Betaserc 24mg Tablet	Meniere's syndrome as defined by the following core symptoms: Vertigo (with nausea/vomiting), hearing loss (hardness of hearing) and tinnitus (ringing in the ears). Symptomatic treatment of vestibular vertigo.
BRU14011204P	Humalog Mix50 100 Units/ml Kwikpen	Treatment of patient with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis.
BRU14011205NP	Panamol Tablet 500mg	For relief of pain and fever, influenza, rheumatic and joint pains, cramps and other muscular pains.
BRU14011206P	Seretide Evohaler Dose Counter 25/50mcg	**Asthma (Reversible Obstructive Airways Disease)** *SERETID* E is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and a This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** *SERETIDE* is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14011207PS1	Tobrex® Eye Drops Solution	Tobrex® Opthalmic Solution is a topical antibiotic indicated in the treatment of external infections of the eye and its adnexa caused by susceptible bacteria. Appropriate monitoring of bacterial response to topical antibiotic therapy should accompany the use of Tobrex® Ophthalmic Solution. Clinical studies have shown tobramycin to be safe and effective for use in children.
BRU14011208P	Pneumovax 23	Pneumovax 23 is indicated for vaccination against pneumococcal disease caused by those pneumococcal types included in the vaccine. Effectiveness of the vaccine in the prevention of pneumococcal pneumonia and pneumococcal bacteremia has been demonstrated in controlled trials in South Africa, France and in case-controlled studies. Pneumovax 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine. If it is known that a person has not received any pneumococcal vaccine or if earlier pneumococcal vaccination status is unknown, then persons in the categories listed below should be administered pneumococcal vaccine; however, if a person has received a primary dose of pneumococcal vaccine, before administering an additional dose of vaccine, please refer to the Revaccination section. Vaccination with Pneumovax 23 is recommended for selected individuals as follows: *Immunocompetent persons* : □ routine vaccination for persons 50 years of age or older □ persons aged ≥ 2years with chronic cardiovascular disease (including congestive heart failure and cardiomyopathies), chronic pulmonary disease (including chronic obstructive pulmonary disease and emphysema), or diabetes mellitus □ persons aged ≥ 2years with alcoholism, chronic liver disease (including cirrhosis) or cerebrospinal fluid leaks □ persons aged ≥ 2years with functional or anatomic asplenia (including sickle cell disease and splenectomy) □ persons aged ≥ 2years living in special environments or social settings (including Alaskan Natives and certain American Indian populations)

		Immunocompromised persons : persons aged ≥ 2years, including those with HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure or nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids); and those who have received an organ or bone marrow transplant (for selected groups, see indications and usage, Timing of Vaccination). Pneumovax 23 may not be effective in preventing infection resulting from basilar skull fracture or from external communication with cerebrospinal fluid.
BRU14011209P	Neupogen Pre-Filled Syringe 30MU/0.5ml	<u>*Established cytotoxic chemotherapy*</u> Neupogen is indicated for reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia and its clinical sequelae in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia (see section 2.5.3 Paediatric Use). <u>*Peripheral blood progenitor cell mobilisation (PBPC)*</u> Neupogen is indicated for the mobilisation of autologous peripheral blood progenitor cells alone, or following myelosuppressive chemotherapy and the mobilisation of peripheral blood progenitor cells in normal donors (allogenic PBPC). <u>*Severe chronic neutropenia (SCN)*</u> Long term administration of Neupogen is indicated in patients, children or adults, with severe congenital, cyclic or idiopathic neutropenia with an Absolute Neutrophil Count (ANC) ≤ $0.5x10^9$/l, and a history of severe or recurrent infections, to increase neutrophil counts and to reduce the incidence and duration of infection-related events. <u>*HIV infection*</u> Neupogen is indicated for the treatment of persistent neutropenia ((ANC) ≤ $1.0 x10^9$/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections, when other options to manage neutropenia are inappropriate.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14011212P	Axcel Chlorpheniramine-4 Syrup	For allergic conditions including hay fever, urticaria, angioedema, vasomotor rhinitis, allergic eczema, atopic and contact dermatitis, drug and serum reactions, insect bites and pruritus.

BRU14021215P	Havrix 1440 Pre-Filled Syringe	Havrix is indicated for active immunization against hepatitis A virus (HAV) infection in subjects at risk of exposure to HAV. Havrix will not prevent hepatitis infection caused by other agents such as hepatitis B virus, hepatitis C, hepatitis E virus or other pathogens known to infect the liver. In areas of low to intermediate prevalence of hepatitis A, immunisation with Havrix is particularly recommended in subjects who are, or will be, at increased risk of infection such as: • Travellers. Persons travelling to areas where the prevalence of hepatitis A is high. The areas include Africa, Asia, the Mediterranean basin, the Middle East, Central and South America. • Armed Forces. Armed Forces personnel who travel to higher endemicity areas or to areas where hygiene is poor have an increased risk of HAV infection. Active immunisation is indicated for these individuals. • Persons for whom hepatitis A is an occupational hazard or for whom there is an increased risk of transmission. These include employees in day-care centres, nursing, medical and paramedical personnel in hospitals and institutions, especially gastroenterology and paediatric units, sewage workers, food handlers, among others. • Persons at increased risk due to their sexual behaviour. Homosexuals, persons with multiple sexual partners. • Haemophiliacs. • Abusers of Injectable Drugs. • Contacts of Infected Persons. Since virus shedding of infected persons may occur for a prolonged period, active immunisation of close contacts is recommended. • Persons who require protection as part of hepatitis A outbreak control or because of regionally elevated morbidity. • Specific population groups known to have a higher incidence of hepatitis A. For example American Indians, Eskimos, recognised community-wide HAV epidemics. • Subjects with chronic liver disease or who are at risk of developing chronic liver disease (e.g. Hepatitis B (HB) and Hepatitis C(HC) chronic carriers and alcohol abusers). In areas of intermediate to high prevalence of hepatitis A (e.g. Africa, Asia, the Mediterranean basin, the Middle East, Central and South America) susceptible individuals may be considered for active immunisation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14021216P	Co-Plavix® 75/100 Film-Coated Tablets	CoPlavix is indicated for the secondary prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). CoPlavix is a fixed-dose combination medicinal product for continuation of therapy in: • Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction) including patients undergoing a stent placement following percutaneous coronary intervention (PCI). • ST segment elevation acute myocardial infarction (STEMI) in patients undergoing PCI (including patients undergoing a stent placement) or medically treated patients eligible for thrombolytic / fibrinolytic therapy. For further information please refer to *Pharmacodynamic properties* .
BRU14021217P	Votrient™ Film-Coated Tablets 400mg	**Renal cell carcinoma (RCC)** Votrient is indicated for the treatment of patients with advanced and/or metastatic renal cell carcinoma (RCC). **Soft tissue sarcoma (STS)** Votrient is indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. The Phase III trial population excluded patients with gastrointestinal stromal tumor (GIST) or adipocytic STS.
BRU14021219PS1; BRU14021219PS2; BRU14021219PS3	Novorapid® Flexpen® 100IU/ml	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14021220P	Omelon Enteric Microencapsulated Capsule 20mg	Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy treatment of reflux oesophagitis, Zollinger-Ellison syndrome, eradication of Helicobacter pylori and long term treatment for recurrent duodenal ulcer.
BRU14021223P	Invega® Sustenna Prolonged Release Suspension For Intramuscular Injection 50mg/0.5ml	INVEGA SUSTENNA is indicated for the acute and maintenance treatment of schizophrenia in adults. INVEGE SUSTENNA is indicated for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.
BRU14021224P	Invega® Sustenna Prolonged Release Suspension For Intramuscular Injection 75mg/0.75ml	INVEGA SUSTENNA is indicated for the acute and maintenance treatment of schizophrenia in adults. INVEGE SUSTENNA is indicated for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14021225P	Invega® Sustenna Prolonged Release Suspension For Intramuscular Injection 100mg/1.0ml	INVEGA SUSTENNA is indicated for the acute and maintenance treatment of schizophrenia in adults. INVEGE SUSTENNA is indicated for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.
BRU14021229P	NovoSeven® Powder And Solvent For Solution For Injection 2mg	NovoSeven® is indicated for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in the following patient groups: • in patients with congenital haemophilia with inhibitors to coagulation factors VIII or IX > 5 Bethesda Units (BU) • in patients with congenital haemophilia who are expected to have a high anamnestic response to factor VIII or factor IX administration • in patients with acquired haemophilia
BRU14021230NP	Axcel Eviline Tablet	Axcel Eviline is an antacid/deflatulent for symptomatic treatment of peptic ulcer, dyspepsia of functional or organic origin, heartburn in hiatus hernia or pregnancy, flatulence and abdominal distension, gastritis oesophagitis and other conditions where hyperacidity or flatulence may be present.
BRU14021231P	Axcel Loratadine Syrup	Relief of symptoms associated with allergic rhinitis eg. Sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching & burning, chronic urticaria and other allergic dermatologic disorders.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14021232P	Cymbalta Capsule 30mg	Treatment of major depressive disorder. Management of neuropathic pain associated with diabetic peripheral neuropathy in adults. Treatment of generalised anxiety disorder.
BRU14021233P	Tykerb™ Tablets 250mg	TYKERB is indicated in combination with: • capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. Limitations of Use: Patients should have disease progression on trastuzumab prior to initiation of treatment with TYKERB in combination with capecitabine. • letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. TYKERB in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.
BRU14021235P	Dostinex Tablet 0.5mg	1. Inhibition/Suppression of Physiological Lactation • Inhibition of physiological lactation soon after parturition • Suppression of established lactation 2. Treatment of Hyperprolactinaemic Disorders

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14021236NP; BRU14021236NPS2	Lactated Ringer's Injection USP	Lactated Ringer's Injection USP is indicated as a source of water and electrolytes or as an alkalinizing agent.
BRU14021237P	Imuran 50mg Tablet	Azathioprine is used as an immunosuppressant antimetabolite either alone or, more commonly, in combination with other agents (usually corticosteroids) and procedures which influence the immune response. Therapeutic effect may be evident only after weeks or months and can include a steroid-sparing effect, thereby reducing the toxicity associated with high dosage and prolonged usage of corticosteroids. Azathioprine, in combination with corticosteroids and/or other immunosuppressive agents and procedures, is indicated to enhance the survival of organ transplants, such as renal transplants, cardiac transplants and hepatic transplants. It also reduces the corticosteroid requirements of renal transplant recipients. Azathioprine, either alone or more usually in combination with corticosteroids and/or other drugs and procedures, has been used with clinical benefit (which may include reduction of dosage or discontinuation of corticosteroids) in a proportion of patients suffering from the following: • Severe rheumatoid arthritis • Systemic lupus erythematosus • Dermatomyositis and polymyositis • Auto-immune chronic active hepatitis • Pemphigus vulgaris • Polyarteritis nodosa • Auto-immune haemolytic anaemia • Chronic refractory idiopathic thrombocytopenic purpura

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14021238NP	Axcel Dicyclomine-S Syrup	Relief of gastro-intestinal colic, flatulence & abdominal discomfort due to entrapped gas.
BRU14021240NP	5% Dextrose And 0.45% Sodium Chloride Injection, USP	Dextrose and Sodium Chloride Injection is indicated as a source of water, electrolytes and calories.
BRU14021241P	Giona Easyhaler 200mcg/Dose Inhalation Powder	Treatment of mild, moderate and severe asthma.
BRU14021242P	YSP Amoxicillin Capsules 500mg	For the treatment of infections due to the following susceptible microganisms: Gram-negative organisms-*H.influenzae* , *E.coli* , *P.mirabilis* and *N.gonorrhoeae* . Gram-positive organisms-streptococci (including *S.faecalis*), D.Pneumoniae, and nonpenicillinase-producing staphylococci.
BRU14021243NP	Neurobion Tablet	It is indicated for nerve pain expressed in one or more of the following symptoms: pricking/tingling sensation, numbness, muscle stiffness, muscle cramp, impaired sensation.
BRU14021244P	Gastrazole Omeprazole For Injection 40mg/Vial	Treatment of duodenal and gastric ulcer, NSAID-associated gastric acid and duodenal ulcers or erosions, Helicobacter pylori eradication in peptic ulcer disease, reflux oesophagitis, symptomatic gastro-oesophageal reflux disease, acid related dyspepsia and Zollinger-Ellison syndrome.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14021245P	Keppra Concentrate For Solution For Infusion 500mg/5ml	Keppra is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy. Keppra is indicated as adjunctive therapy • in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy. • in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • in the treatment of primary generalised tonic-clonic seizures in adults and children from 12 years of age with Idiopathic Generalised Epilepsy. Keppra Concentrate is an alternative for patients (adults and children from 4 years of age) when oral administration is temporarily not feasible.
BRU14021246P	Imojev Japanese Encephalitis Vaccine (Live, Attenuated)	IMOJEV is indicated for prophylaxis of Japanese encephalitis caused by the Japanese encephalitis virus, in persons from 9 months of age and over.
BRU14021247P	Pradaxa® Hard Capsules 75mg	Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14021248P	Axcel Flemin Expectorant	Relief of cough & alleviate nasal & bronchial congestion.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14031249P	Tygacil (Tigecycline) 50mg Lyophilised Powder For Intravenous Infusion	Tigecycline is indicated for the treatment of the following infections caused by susceptible strains of the designated microorganisms in the conditions listed below for patients 18 years of age and older: Complicated skin and skin structure infections caused by *Escherichia coli, Enterococcus faecalis* (vancomycin-susceptible isolates only), *Staphylococcus aureus* (methicillin-susceptible and –resistant isolates), *Streptococcus agalactiae, Streptococcus anginosus* grp. (includes *S. anginosus, S. intermedius, and S. constellatus*), *Streptococcus pyogenes, Enterobacter cloacae, Klebsiella pneumoniae* , and *Bacteroides fragilis* . Complicated intra-abdominal infections caused by *Citrobacter freundii, Enterobacter cloacae, E. coli, Klebsiella oxytoca, Klebsiella pneumoniae, Enterococcus faecalis* (vancomycin-susceptible isolates), *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates only), *Streptococcus anginosus* grp. (includes *S. anginosus, S. intermedius, and S. constellatus*), *Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens* , and *Peptostreptococcus micros* . Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to tigecycline. Tigecycline may be initiated as empiric monotherapy before results of these tests are known. To reduce the development of drug-resistant bacteria and maintain the effectiveness of tigecycline and other antibacterial drugs, tigecycline should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
BRU14031250PS1; BRU14031250PS2; BRU14031250PS3	Levemir Flexpen 100IU/ml	Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14031256P	Gonal-F 300IU/0.48ml (22mcg/0.48ml) Solution For Injection In A Pre-Filled Pen	In adult women • Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intrafallopian transfer.
BRU14031257P	Gonal-F 900IU/1.44ml (66mcg/1.44ml) Solution For Injection In A Pre-Filled Pen	In adult women • Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intrafallopian transfer.
BRU14031261P	Prograf Capsule 1mg	Primary immunosuppression in liver and kidney allograft recipients and liver and kidney allograft rejection resistant to conventional immunosuppressive agents.
BRU14031263P	Patanol 0.1% Olopatadine Hydrochloride Sterile Ophthalmic Solution	**Patanol** eye drops contains olopatadine, a relatively selective H1-receptor antagonist and inhibitor of histamine release from the mast cell. **Patanol** eye drops is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14031264PS1	Travatan® Eye Drops 40mcg/ml	Decrease of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.
BRU14031268P	Elonva Solution For Injection 100mcg/0.5ml	Controlled Ovarian Stimulation (COS) in combination with a GnRH antagonist for the development of multiple follicles in women participating in Assisted Reproductive Technology (ART) program.
BRU14031269P	Menveo Powder & Solution For Solution For Injection	Menveo is indicated for active immunization of children (from 2 years of age) and adults at risk of exposure to Neisseria meningitides groups A, C, W135 and Y, to prevent invasive disease. The use of this vaccine should be in accordance with official recommendations.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14031270P	Enbrel® 50mg Solution For Injection In Pre-Filled Syringe	*Rheumatoid arthritis* Treatment of signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis. Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. *Polyarticular juvenile idiopathic arthritis* Treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Enbrel has not been studied in children aged less than 2 years. *Psoriatic arthritis* Enbrel is indicated for reducing signs and symptoms of active arthritis in patients with psoriatic arthritis. Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. *Axial Spondyloarthritis* *Ankylosing spondylitis* Treatment of active ankylosing spondylitis in adults. *Non-radiographic axial spondyloarthritis* Treatment of adults with active* non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs NSAIDs). *Active disease is defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥4.

		Plaque psoriasis Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA (see Pharmacodynamic Properties). *Pediatric plaque psoriasis* Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.
BRU14031272P	Seretide Evohaler Dose Counter 25/250mcg	**Asthma (Reversible Obstructive Airways Disease)** *SERETIDE* is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. Patients who are symptomatic on current inhaled corticosteroid therapy. Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** *SERETIDE* is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14031274PS2	Galvus Met 50/1000mg Film-Coated Tablet	Galvus Met is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus: - as initial therapy when diabetes is not adequately controlled by diet and exercise alone - in patients who are inadequately controlled with metformin hydrochloride alone - in patients who are already being treated with the combination of vildagliptin and metformin hydrochloride, as separate tablets. - in combination with other medicinal products for the treatment of diabetes, including insulin a when these do not provide adequate glycaemic control.
BRU14031275PS2	Galvus Met 50/850mg Film-Coated Tablet	Galvus Met is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus: - as initial therapy when diabetes is not adequately controlled by diet and exercise alone - in patients who are inadequately controlled with metformin hydrochloride alone - in patients who are already being treated with the combination of vildagliptin and metformin hydrochloride, as separate tablets. - in combination with other medicinal products for the treatment of diabetes, including insulin a when these do not provide adequate glycaemic control.
BRU14031276P	Galvus 50mg Tablet	Galvus is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus: • As monotherapy • As combination therapy - o Initial combination with metformin when diabetes is not adequately controlled by diet and exercise alone o In combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control.
BRU14031279NP	Axcel Paracetamol-250 Suspension (Orange)	For the relief of fever, symptoms of cold and influenza, teething pain and headache.

BRU14031280P	Lamictal Dispersible Tablet 25mg	**EPILEPSY** **• Adults and Adolescents** *LAMICTAL* is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. **• Children (2 to 12 years of age)** *LAMICTAL* is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalised seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome (above 3 years of age only). Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti- epileptic drugs (AEDs) may be withdrawn and patients continued on *LAMICTAL* monotherapy. If *LAMICTAL* 2 mg Chewable Dispersible Tablet is not available and the calculated dose in children is less than 2.5 mg daily, then *LAMICTAL* cannot be used. DO NOT attempt to administer partial quantities of the dispersible tablets. **BIPOLAR DISORDER** **• Adults (18 years of age and over)** *LAMICTAL* is indicated for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14031281P	Panaco Tablets	For relief of pain and fever from various causes including but not restricted to the following: influenza and other viral diseases, rheumatism and joint diseases, infections, wounds and bruises, oral diseases, headache of different types, cramps and other muscular pains.
BRU14031282P	Voren Injection	Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis; osteoarthritis and spondylarthritis. Non-articular rheumatism, post-traumatic inflammation and swelling.
BRU14031284P	Xalatan Eye Drops	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, chronic angle closure glaucoma and ocular hypertension. Reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma.
BRU14041285P	Giona Easyhaler® 100mcg/Dose Inhalation Powder	Treatment of mild, moderate, and severe asthma.
BRU14041286P	Axcel Nasatab Tablet	Symptomatic relief of headache, fever and pain, sinus and nasal congestion associated with sinusitis or common cold.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14041287P; BRU14041287PS2	Xarelto™ Film-Coated Tablet 15mg	Xarelto is indicated for prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation. There are limited data on the relative effectiveness of Xarelto and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well-controlled. Xarelto is indicated for the treatment of Deep Vein Thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT, PE in adults.
BRU14041288P; BRU14041288PS2	Xarelto™ Film-Coated Tablet 20mg	Xarelto is indicated for prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation. There are limited data on the relative effectiveness of Xarelto and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well-controlled. Xarelto is indicated for the treatment of Deep Vein Thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT, PE in adults.
BRU14041291NP	Sodium Chloride Injection USP 0.9% In Mini-Bag Plus Container	0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes and may also be used as diluent for reconstitution of a powdered or liquid (up to 10 mL) drug product packaged in a vial with a 13 mm or 20 mm closure.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14041293P	Endoxan® Injection 200mg/Vial	Endoxan is used within a combination chemotherapy regimen or as monotherapy in • **Leukaemias**: acute or chronic lymphocytic and myelogenous leukaemias • **Malignant lymphomas**: Hodgkin's disease, non-Hodgkin's lymphomas, plasmacytoma • **Metastasizing and non-metastasizing malignant solid tumours**: ovarian cancer, testicular cancer, breast cancer, small cell lung cancer, neuroblastoma, Ewing's sarcoma • **Progressive 'autoimmune diseases'**: eg. Rheumatoid arthritis, psoriatic arthropathy, systemic lupus erythematosus, scleroderma, systemic vasculitides (eg. With nephrotic syndrome), certain types of glomerulonephritis (eg. with nephrotic syndrome), myasthenia gravis, autoimmune haemolytic anaemia, cold agglutinin diseases. • **Immunosuppressive treatment in organ transplantations**
BRU14041294P	Certican Tablet 0.25mg	**Kidney and heart transplantation** Certican is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogenic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and corticosteroids. **Liver transplantation** Certican is indicated for the prophylaxis of organ rejection in adult patients receiving a hepatic transplant. In liver transplantation, Certican should be used in combination with tacrolimus and corticosteroids.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14041295P	Certican Tablet 0.75mg	**Kidney and heart transplantation** Certican is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogenic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and corticosteroids. **Liver transplantation** Certican is indicated for the prophylaxis of organ rejection in adult patients receiving a hepatic transplant. In liver transplantation, Certican should be used in combination with tacrolimus and corticosteroids.
BRU14041296P	Shincort Injection 40mg/ml (5ml Vial)	Rheumatoid arthritis, synovitis, allergic rhinitis, allergic asthma, allergic dermatitis, pemphigus, allergic and inflammatory ophthalmic diseases.
BRU14041297PS1	DuoTrav Eye Drops Solution	Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14041302P	Tasigna Capsule 150mg	Tasigna is indicated for: • the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). Clinical effectiveness of TASIGNA in adults with newly diagnosed Ph+ CML-CP is based on major molecular response rate at 12 months and complete cytogenetic response rate by 12 months. • the treatment of pediatric patients 2 years of age and older with newly diagnosed Ph+ CML-CP. Clinical effectiveness of TASIGNA in pediatric patients with newly diagnosed Ph+ CML-CP is based on major molecular response by 12 cycles and complete cytogenetic response at 12 cycles. • the treatment of chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib. Clinical effectiveness of TASIGNA in adults with imatinib-resistant or -intolerant Ph+ CML-CP was based on the unconfirmed major cytogenetic and complete hematologic response rates. Clinical effectiveness of TASIGNA in imatinib-resistant or -intolerant Ph+ CML-AP for adult patients was based on the confirmed hematologic response rates and the unconfirmed major cytogenetic response rates. • the treatment of pediatric patients 2 years of age and older with Ph+ CML-CP with resistance or intolerance to prior therapy including imatinib. Clinical effectiveness of TASIGNA in pediatric patients with imatinib-resistant or intolerant Ph+ CML-CP was based on the MMR rate at 6 cycles. No overall survival benefit has been demonstrated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14041303P	Tasigna Capsule 200mg	Tasigna is indicated for: • the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). Clinical effectiveness of TASIGNA in adults with newly diagnosed Ph+ CML-CP is based on major molecular response rate at 12 months and complete cytogenetic response rate by 12 months. • the treatment of pediatric patients 2 years of age and older with newly diagnosed Ph+ CML-CP. Clinical effectiveness of TASIGNA in pediatric patients with newly diagnosed Ph+ CML-CP is based on major molecular response by 12 cycles and complete cytogenetic response at 12 cycles. • the treatment of chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib. Clinical effectiveness of TASIGNA in adults with imatinib-resistant or -intolerant Ph+ CML-CP was based on the unconfirmed major cytogenetic and complete hematologic response rates. Clinical effectiveness of TASIGNA in imatinib-resistant or -intolerant Ph+ CML-AP for adult patients was based on the confirmed hematologic response rates and the unconfirmed major cytogenetic response rates. • the treatment of pediatric patients 2 years of age and older with Ph+ CML-CP with resistance or intolerance to prior therapy including imatinib. Clinical effectiveness of TASIGNA in pediatric patients with imatinib-resistant or intolerant Ph+ CML-CP was based on the MMR rate at 6 cycles. No overall survival benefit has been demonstrated.
BRU14041304NP	Infusol NSD5	Dehydration; Sodium and chloride depletion; Calorie supply; Vehicle solution for supplementary medication.
BRU14041305NP	Lactul Solution	For the treatment of constipation and hepatic encephalopathy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14041307P	Alimta 100mg Powder For Solution For Infusion	<u>Malignant pleural mesothelioma</u> ALIMTA in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. <u>Non-small cell lung cancer</u> ALIMTA in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. ALIMTA is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. ALIMTA is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. ALIMTA in combination with pembrolizumab and platinum chemotherapy, is indicated for the first line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.
BRU14041313P	YSP Ibuprofen Suspension 20mg/ml	Relief of fever, pain, muscle and joint inflammation.
BRU14041314NP; BRU14041314NPS2; BRU14041314NPS3	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. It is also indicated for use as a priming solution in hemodialysis procedures.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14041315P	Rivadem 3mg Capsule	Rivadem (Rivastigmine Capsules) is indicated for the treatment of mild to moderate dementia of the Alzheimer's type.
BRU14041316P	Rivadem 1.5mg Capsule	Rivadem (Rivastigmine Capsules) is indicated for the treatment of mild to moderate dementia of the Alzheimer's type.
BRU14071319PS1; BRU14071319PS2	Mixtard® 30 100IU/ml	Treatment of diabetes mellitus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071320PS2	Protopic Ointment 0.03%	Protopic 0.03% ointment is indicated in adults, adolescents and children from the age of 2 years. Flare treatment Adults and adolescents (16 years of age and above) Treatment of moderate to severe atopic dermatitis in adults and adolescents who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids. *Children (2 years of age and above)* Treatment of moderate to severe atopic dermatitis in children (2 years of age and above) who failed to respond adequately to conventional therapies such as topical corticosteroids. Maintenance treatment Treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected).
BRU14071321P	Beathorphan Elixir 15mg/5ml	It is used for the relief of unproductive cough.
BRU14071324P	Luvox® Film-Coated Tablets 50mg	• Treatment of depressive illness and the symptoms of depressive disorder. • Treatment of symptoms of obsessive compulsive disorder (OCD).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071325P	Luvox® Film-Coated Tablets 100mg	• Treatment of depressive illness and the symptoms of depressive disorder. • Treatment of symptoms of obsessive compulsive disorder (OCD).
BRU14071326P	TobraDex® Eye Ointment	TOBRADEX® Ointment is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns or penetration of foreign bodies. The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye. The particular anti-infective drug in this product is active against the following common bacterial eye pathogens: Staphylococci, including S. *aureus* and S. *epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains. Streptococci, including some of the Group A beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae* . *Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis. Morganella morganii* , most *Proteus vulgaris* strains, *Haemophilus influenzae* and *H. aegyptius, Moraxella lacunata* , and *Acinetobacter calcoaceticus (Herellea vaginacola)* and some *Neisseria* species.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071328P	Lanvis® Tablet 40mg	Lanvis is indicated primarily for the treatment of acute leukaemias especially, acute myelogenous leukaemia and acute lymphoblastic leukaemia.
BRU14071329NP	Axcel Papain Tablet	In conjunction with other physical or chemotherapeutic measures for treatment of oedema and inflammation.
BRU14071330P	Humalog® KwikPen™ 100 Units/mL	For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Humalog is also indicated for the initial stabilisation of diabetes mellitus.
BRU14071331P	Shincort Injection 40mg/ml (1ml Amp)	Rheumatoid arthritis, synovitis, allergic rhinitis, allergic asthma, allergic dermatitis, pemphigus, allergic and inflammatory ophthalmic diseases.
BRU14071333PS1	Zytiga Tablets 250mg	ZYTIGA is indicated with prednisone or prednisolone for • the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated (see section 5.1). • the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. ZYTIGA is also indicated in combination with prednisone or prednisolone and androgen deprivation therapy (ADT) for the treatment of patients with newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) who may have received up to 3 months of prior ADT.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071335P	Anlodin Tablet 5mg	Amlodipine is indicated in the treatment of hypertension and, in most cases, can be used as monotherapy. Patients insufficiently controlled with a single antihypertensive e.g. thiazide diuretic, beta-blockers or angiotensin-converting enzyme inhibitors, may benefit from the addition of amlodipine. Amlodipine can also be used as first line treatment of myocardial ischemia, both in cases of fixed obstruction (stable angina), and/or in cases following vasoconstriction or vasospasm (Prinzmetal's angina or variant angina). Amlodipine can therefore be used in cases where the clinical picture suggests a possible vasospastic component even if there is no confirmation of this clinical situation. Amlodipine can be used alone or in combination with other anti-angina drugs, in patients suffering from angina who do not respond to nitrates or adequate doses of beta-blockers.
BRU14071336P	Aldara Cream 5% w/w	Aldara 5% cream is indicated for 1. Treatment of external genital and perianal warts/condyloma accuminata in adults. 2. Treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratosis on the face or scalp in immunocompetent adults. 3. Treatment of biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) in immunocompetent adults, with a maximum tumor diameter of 2.0 cm, located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured. The histological diagnosis of superficial basal cell carcinoma should be established prior to treatment, since safety and efficacy of Aldara Cream have not been established for other types of basal cell carcinomas, including nodular and morpheaform (fibrosing or sclerosing) types.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071337P	Premarin Tablet 0.3mg	1. Treatment of moderate to severe vasomotor symptoms due to menopause. 2. Prevention and management of osteoporosis associated with estrogen deficiency. When prescribing solely for the prevention of post-menopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and for whom non-estrogen medications are not considered to be appropriate. When prescribing solely for the management of post-menopausal osteoporosis, nonestrogen medications should be first considered. 3. Treatment of vulvar and vaginal atrophy due to menopause. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered. 4. Treatment of hypoestrogenism due to hypogonadism, castration or primary ovarian failure. ERT and HRT should not be initiated or continued to prevent coronary heart disease (see also Cardiovascular risk and section DEMENTIA). The benefits and risks of ERT and HRT must always be carefully weighed, including consideration of the emergence of risks as therapy continues (see SPECIAL WARNINGS). Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman. In the absence of comparable data, the risks of HRT should be assumed to be similar to all estrogens and estrogen/progestin combinations.
BRU14071342P	Axcel Ibuprofen Paediatric Syrup	Relief of fever such as fever associated with cold and flu; and pain such as pain from teething and toothache, earache, sore throats, headache and minor aches and sprains. Also indicated for the relief of inflammation of muscles and joints.
BRU14071344P	Bislan Tablet 8mg	A mucolytic agent used in the treatment of respiratory disorders associated with viscid or excessive mucus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071345P	Tren Capsules 250mg	Treatment of haemorrhage, or threatened haemorrhage associated with excessive fibrinolysis. It is also used in the management of haemophiliacs undergoing dental extractions, and in the prophylaxis of hereditary angioedema.
BRU14071346P	YSP Hydrocort Cream 1% w/w	Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
BRU14071348P	Pharmaniaga Atropine Sulphate 1mg/ml	Pre-anaesthetic medication usually in conjugation with morphine sulphate. In conjugation with neostigmine methyl sulphate to reverse the effects of non-depolarising muscle relaxants. Smooth muscle spasm in conditions such as renal and biliary colic. In the management of arrhythmias and in the treatment of bradycardia or asystole due to overdosage with parasympathomimetic agents. Atropine has also been used in the suppression of gastro-intestinal motility in the treatment of peptic ulcer, and diagnosis of colicky pain, as an antidote in carbamate and (with pralidoxime) organo-phosphorus insecticide poisoning.
BRU14071352P	Ipolipid 600mg Tablets	- Treatment of severe hypertriglyceridaemia with or without low HDL cholesterol. - Mixed hyperlipidaemia when a statin is contraindicated or not tolerated. - Primary hypercholesterolaemia when a statin is contraindicated or not tolerated. Primary prevention Reduction of cardiovascular morbidity in males with increased non-HDL cholesterol and at high risk for a first cardiovascular event when a statin is contraindicated or not tolerated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071355P	Axcel Dexchlorpheniramine Tablet	For allergic conditions including hay fever, urticaria, angioedema, vasomotor rhinitis, allergic eczema, atopic and contact dermatitis, drug and serum reactions, insect bites and pruritus.
BRU14071358NP	20% Glucose Intravenous Infusion BP	- Administration of glucose for caloric support. - Carbohydrate component in parenteral nutrition regimens. - Therapy of hypoglycaemia.
BRU14071360P	Maxidex Sterile Opthalmic Suspension	MAXIDEX contains dexamethasone, a synthetic corticosteroid. MAXIDEX is indicated in the management of conditions generally responsive to corticosteroids such as: • Certain inflammatory eye conditions of the anterior segment: acute and chronic anterior uveitis, iridocyclitis, iritis and cyclitis, herpes zoster ophthalmicus. • Certain external diseases such as phlyctenular kerato-conjunctivitis, nonpurulent conjunctivitis, including vernal, allergic, catarrhal. It is very effective where allergy is a main factor. • Recurrent marginal ulceration of toxic or allergic etiology. • Thermal and chemical burns. • Post-operatively to reduce inflammatory reactions.
BRU14071361P	Heparinol 1000IU/ml	Heparin is indicated for prophylaxis and treatment of thrombo-embolic disorders such as thrombophlebitis, pulmonary embolism, myocardial infarction, arterial embolism and other occlusive vascular disease. It is also used to prevent thrombo-embolic complication from cardiac and vascular surgery, dialysis, frostbite and other perfusion procedures. Heparin is also used as anticoagulant in blood transfusions and for laboratory purposes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071367P	Invega Sustenna Prolonged Release Suspension For IM Injection 150mg/1.5ml	INVEGA SUSTENNA is indicated for the acute and maintenance treatment of schizophrenia in adults. INVEGE SUSTENNA is indicated for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.
BRU14071368P	Yondelis® Powder for Injection 1mg/vial	YONDELIS® is indicated for the treatment of adult patients with advanced soft tissue sarcoma (STS), after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. YONDELIS® in combination with pegylated liposomal doxorubicin hydrochloride (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer.
BRU14071369P; BRU14071369PS2	Trajenta Film-Coated Tablet 5mg	Trajenta is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071370P	Novoseven® 1mg Powder And Solvent For Solution For Injection	NovoSeven® is indicated for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in the following patient groups: • in patients with congenital haemophilia with inhibitors to coagulation factors VIII or IX > 5 Bethesda Units (BU) • in patients with congenital haemophilia who are expected to have a high anamnestic response to factor VIII or factor IX administration • in patients with acquired haemophilia
BRU14071372PS2	Invega® Extended-Release Tablet 9mg	INVEGA® is indicated for the treatment of schizophrenia in adolescents 15 years and older, including acute treatment and recurrence prevention. INVEGA® is indicated for the treatment of acute exacerbations of schizoaffective disorder as monotherapy and in combination with antidepressants and/or mood stabilizers (lithium and valproate).
BRU14071373PS2	Invega® Extended-Release Tablet 3mg	INVEGA® is indicated for the treatment of schizophrenia in adolescents 15 years and older, including acute treatment and recurrence prevention. INVEGA® is indicated for the treatment of acute exacerbations of schizoaffective disorder as monotherapy and in combination with antidepressants and/or mood stabilizers (lithium and valproate).
BRU14071374PS2	Invega® Extended-Release Tablet 6mg	INVEGA® is indicated for the treatment of schizophrenia in adolescents 15 years and older, including acute treatment and recurrence prevention. INVEGA® is indicated for the treatment of acute exacerbations of schizoaffective disorder as monotherapy and in combination with antidepressants and/or mood stabilizers (lithium and valproate).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071375P	Lucentis 10mg/ml Solution For Injection	Lucentis is indicated in adults for: • the treatment of neovascular (wet) age-related macular degeneration (AMD), • the treatment of visual impairment due to diabetic macular oedema (DME), • the treatment of proliferative diabetic retinopathy (PDR) • the treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (RVO) • the treatment of visual impairment due to choroidal neovascularization (CNV) Lucentis is indicated in preterm infants for: • The treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) disease.
BRU14071376PS2	Onbrez Breezhaler 150mcg Inhalation Powder, Hard Capsule	Onbrez Breezhaler is a long-acting beta$_2$-agonist indicated for maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD).
BRU14071378P	Requip PD 24 Hour™ Prolonged Release Tablet 2mg	• REQUIP PD 24 HOUR is indicated for the treatment of idiopathic Parkinson's disease. • REQUIP PD 24 HOUR may be used alone (without levodopa [L-dopa]) in the treatment of idiopathic Parkinson’s disease. • Addition of REQUIP PD 24 HOUR to levodopa may be used to control ‘on-off’ fluctuations and permit a reduction in the total daily dose of L-Dopa.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071379P	Difflam Anti-Inflammatory Anti-Bacterial Lozenges (Raspberry)	For the temporary relief of painful conditions of the oral cavity including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post-orosurgical and periodontal procedures, pharyngitis, swelling, redness and inflammatory conditions.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071380P	Vfend Powder For Oral Suspension 40mg/ml	Voriconazole is a broad spectrum, triazole antifungal agent and is indicated in adults and children aged 2 years and above as follows: Treatment of invasive aspergillosis; Treatment of fluconazole-resistant serious invasive *Candida* infections (including C. *krusei*); Treatment of serious *Candida* infections including esophageal candidiasis; Treatment of candidemia in non-neutropenic patients and the following *Candida* infections: disseminated infection in skin and infections in abdomen, kidney, bladder wall and wounds; Treatment of serious fungal infections caused by *Scedosporium* spp. and *Fusarium* spp.; Prevention of breakthrough of fungal infections in febrile high-risk neutropenic patients. Prophylaxis in patients ≥12 years old who are at high risk of developing invasive fungal infections. The indication is based on a study which includes patients ≥12 years old undergoing haematopoietic stem cell transplantation. Voriconazole should be administered primarily to immunocompromised patients with progressive, possibly life-threatening infections.

BRU14071381P	Norditropin® FlexPro Solution For Injection 10mg/1.5ml	Children: Growth failure due to growth hormone deficiency (GHD) Growth failure in girls due to gonadal dysgenesis (Turner syndrome) Growth retardation in prepubertal children due to chronic renal disease. Growth disturbance (current height standard deviation score (SDS) < -2.5 and parental adjusted height SDS < -1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 standard deviation SD, who failed to show catch-up growth (height velocity standard deviation (HV SDS) < 0 during the last year) by 4 years of age or later. Adults: Childhood onset growth hormone deficiency: Patients with childhood onset GHD should be re-evaluated for growth hormone secretory capacity after growth completion. Testing is not required for those with more than three pituitary hormone deficits, with severe GHD due to a defined genetic cause, due to structural hypothalamic pituitary abnormalities, due to central nervous system tumours or due to high-dose cranial irradiation, or with GHD secondary to a pituitary/hypothalamic disease or insult, if measurements of serum insulin-like growth factor 1 (IGF-1) is <-2 SDS after at least four weeks off growth hormone treatment. In all other patients an IGF-1 measurement and one growth hormone stimulation test is required.

		Adult onset growth hormone deficiency: Pronounced GHD in known hypothalamic-pituitary disease, cranial irradiation and traumatic brain injury. GHD should be associated with one other deficient axis, other than prolactin. GHD should be demonstrated by one provocative test after institution of adequate replacement therapy for any other deficient axis. In adults, the insulin tolerance test is the provocative test of choice. When the insulin tolerance test is contraindicated, alternative provocative tests must be used. The combined arginine-growth hormone releasing hormone is recommended. An arginine or glucagon test may also be considered; however, these tests have less established diagnostic value than the insulin tolerance test.
BRU14071383P	Mapenem® IV Injection 500mg	Infections caused by pathogens sensitive to Meropenem including: 1. Intra-abdominal Infection 2. Skin and Skin Structure Infection 3. Lower respiratory tract infections including bronchitis, pneumonia and Hospital-acquired pneumonia 4. Meningitis 5. Urinary tract infections 6. Gynaecological Infections including endometritis and pelvic inflammatory disease 7. Bacterial septicaemia 8. Empiric therapy in febrile neutropenia

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071385P; BRU14071385PR2	Topamax® 25 Tablet 25mg	**Epilepsy** TOPAMAX is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy. TOPAMAX is indicated as adjunctive therapy for adults and children aged 2 and above with partial onset seizures or generalized tonic-clonic seizures. TOPAMAX is also indicated in adults and children as adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome. **Migraine** TOPAMAX is indicated in adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX in the acute treatment of migraine headache has not been studied.
BRU14071386P	Tussils 5 Lozenge 5mg	To control non-productive cough.
BRU14071387P	Kivexa Tablets	Kivexa is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults, ~~and~~ adolescents and children weighing at least 25kg. Before initiating treatment with abacavir, screening for carriage of the HLA-B*5701 allele should be performed in any HIV-infected patient, irrespective of racial origin. Abacavir should not be used in patients known to carry the HLA-B*5701 allele.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071390P	Axcel Diclofenac-50 Tablet	Inflammatory, degenerative and non-articular forms of rheumatism and juvenile arthritis. Acute gout. Post-traumatic and post-operative inflammatory and swelling. Primary dysmenorrhea.
BRU14071394P	Duodart 0.5mg/0.4mg Capsules	Duodart is indicated as combination therapy for the treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH). Duodart reduces the risk of acute urinary retention and the need for surgery in patients with moderate to severe symptoms of BPH.
BRU14071395P	Axcel Metronidazole-400 Tablet	Treatment of protozoal infection, intestinal and extra-intestinal amoebiasis, lambliasis, acute ulcerative gingivitis, urogenital trichomoniasis, glardiasis, and Vincent's infection.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071396P	Cefazolin Sandoz 1g Vial	Cefazolin is indicated in a number of infections caused by cefazolin-sensitive microorganisms. These include: - Infections of the respiratory tract like bronchitis and pneumonia - Infections of the urogenital tract like pyelonephritis, cystitis, urethritis and prostatitis - Infections of the skin and soft tissues - Infections of the bile ducts - Bone and joint infections - Endocarditis - Systemic septic infections - Perioperative prophylaxis (hysterectomy, cholecystectomy, open-heart surgery, bone and joint surgery). Use of cefazolin should be restricted to cases needing to be treated parenterally. Consideration should be given to official guidance (e.g. national recommendations) on the appropriate use of antibacterial agents. Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.

BRU14071397PS3; BRU14071397PS4	MABTHERA Concentrate For Solution For Infusion 500mg/50ml	***MabThera IV and MabThera SC*** **Non-Hodgkin's Lymphoma**: MabThera IV and MabThera SC are indicated for the treatment of: - patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) chemotherapy. - previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. MabThera IV and MabThera SC maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. ***MabThera IV only*** **Non-Hodgkin's Lymphoma**: MabThera IV is indicated for the treatment of patients with relapsed or chemoresistant indolent B-cell non-Hodgkin's lymphomas. **Chronic Lymphocytic Leukaemia**: MabThera IV is indicated in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. ***Rheumatoid Arthritis*** : MabThera IV in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumour necrosis factor (TNF) inhibitor therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071398P	Lamitor 100mg Tablet	LAMITOR is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalized seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome.

BRU14071399PS2	Vigamox® Ophthalmic Solution 0.5%	VIGAMOX Solution is indicated for the treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of the following organisms. **Gram-positive bacteria**: *Corynebacterium* species† *Microbacterium* species *Micrococcus luteus* † [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains] *Staphylococcus aureus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus epidermidis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus haemolyticus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus hominis* † [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] Staphylococcus warneri† [including erythromycin resistant strains] *Streptococcus miti* s† [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains] *Streptococcus pneumoniae* [including penicillin, erythromycin, gentamicin, tetracycline and/or trimethoprim resistant strains] *Streptococcus viridans* [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains] **Gram-negative bacteria**: *Acinetobacter* species *Haemophilus 'alconae'* [including ampicillin resistant strains] *Haemophilus influenza* e [including ampicillin resistant strains] *Klebsiella pneumoniae* † *Moraxella catarrhalis* † *Pseudomonas aeruginosa* *

		Other microorganisms: *Chlamydia trachomatis* †Efficacy for this organism was studied in fewer than 10 infections Preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required).
BRU14071401PS2	Voltaren Emulgel 1%	Treatment of i) Localised forms of soft-tissue rheumatism, eg. tendovaginitis, shoulder-hand syndrome, bursitis, and periarthropathy; ii) Localised rheumatic disease eg. osteo-arthritis of the spine and peripheral joints; iii) Post-traumatic inflammation of the tendons, ligaments, muscles and joints, eg. due to sprains, strains or bruises.
BRU14071402P	Imexa Film-Coated Tablet 250mg	Imexa is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present). In sexually transmitted diseases in men and women, Imexa is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated in the treatment of uncomplicated genital infection due to non-multiresistant *Neisseria gonorrhoea* , concurrent infection with Treponema pallidum should be excluded. Imexa is indicated, either alone or in combination with rifabutin, for prophylaxis against *Mycobacterium avium – Intracellulare complex* (MAC) infection, an opportunistic infection prevalent in patients with advanced human immunodeficiency virus (HIV).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071403P	Cymbalta Capsule 60mg	Treatment of major depressive disorder. Management of neuropathic pain associated with diabetic peripheral neuropathy in adults. Treatment of generalised anxiety disorder.
BRU14071404P	Beanamine Expectorant	The combination of an antihistamine, diphenhydramine and an expectorant, ammonium chloride provide a rapid relief to symptoms of allergic conditions such as hay fever, rhinitis, urticaria and cough.
BRU14071405P	Setrof Tablet 50mg	For treatment of symptoms of depression including depression accompanied by symptoms of anxiety. For treatment of obsessions and compulsions in patients with obsessive-compulsive disorder (OCD). For treatment of panic disorder with or without agoraphia.
BRU14071408P	Melashine Cream 4%	Melashine Cream 4% is used topically as a depigmenting agent for the skin in hyperpigmentation conditions such as chloasma (melasma), freckles and lentigines (Small macules that resemble freckles).
BRU14071409P	Asumalife Syrup 1.38mg/5ml	Prophylactic treatment of bronchial asthma and symptomatic treatment of allergic rhinitis, dermatitis, urticaria and pruritus. It is not effective in aborting established attacks of asthma.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071410P	Lovastin Tablet 20mg	For the reduction of elevated total and LDL cholesterol levels in patients with primary hypercholesterolemia (Type IIa and IIb), when the response to diet and other non-pharmacological measures alone has been inadequate. Lovastin may be useful to reduce elevated LDL cholesterol levels in patients with combined hypercholesterolemia and hypertriglyceridemia. Before instituting attempt with Lovastatin, an attempt should be made to control hypercholesterolemia with appropriate diet, exercise, weight reduction in obese patients.
BRU14071411P	Requip Tablet 0.25mg	Requip is indicated for the treatment of idiopathic Parkinson's disease: • Requip may be used alone (without levodopa [L-Dopa]) in the treatment of idiopathic Parkinson's disease. • Addition of Requip to levodopa may be used to control 'on-off' fluctuations and permit a reduction in the total daily dose of L-Dopa. Treatment of Restless Legs Syndrome: • Ropinirole is indicated for the treatment of idiopathic/primary Restless Legs Syndrome.
BRU14071412NP	Zoben Tablet 200mg	Albendazole is used in the treatment of roundworm, pinworm, hookworm, threadworm, (strongyloidiasis), and whipworm infections.
BRU14071414P	Garbose Tablet 50mg	Additional therapy in association with diet in patients with diabetes mellitus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14071415P	Dexamethasone 4mg Tablet	Dexamethasone is a synthetic corticosteroid with predominantly glucocorticoid activity. Dexamethasone is used for its anti-inflammatory and immune-suppressant glucocorticoid activity. Conditions in which glucocorticoid therapy is indicated include allergic disorders, autoimmune haemolyticanaemia and idiopathic thrombocytopenic purpura, selected collagen and rheumatic disorders, connective tissue disorders such as arthritis and systemic lupus erythematosus, gastro-intestinal disorders, hepatic disorders, neuromuscular disorders, selected ocular disorders, renal disorders and severe skin disorders.
BRU14081416PS2	Sevorane Inhalation Liquid	Sevoflurane may be used for induction and maintenance of general anaesthesia in adult and pediatric patients for inpatient and outpatient surgery.
BRU14081417PS2	Emend Tri-Pack Capsule	EMEND is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of: • highly emetogenic cancer chemotherapy. • moderately emetogenic cancer chemotherapy. EMEND should be given in combination with a corticosteroid and a 5-HT_3 antagonist.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081418PS2	Protopic Ointment 0.1%	Protopic 0.1 % ointment is indicated in adults and adolescents (16 years of age and above). <u>Flare treatment</u> Adults and adolescents (16 years of age and above) Treatment of moderate to severe atopic dermatitis in adults and adolescents who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids. *Children (2 years of age and above)* Treatment of moderate to severe atopic dermatitis in children (2 years of age and above) who failed to respond adequately to conventional therapies such as topical corticosteroids. <u>Maintenance treatment</u> Treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected).
BRU14081419PS2	Exforge HCT 10/160/12.5mg Film-Coated Tablet	Treatment of essential hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension.
BRU14081420PS2	Exforge HCT 10/160/25mg Film-Coated Tablet	Treatment of essential hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081421PS2	Exforge HCT 5/160/12.5mg Film-Coated Tablet	Treatment of essential hypertension. This fixed combination drug is not indicated for the initial therapy of hypertension.
BRU14081424P	Luveris For Injection 75IU/Vial (Revised Formula)	Luveris® in association with a follicle stimulating hormone (FSH) preparation is Indicated for the stimulation of follicular development in women with severe LH and FSH deficiency. *(See clinical efficacy section)*
BRU14081425P	Lipanthyl Penta 145 Film-Coated Tablet	LIPANTHYL® PENTA 145, film-coated tablet is indicated as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) for the following: - Treatment of severe hypertriglyceridaemia with or without low HDL cholesterol. - Mixed hyperlipidaemia when a statin is contraindicated or not tolerated - Mixed hyperlipidaemia in patients at high cardiovascular risk in addition to a statin when triglycerides and HDL cholesterol are not adequately controlled. LIPANTHYL® PENTA 145, film-coated tablet is indicated for the reduction in the progression of diabetic retinopathy in patients with type 2 diabetes and existing diabetic retinopathy. Lipanthyl does not replace the appropriate control of blood pressure, blood glucose and blood lipids in reducing the progression of diabetic.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081426P	Dexamethasone Tablet 0.5mg	Dexamethasone is a synthetic corticosteroid with predominantly glucocorticoid activity. Dexamethasone is used for its anti-inflammatory and immune-suppressant glucocorticoid activity. Dexamethasone is used for its anti-inflammatory and immune-suppressant glucocorticoid activity. Conditions in which glucocorticoid therapy is indicated include allergic disorders, autoimmune haemolyticanaemia and idiopathic thrombocytopenic purpura, selected collagen and rheumatic disorders, connective tissue disorders such as arthritis and systemic lupus erythematosus, gastro-intestinal disorders, hepatic disorders, neuromuscular disorders, selected ocular disorders, renal disorders and severe skin disorders.

BRU14081428PS1; BRU14081428PS3	Janumet™ Tablet 50mg/850mg	JANUMET is indicated as initial therapy in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise do not provide adequate glycemic control. JANUMET is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin. JANUMET is also indicated in combination with a sulfonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in adult patients with type 2 diabetes mellitus inadequately controlled with any two of the three agents: metformin, sitagliptin, or a sulfonylurea. JANUMET is indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycemic control in patients when insulin and metformin alone do not provide adequate glycemic control. *Important Limitations of Use* JANUMET should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. JANUMET has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081429PS1; BRU14081429PS3	Janumet™ Tablet 50mg/500mg	JANUMET is indicated as initial therapy in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise do not provide adequate glycemic control. JANUMET is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin. JANUMET is also indicated in combination with a sulfonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in adult patients with type 2 diabetes mellitus inadequately controlled with any two of the three agents: metformin, sitagliptin, or a sulfonylurea. JANUMET is indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycemic control in patients when insulin and metformin alone do not provide adequate glycemic control. *Important Limitations of Use* JANUMET should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. JANUMET has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET.

BRU14081430PS1; BRU14081430PS3	Janumet™ Tablet 50mg/1000mg	JANUMET is indicated as initial therapy in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise do not provide adequate glycemic control. JANUMET is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin. JANUMET is also indicated in combination with a sulfonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in adult patients with type 2 diabetes mellitus inadequately controlled with any two of the three agents: metformin, sitagliptin, or a sulfonylurea. JANUMET is indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycemic control in patients when insulin and metformin alone do not provide adequate glycemic control. *Important Limitations of Use* JANUMET should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. JANUMET has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET.

BRU14081432PS3; BRU14081432PS4	Mabthera Concentrate For Solution For Infusion 100mg/10ml	***MabThera IV and MabThera SC*** **Non-Hodgkin's Lymphoma**: MabThera IV and MabThera SC are indicated for the treatment of: - patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) chemotherapy. - previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. MabThera IV and MabThera SC maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. ***MabThera IV only*** **Non-Hodgkin's Lymphoma**: MabThera IV is indicated for the treatment of patients with relapsed or chemoresistant indolent B-cell non-Hodgkin's lymphomas. **Chronic Lymphocytic Leukaemia**: MabThera IV is indicated in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. ***Rheumatoid Arthritis*** : MabThera IV in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumour necrosis factor (TNF) inhibitor therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081433P	Eraxis™ 100mg For Injection	Treatment of invasive candidiasis, including candidemia, in adult and in paediatric patients aged 1 month to <18 years old.
BRU14081434P	Moxiclav 1g Tablet	MOXICLAV is indicated for the treatment of bacterial infections such as: • Upper respiratory tract infections (including ENT): tonsillitis, sinusitis, otitis media. • Lower respiratory tract infections: acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. • Genito-urinary tract infections: cystitis, urethritis, pyelonephritis. • Skin and soft tissue infections, e.g. boils, abscesses, cellulites, wound infections. • Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis.
BRU14081439P	Carzepin 200mg Tablet	For treatment of: - Partial seizures with complex symptomatology (psychomotor, temporal lobe) - Generalized tonic-clonic seizures (grand mal) - Mixed seizure patterns - Pain due to trigeminal neuralgia and glossopharyngeal neuralgia
BRU14081440PS2	Naphcon-A Sterile Ophthalmic Solution	For relief of ocular irritation and/or congestion or for the treatment of allergic or inflammatory ocular conditions.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081441P	Lamictal 100mg Tablet	**EPILEPSY** **• Adults and Adolescents** LAMICTAL is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. **• Children (2 to 12 years of age)** LAMICTAL is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalised seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome (above 3 years of age only). Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti- epileptic drugs (AEDs) may be withdrawn and patients continued on LAMICTAL monotherapy. If LAMICTAL 2 mg Chewable Dispersible Tablet is not available and the calculated dose in children is less than 2.5 mg daily, then LAMICTAL cannot be used. DO NOT attempt to administer partial quantities of the dispersible tablets. **BIPOLAR DISORDER** **• Adults (18 years of age and over)** LAMICTAL is indicated for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes.
BRU14081442P	Axcel Loratadine Tablet 10mg	Relief of symptoms associated with allergic rhinitis e.g. sneezing, nasal discharge (rhinorrhoea) and itching, as well as ocular itching & burning, chronic urticarial and other allergic dermatologic disorders.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081447P	Axcel Cefaclor-125 Suspension	Treatment of the following infections caused by susceptible organisms: otitis media, lower respiratory tract infections, pharyngitis and tonsillitis; urinary tract infection, skin and soft tissue infections. Cefaclor is generally effective in the eradication of streptococci from the nasopharynx.
BRU14081449PS2	Mircera Pre-Filled Syringe 75mcg/0.3ml	Treatment of anaemia associated with chronic kidney disease (CKD). The safety and efficacy of MIRCERA therapy in other indications has not been established, therefore such use is not recommended.
BRU14081450P	Creobic Cream	All fungal skin infections due to dermatophytes (e.g. Trichophyton species), yeast (e.g. Candida species), moulds and other fungi. These include ringworm (tinea) infections, athlete's foot, paronychia, pityriasis versicolor, erythrasma, intertrigo, fungal nappy rash, candida vulvitis and candida balanitis.
BRU14081451P	Axcel Cetirizine Syrup 5mg/5ml	For symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticarial of allergic origin.
BRU14081453P	Sunex Cough Syrup	It is indicated as an expectorant for control of cough due to cold or allergy.
BRU14081456P	Nurofen For Children 100mg/5ml	Indicated for the reduction of fever (including that associated with immunization), and the relief of pain from teething, toothache, earache, sore throats, minor aches and sprains.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081457P	Axcel Salbutamol Syrup	For the relief of bronchospasm in asthma, chronic bronchitis and other conditions involving airways obstruction.
BRU14081458P	Doxymycin Capsule 100mg	Doxymycin has been found effective in the treatment of a variety of infections caused by susceptible strains of Gram-positive and Gram-negative bacteria such as pneumonia and other lower respiratory tract infections, chronic bronchitis, sinusitis, urinary tract infections, ophthalmic infections, sexually transmitted diseases and acne vulgaris.
BRU14081459P	Clamentin Powder For Syrup 31.25mg/ml	For the treatment of infections caused by staphylococci, *streptococcus pneumoniae* , *streptococcus meningitis* and other susceptible pathogens. Clamentin is indicated for short-term treatment of bacterial infections at the following sites: Upper Respiratory Tract Infections e.g. Sinusitis, tonsillitis, otitis media. Lower Respiratory Tract Infections e.g. Acute and chronic bronchitis, lobar and bronchopneumonia, empyema, lung abscess. Skin and Soft Tissue Infections e.g. Boils, abscesses, cellulites, wound infections, intra-abdominal sepsis. Genito-Urinary Tract Infections e.g. Cystitis, urethritis, pyelonephritis, septic abortion, puerperal sepsis, pelvic infections, chancroid, gonorrhoea. Other Infections e.g. Osteomyelitis, septicaemia, peritonitis, post-operative infections.
BRU14081460P	Clarimycin Film Coated Tablet 500mg	Treatment of infections caused by pathogens sensitive to Clarithromycin. Infections of nose-pharinx tract (tonsillitis, pharyngitis), and of paranasal sinuses. Infections of lower respiratory tract: bronchitis, bacterial pneumonia and atypical pneumonia. Skin infections: impetigo, erysipelas, folliculitis, furunculosis and septic wounds.
BRU14081461NP	Mentar Shampoo	For the control of dandruff, seborrhoea and psoriasis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081462NP	Menzza Cream	Menzza Cream is indicated for the relief of joint and muscular pains, sprains and strains as well as pain associated with rheumatism and arthritis. Menzza Cream is also suitable for the temporary relief of pain associated with musculoskeletal soreness and discomfort.
BRU14081465NP	Bayer Aspirin Tablet 500mg	Temporary relief of headaches, toothache, neuralgia and muscular pains as well as colds, influenza complaints, and fever.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14081467P	Tobradex® Eye Drops Suspension	TOBRADEX® Ophthalmic Suspension is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical, radiation or thermal burns or penetration of foreign bodies. The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye. The particular anti-infective drug in this product is active against the following common bacterial eye pathogens: Staphylococci, including S. *aureus* and S. *epidermidis* (coagulase-positive and coagulase-negative), including penicillin-resistant strains. Streptococci, including some of the Group A beta-hemolytic species, some nonhemolytic species, and some *Streptococcus pneumoniae* . *Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, Proteus mirabilis. Morganella morganii* , most *Proteus vulgaris* strains, *Haemophilus influenzae* and *H. aegyptius, Moraxella lacunata* , and *Acinetobacter calcoaceticus (Herellea vaginacola)* and some *Neisseria* species.

BRU14081470P	Rotaqor 10mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Fredrickson Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia when response to diet and other non-pharmacological measures are inadequate. *Prevention of Cardiovascular Disease* In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: - reduce the risk of non-fatal myocardial infarction, - reduce the risk of fatal and non-fatal stroke, - reduce the risk for revascularization procedures, - reduce the risk of hospitalization for CHF, - reduce the risk of angina.

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dL or b. LDL-C remains ≥ 160 mg/dL and: • there is a positive family history of premature cardiovascular disease or • two or more other CVD risk factors are present in the pediatric patient
BRU14081473P	Clofenac SR Tablet 100mg	Used for relief of pain and inflammation in conditions such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout and following some surgical procedures.
BRU14081474P	Strepsils Max Plus Lozenges	For the symptomatic relief of mouth and throat infections including severe sore throats.
BRU14081475NP	Cera-Scalp Ointment	For the treatment of common scaly skin disorders of the scalp such as psoriasis, eczema, seborrhoeic dermatitis and dandruff.
BRU14091477P	Suprane Inhalation Liquid 100%	Suprane (desflurane) is indicated as an inhalation agent for induction and/or maintenance of anaesthesia in adults and maintenance of anaesthesia for inpatient and outpatient in adults and maintenance of anaesthesia in infants and children.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091479PS1; BRU14091479PS2; BRU14091479PS3	Cetrotide Injection 0.25mg	Prevention of premature ovulation in patients undergoing a controlled ovarian stimulation, followed by pick-up and assisted reproductive techniques. In clinical trials Cetrotide 0.25mg was used with human menopausal gonadotropin (HMG), however, limited experience with recombinant FSH suggested similar efficacy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091481P	Xolair Powder And Solvent For Solution For Injection	**Allergic Asthma** **<u>Adults and adolescents (12 years of age and above)</u>** Xolair (omalizumab) is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). **<u>Children (6 to < 12 years of age)</u>** Xolair is indicated as add-on therapy to improve asthma control with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions. **Chronic rhinosinusitis with nasal polyps (CRSwNP)** Xolair is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with CRSwNP for whom therapy with INC does not provide adequate disease control. **Chronic Spontaneous Urticaria (CSU)** Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.
BRU14091483P	Pengesic 50 Capsule	Pengesic 50 Capsule is used in the treatment of moderate to severe acute or chronic pain and in painful diagnostic or therapeutic measures.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091486P	Crinone Progesterone Vaginal Gel 8%	Treatment of disorders associated with progesterone deficiency, such as: - infertility due to inadequate luteal phase. - for use during in-vitro fertilisation, where infertility is mainly due to tubal, idiopathic or endometriosis linked sterility associated with normal ovulatory cycles.
BRU14091487NP	Pinetarsol Gel	Pinetarsol Gel is a soap free cleansing gel that can be used as an adjunct treatment to help relieve itchy and inflamed skin conditions including dermatitis, inflamed scaly skin, jock itch, anal and genital itching and other minor skin irritations. Can be used in the shower, bath or hand basin. pH 6 to maintain the skin's natural protection. Pinetarsol Gel is a soap alternative. Avoid using soap as soap may irritate tender inflamed skin.
BRU14091488P	Defungo Vaginal Tablet	• Infections vaginal discharge • Vaginalis due to fungi – mainly Candida and/or Trichomonas, superinfections with sensitive clotrimazole-bacteria.
BRU14091489P	Magrilan 20mg Capsules	Depression of various origins. Depression with anxiety symptoms.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091490P	Trileptal® 600mg Film-Coated Tablet	Trileptal is indicated for the treatment of partial seizures (which include the seizure subtypes of simple, complex and partial seizures evolving to secondarily generalized seizures) and generalized tonic-clonic seizures, in adults and children. Trileptal is indicated as a first-line antielpileptic medicinal product for use as monotherapy or adjunctive therapy. Trileptal can replace other antiepileptic medicinal products when current therapy provides insufficient seizure control.
BRU14091494P	Eprex® 10000 Prefilled Syringes 10,000IU/1ml	• Treatment of anemia associated with chronic renal failure in adult hemodialysis, peritoneal dialysis and predialysis patients and pediatric patients on hemodialysis. • Treatment of anemia and reduction of transfusion in adult cancer patients with non-myeloid malignancies receiving chemotherapy. • Treatment of anemia in HIV-infected patients being treated with zidovudine who have endogenous erythropoietin levels ≤ 500 mIU/mL. • To facilitate autologous blood collection within a predeposit program and decrease the risk of receiving allogeneic blood transfusions in patients with hematocrits of 33 - 39%, who are scheduled for major elective surgery and are expected to require more blood than that which can be obtained through autologous blood collection techniques in the absence of Eprex. • Eprex is indicated in adult patients with mild to moderate anemia (hemoglobin > 10 to ≤ 13 g/dL) scheduled for elective surgery with an expected moderate blood loss (2 - 4 units or 900 to 1800 mL) to reduce exposure to allogeneic blood transfusions and to facilitate erythropoietic recovery). • Eprex is indicated for the treatment of anemia (hemoglobin concentration of ≤ 10 g/dL) in adults with low- or intermediate-1-risk myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/mL).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091501P	Yucomy Cream	Yucomy Cream is effective for the treatment of fungal infection caused by dermatophytes and yeasts as below: Clinical manifestations 1. Tinea corporis (ringworm of the body) 2. Tinea cruris (Jock itch) 3. Tinea pedis (athlete's foot) 4. Tinea manus (tinea involving the intradigutal spaces of hands) 5. Tinea versicolor (white spots) 6. Seborrhoeic dermatitis 7. Cutaneous candidiasis Causative microorganism *1. Trichophyton rubrum,* *2. T. mentagrophytes,* *3. Microsporum canis,* *4. Epidermophyton floccosum* *5. Malassezia furfur* *6. Pityrosporum ovale* *7. Candida albicans, C. tropicalis*
BRU14091502P	Loradine Tablet 10mg	Relief of symptoms associated with allergic rhinitis e.g. sneezing, nasal discharge and itching, as well as ocular itching and burning. Chronic urticarial and other allergic dermatologic disorders.
BRU14091503P	Rasitol Tablet 40mg	Oedema (cardiac, hepatic, renal) and hypertension.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091508P	Glucagen® 1mg Powder And Solvent For Solution For Injection	<u>Therapeutic indication</u> GlucaGen® is indicated for treatment of severe hypoglycaemic reactions, which may occur in the management of insulin treated children and adults with diabetes mellitus. <u>Diagnostic indication</u> GlucaGen® is indicated for motility inhibition in examinations of the gastrointestinal tract in adults.
BRU14091509P	Chloramine Syrup 4mg/5ml	Treatment of allergic reactions of the skin and mucous membranes, such as acute urticarial, atopic dermatitis, allergic rhinitis, hayfever.
BRU14091511NP	B. Braun 0.9% Sodium Chloride Injection B.P.	Solvent or diluent for compatible electrolyte concentrates or drugs.
BRU14091512NP	Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution)	- Fluid substitution under the conditions of undisturbed acid-base balance or mild acidosis. - Isotonic and hypotonic dehydration. - Short term intravascular volume replacement. - Vehicle solution for compatible electrolyte concentrates and drugs.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091519P	Afinitor 5mg Tablet	AFINITOR tablets are indicated for the ♦treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole. ♦treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF-targeted therapy. ♦treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors. ♦treatment of adult patients with progressive, well-differentiated (Grade 1 or Grade 2), non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin with unresectable, locally advanced or metastatic disease. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors. ♦treatment of adult and pediatric patients, 1 years of age and older, with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not candidates for curative surgical resection. The effectiveness of AFINITOR is based on an analysis of change in SEGA volume (see section CLINICAL STUDIES). Clinical benefit such as improvement in disease-related symptoms or increase in overall survival has not been demonstrated. ♦treatment of adult patients with renal angiomyolipoma (AML) and tuberous sclerosis complex (TSC), not requiring immediate surgery. The effectiveness of AFINITOR in the treatment of renal angiomylipoma is based on an analysis of durable objective responses in patients treated for a median of 8.3 months. Further follow-up of patients is required to determine long-term outcomes.
BRU14091524P	Melaquin Cream 4% w/w	Melaquin Cream 4% is used topically as a depigmenting agent for the skin in hyperpigmentation conditions such as chloasma (melisma), freckles, and lentigines (small macules that resemble freckles).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091526P	Glucomet Tablet 500mg	Treatment of type 2 diabetes mellitus in adults, when dietary management and exercise alone does not result in adequate glycaemic control. Metformin may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin. A reduction of diabetic complications has been shown on overweight type-2 diabetic patients treated with metformin as 1st line therapy after diet failure. In type I diabetes, metformin may be given as an adjuvant to patients whose symptoms are poorly controlled.
BRU14091527P	Quemox Tablet 500mg	Quemox (Mebendazole) is very specifically indicated for the treatment of *Trichuris trichiura* (whipworm), *Enterobius vermicularis* (pinworm), *Ascaris lumbricoides* (roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm) and *Strongyloides stercoralis* (threadworm) in single and / or mixed infestations in adults and children.
BRU14091528P	Campto 300mg/15ml Injection	CAMPTO® (Irinotecan hydrochloride) is indicated for the treatment of patients with advanced colorectal cancer: • In combination with 5-fluorouracil and folinic acid in patients without prior chemotherapy for advanced disease. • As a single agent in patients who have failed an established 5-fluorouracil containing treatment regimen.
BRU14091529NP	Strepsils Cool Lozenges	For relief of sore throats.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091530NP	Strepsils Sugar Free Lemon Lozenges	An antiseptic lozenge for the symptomatic relief of mouth and throat infections including sore throat.
BRU14091534P	Deplatt Tablet 75mg	Clopidogrel is indicated to prevent atherothrombotic events in adults as given below. • Patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. • Patients suffering from acute coronary syndrome: - Non-ST segment elevation acute coronary syndrome (unstable angina or non-Qwave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention. - ST segment elevation acute myocardial infarction, in combination with acetylsalicylic acid (ASA) in medically treated patients eligible for thrombolytic therapy.
BRU14091535NP	Livolin Forte Softgel Capsules	As a Health Supplement.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091538P	Clamentin Injection 1.2g	Clamentin Intravenous is indicated for short-term treatment of bacterial infections at the following sites when Amoxicillin-resistant ß-lactamase-producing strains are suspected as the cause: **Upper Respiratory Tract Infections** (Including ENT) in particular sinusitis, otitis media, recurrent tonsillitis. These infections are often caused by *Streptococcus Pneumoniae* , *Haemophilus influenzae** , *Moraxella catarrhalis** and *streptococcus pyogenes* . **Lower Respiratory Tract Infections** in particular acute exacerbations of chronic bronchitis (especially if considered severe), bronchopneumonia. These infections are often caused by *Streptococcus Pneumoniae* , *Haemophilus influenzae** and *Moraxella catarrhalis** . **Genito-Urinary Tract and Abdominal Infections** in particular cystitis (especially when recurrent or complicated-excluding prostatitis), septic abortion, pelvic or puerperal sepsis and intra-abdominal sepsis. These infections are often caused by *Enterobacteriaceae** (mainly *Escherichia coli**), *Staphylococcus saprophyticus* , *Enterococcus species** . **Skin and Soft Tissue Infections** in particular cellulitis, animal bites and severe dental abscess with spreading cellutitis. These infections are often caused by *Staphylococcus aureus** , *Streptococcus pyogenes* and *Bacteroides species** . **Prophylaxis of wound infection associated with surgical procedures** in particular gastrointestinal, pelvic, major head and neck surgery and after limb amputation for infection. *Some member of these species of bacteria produces ß-lactamase, rendering them insensitive to Amoxicillin alone.

BRU14091540P	Zarator 10mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (*Fredrickson* Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD), such as age, smoking, hypertension, low HDLC, or a family history of early CHD, ZARATOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease, such as retinopathy, albuminuria, smoking, or hypertension, ZARATOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and post-menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if, after an adequate trial of diet therapy the following findings are present: LDL-C remains ≥190 mg/dL or LDL-C remains ≥160 mg/dL and: • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091541P	Zarator 20mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (*Fredrickson* Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD), such as age, smoking, hypertension, low HDLC, or a family history of early CHD, ZARATOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease, such as retinopathy, albuminuria, smoking, or hypertension, ZARATOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and post-menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if, after an adequate trial of diet therapy the following findings are present: LDL-C remains ≥190 mg/dL or LDL-C remains ≥160 mg/dL and: • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14091542P	Zarator 40mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (*Fredrickson* Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD), such as age, smoking, hypertension, low HDLC, or a family history of early CHD, ZARATOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease, such as retinopathy, albuminuria, smoking, or hypertension, ZARATOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and post-menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if, after an adequate trial of diet therapy the following findings are present: LDL-C remains ≥190 mg/dL or LDL-C remains ≥160 mg/dL and: • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient

BRU14091543P	Zarator 80mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum TG levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (*Fredrickson* Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD), such as age, smoking, hypertension, low HDLC, or a family history of early CHD, ZARATOR is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease, such as retinopathy, albuminuria, smoking, or hypertension, ZARATOR is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and post-menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if, after an adequate trial of diet therapy the following findings are present: LDL-C remains ≥190 mg/dL or LDL-C remains ≥160 mg/dL and: • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the pediatric patient
BRU14111546P	Binocrit Solution For Injection 2000 IU/ml In Pre-Filled Syringe	• Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adult hemodialysis, peritoneal dialysis and predialysis patients and pediatric patients on hemodialysis. • Treatment of anemia and reduction of transfusion in adult cancer patients with non-myeloid malignancies receiving chemotherapy. • To facilitate autologous blood collection within a predeposit program and decrease the risk of receiving allogeneic blood transfusions in patients with hematocrits of 33 - 39%, who are scheduled for major elective surgery and are expected to require more blood than that which can be obtained through autologous blood collection techniques in the absence of Binocrit. • Binocrit is indicated in adult patients with mild to moderate anemia (hemoglobin > 10 to ≤ 13 g/dL) scheduled for elective surgery with an expected moderate blood loss (2 - 4 units or 900 to 1800 mL) to reduce exposure to allogeneic blood transfusions and to facilitate erythropoietic recovery). • Binocrit is indicated for the treatment of anaemia (haemoglobin concentration of ≤ 10 g/dl) in adults with low- or intermediate-1-risk primary myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/ml).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111547P	Binocrit Solution For Injection 4000 IU/0.4ml In Pre-Filled Syringe	• Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adult hemodialysis, peritoneal dialysis and predialysis patients and pediatric patients on hemodialysis. • Treatment of anemia and reduction of transfusion in adult cancer patients with non-myeloid malignancies receiving chemotherapy. • To facilitate autologous blood collection within a predeposit program and decrease the risk of receiving allogeneic blood transfusions in patients with hematocrits of 33 - 39%, who are scheduled for major elective surgery and are expected to require more blood than that which can be obtained through autologous blood collection techniques in the absence of Binocrit. • Binocrit is indicated in adult patients with mild to moderate anemia (hemoglobin > 10 to ≤ 13 g/dL) scheduled for elective surgery with an expected moderate blood loss (2 - 4 units or 900 to 1800 mL) to reduce exposure to allogeneic blood transfusions and to facilitate erythropoietic recovery). • Binocrit is indicated for the treatment of anaemia (haemoglobin concentration of ≤ 10 g/dl) in adults with low- or intermediate-1-risk primary myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/ml).
BRU14111553P	Dynastat Injection 40mg	Management of post-operative pain in the immediate post-operative setting only with the exception of patients undergoing coronary artery bypass grafting (CABG) procedures and in those patients with elevated cardiovascular risk such as those with congestive heart failure (NYHA II-IV), established ischaemic heart disease and/or cerebrovascular disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111554P	Invanz Powder For Injection 1g/Vial	<u>Treatment</u> Invanz for injection 1g/vial is indicated for the treatment of patients with moderate to severe infections caused by susceptible strains of microorganisms. It is also indicated in the initial empirical therapy prior to the identification of causative organisms in the infections listed below: • Complicated intra-abdominal infections • Complicated skin and skin structure infections including diabetic lower extremity infections • Community acquired pneumonia • Complicated urinary tract infections including pyelonephritis • Acute pelvic infections including postpartum endomyometritis, septic abortion and post-surgical gynaecologic infections To reduce the development of drug-resistant bacteria and maintain the effectiveness of Invanz and other antibacterial drugs, Invanz should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. <u>Prevention</u> Invanz is also indicated as a prophylaxis treatment for surgical site infection following elective colorectal surgery and is administered as a single intravenous dose 1 hour prior to surgery.
BRU14111555P	Humalog Mix25 100 Units/ml Kwikpen	Humalog Mix 25 is indicated for the treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111556P	Brozil Capsule 300mg	Hyperlipidemia.
BRU14111557NP	Counterpain Cool Gel 4% w/w	Provides temporary relief from muscular aches and pains.
BRU14111558P	Trileptal 300mg Film-Coated Tablet	Trileptal is indicated for the treatment of partial seizures (which include the seizure subtypes of simple, complex and partial seizures evolving to secondarily generalized seizures) and generalized tonic-clonic seizures, in adults and children. Trileptal is indicated as a first-line antielpileptic medicinal product for use as monotherapy or adjunctive therapy. Trileptal can replace other antiepileptic medicinal products when current therapy provides insufficient seizure control.
BRU14111560P	Voren Plus Gel	Topical treatment of inflammatory or pain conditions caused by chronic rheumatoid arthritis, degenerative arthritis and soft tissue rheumatism.
BRU14111561NP	Strepsils Original Lozenges	For relief of sore throat for children and adults.
BRU14111562NP	Strepsils Orange with Vitamin C Lozenges	An antiseptic lozenge for relief of sore throat for children and adults.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111564P	Axcel Promethazine-5 Syrup	It is indicated in the symptomatic relief of allergy or hypersensitivity reactions such as hayfever, urticaria, angioderma, rhinitis, conjunctivitis and pruritic skin disorders; night sedation, treatment and prevention of motion sickness; vertigo of various causes.
BRU14111565P	NIMBEX™ Injection 2mg/ml (5ml)	*NIMBEX* is an intermediate-duration, non-depolarising neuromuscular blocking agent for intravenous (i.v.) administration. *NIMBEX* is indicated for use during surgical and other procedures and in intensive care. It is used as an adjunct to general anaesthesia, or sedation in the Intensive Care Unit (ICU), to relax skeletal muscles, and to facilitate tracheal intubation and mechanical ventilation. *NIMBEX* injection contains no antimicrobial preservative and is intended for single patient use.
BRU14111566P	Aggrastat Concentrate For Infusion 0.25mg/ml	AGGRASTAT, in combination with heparin, is indicated for patients with unstable angina or non-Q-wave myocardial infarction to prevent cardiac ischemic events and is also indicated for patients with coronary ischemic syndromes undergoing coronary angioplasty or atherectomy to prevent cardiac ischemic complications related to abrupt closure of the treated coronary artery.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111567P	Promezine Syrup 1mg/ml	1. As symptomatic relief in perennial and seasonal rhinitis, pruritus, urticarial, dermographism, angioedema, allergic conjunctivitis and amelioration of allergic reaction to blood or plasma. 2. As an adjunct in preoperative sedation in surgery and obstetrics. 3. As an antiemetic. 4. For short term use: a. Sedation and treatment of insomnia in adults. b. As a paediatric sedative.
BRU14111568P	Cephanmycin Capsules 500mg	Treatment of the following infections caused by susceptible strains of microorganisms: 1. Respiratory tract infections caused by *S. pneumoniae* and *S. pyogenes* . 2. Otitis media due to *S. pneumoniae* , *H. influenzae* , staphylococci, streptococci, and *M. catarrhalis* . 3. Skin and skin structure infections caused by staphylococci and/or streptococci. 4. Bone infections caused by staphylococci and/or *P. mirabilis* . 5. Genitourinary tract infections, including acute prostatitis, caused by *E. coli* , *P. mirabilis* , and *K. pneumoniae* .
BRU14111569NPS2	Ferinject® 50mg Iron/ml Solution For Injection/Infusion	Ferinject is indicated for the treatment of iron deficiency when: – oral iron preparations are ineffective. – oral iron preparations cannot be used. – there is a clinical need to deliver iron rapidly. The diagnosis of iron deficiency must be based on laboratory tests. [e.g., plasma ferritin levels, haemoglobin, haematocrit, red cell count, MCV, MCH and transferrin saturation (TSAT).]

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111573P	Eliquis Film-Coated Tablets 2.5mg	For 2.5 mg Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery. For 2.5 mg and 5 mg Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II). Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults for haemodynamically unstable PE patients.
BRU14111574P	Tren Injection 100mg/ml	Treatment of haemorrhage, or threatened harmorrhage, associated with excessive fibrinolysis. It is also used in the management of haemophiliacs undergoing dental extractions and in the prophylaxis of hereditary angioedema.
BRU14111575P; BRU14111575PS2	Ryzodeg Flex Touch 100 Units/ml	Treatment of diabetes mellitus in adults and, adolescents from the age of 12 years and above.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111578P	Tolanz Tablet 5mg	*Adults* Olanzapine is indicated for the treatment of schizopherenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder.
BRU14111579P	Tolanz Tablet 10mg	*Adults* Olanzapine is indicated for the treatment of schizopherenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder.
BRU14111580P	Somin Tablet 2mg	For symptomatic relief of allergic condition, for example treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, mild or uncomplicated allergic skin manifestation of urticaria and angiodema, amelioration of allergic reaction to blood or plasma, dermagraphism. Somin is also indicated as therapy for anaphylactic reaction adjunctive to Epinephrine and other standard measure after the acute manifestations have been controlled.
BRU14111581P	Vaminolact Solution	Vaminolact is indicated as a source of amino acids for protein synthesis and of taurine in infants and children requiring intravenous nutrition.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111582P	Covinace Tablet 4mg	<u>Hypertension</u> Treatment of hypertension. <u>Stable coronary artery disease</u> Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation.
BRU14111583NP	Oralite Natural Oral Rehydration Salts	For replacement of body fluids and electrolytes lost in diarrhoea and vomiting.
BRU14111584NP	Panamol Forte Suspension 250mg/5ml	For relief of pain and fever, influenza, rheumatic and joint pains, cramps and other muscular pains.

BRU14111585PS3, BRU14111585PS4; BRU14111585PS5	Avastin 100mg/4ml	***Metastatic carcinoma of the colon or rectum(mCRC)*** Avastin in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum. ***Metastatic Breast Cancer (mBC)*** Avastin in combination with paclitaxel is indicated for the treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer. Avastin in combination with capecitabine is indicated for first-line treatment of patients with HER2-negative metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. Patients who have received taxane and anthracycline-containing regimens in the adjuvant setting within the last 12 months should be excluded from treatment with Avastin in combination with capecitabine. The effectiveness of Avastin in metastatic breast cancer (mBC) is based on an improvement in progression-free survival. Currently, no data are available that demonstrate an improvement in disease-related symptoms or increased survival with Avastin in breast cancer. ***Non-Small Cell Lung Cancer (NSCLC)*** Avastin, in combination with carboplatin and paclitaxel, is indicated for first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic nonsquamous, non-small cell lung cancer. Avastin, in combination with erlotinib, is indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations. ***Malignant Glioma (WHO Grade IV) - Glioblastoma*** Avastin, as a single agent is indicated for the treatment of patients with glioblastoma after relapse or disease progression following prior therapy.

		The effectiveness of Avastin in glioblastoma is based on an improvement in objective response rate. There are no data demonstrating an improvement in disease-related symptoms or increased survival with Avastin. ***Advanced and/or metastatic Renal Cell Cancer (mRCC)*** Avastin in combination with interferon alfa-2a is indicated for first-line treatment of patients with advance and/or metastatic renal cell cancer. ***Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer*** Avastin, in combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (FIGO stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. Avastin, in combination with carboplatin and gemcitabine or in combination with carboplatin and paclitaxel is indicated for the treatment of patients with recurrent, platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer who have not received prior bevacizumab or other VEGF-targeted angiogenesis inhibitors. Avastin in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin is indicated for the treatment of patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents. ***Cervical Cancer*** Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.

BRU14111586P	Zyvox 20mg/ml Granules For Oral Suspension	Linezolid formulations are indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms. Linezolid is active against Gram-positive bacteria only. Linezolid has no clinical activity against Gram-negative pathogens. Specific Gram-negative therapy is required if a concomitant Gram-negative pathogen is documented or suspected. **Vancomycin-Resistant *Enterococcus faecium* infections**, including cases with concurrent bacteremia. **Nosocomial pneumonia** caused by *Staphylococcus aureus* (methicillin-susceptible and –resistant strains), or *Streptococcus pneumoniae* (penicillin-susceptible strains). Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. C**omplicated skin and skin structure infections including diabetic foot infections, without concomitant osteomyelitis** caused by *Staphylococcus aureus* (methicillin-susceptible and –resistant strains), *Streptococcus pyogenes* , or *Streptococcus agalactiae* . ZYVOX has not been studied in the treatment of decubitus ulcers. Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. **Uncomplicated skin and skin structure infections** caused by *Staphylococcus aureus* (methicillin-susceptible only) or *Streptococcus pyogenes* . **Community-acquired pneumonia** caused by *Streptococcus pneumoniae* (penicillin-susceptible strains only), including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible strains only). Due to concerns about inappropriate use of antibiotics leading to an increase in resistant organisms, prescribers should carefully consider alternatives before initiating treatment with linezolid in the outpatient setting.

		Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to linezolid. Therapy may be instituted empirically while awaiting the results of these tests. Once these results become available, antimicrobial therapy should be adjusted accordingly.
BRU14111587P	Axcel Cimetidine-400 Tablet	Treatment of active duodenal, benign gastric, stomal and recurrent ulceration, persistent dyspeptic symptoms with or without ulceration. NSAID-induced lesions (ulcers, erosions) and symptoms, gastro-esophageal reflux disease (including conditions ranging from heartburn to peptic esophagitis), Zollinger-Ellison syndrome and other cases of high gastric secretion, in pancreatic insufficiency as an adjunct to enzyme supplement therapy.
BRU14111589P	Resolor™ Film-Coated Tablet 1mg	RESOLOR® is indicated for symptomatic treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief.
BRU14111590NP	Maltofer Fol Chewable Tablet	Treatment of iron deficiency without anaemia and iron deficiency anaemia, and prevention of iron and folic acid deficiency before, during and after pregnancy (during lactation).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111591P	Pristiq 50mg Extended-Release Tablets	PRISTIQ, a selective serotonin and norepinephrine reuptake inhibitor (SNRI), is indicated for the treatment of major depressive disorder (MDD). The efficacy of PRISTIQ has been established in four 8-week, placebo controlled studies of outpatients who met DSM-IV criteria for major depressive disorder. A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least 5 of the following 9 symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, or a suicide attempt or suicidal ideation. The efficacy of PRISTIQ in maintaining a response in major depressive disorder for up to 24 weeks following 12 weeks of acute treatment was demonstrated in a placebo-controlled trial. Nevertheless, the physician who elects to use PRISTIQ for extended periods, i.e., beyond 9 months, should continue to periodically re-evaluate the long-term usefulness of the drug for the individual patients.
BRU14111592P	Eliquis 5mg Film-Coated Tablet	For 2.5 mg and 5 mg Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II). Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults for haemodynamically unstable PE patients.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111593P	Pulin Film-Coated Tablet 10mg	Adult population This product is indicated for use in adults for: - Prevention of delayed chemotherapy induced nausea and vomiting (CINV) - Prevention of radiotherapy induced nausea and vomiting (RINV) - Symptomatic treatment of nausea and vomiting including acute migraine induced nausea and vomiting Pediatric population This product is indicated in children (aged 1 to 18 years) for: - Prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second-line option
BRU14111597NP	B. Braun 0.45% Sodium Chloride & 5% Glucose IV Infusion B.P.	• Isotonic dehydration • Hypertonic dehydration • Vehicle solution for compatible medicinal products • Partial coverage of energy requirements
BRU14111603P	Domper Tablet 10mg	Domperidone is indicated for the symptomatic relief of nausea and vomiting. This includes: • Nausea and vomiting of functional, organic, infectious and dietary origin. • Nausea and vomiting induced by: • Radiotherapy or drug therapy • Dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson’s disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111604NP	Davmorid Film-Coated Tablet	Treatment of organic and functional chronic venous insufficiency of the lower limbs with the following symptoms: heavy legs, pain and nocturnal cramps. Treatment of chronic haemorrhoids and acute haemorrhoidal attacks.
BRU14111606NP	Strepsils Warm Lozenges	For the symptomatic relief of mouth and throat infections.
BRU14111607NP	Pharmaniaga Sodium Bicarbonate 8.4% w/v Injection	Sodium Bicarbonate 8.4% w/v Injection is indicated in the treatment of metabolic acidosis and renal calculi caused by uric acid, renal failure, diabetic coma, or following cardiac arrest.
BRU14111608P	Binozyt 200mg/5ml Powder For Oral Suspension	Binozyt can be applied in situations where micro-organisms sensitive to azithromycin have caused: i) Upper respiratory tract infections: sinusitis, pharyngitis, tonsillitis ii) Acute otitis media iii) Lower respiratory tract infections: acute bronchitis and mild to moderately severe community acquired pneumonia iv) Skin and soft tissue infections v) Uncomplicated *Chlamydia trachomatis* urethritis and cervicitis Consideration should be given to official guidance on the appropriate use of antibacterial agents.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111611P	Kogrel 75mg Film Coated Tablet	Clopidogrel is indicated for the prevention of atherothrombotic events in: • Adult patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. • Adult patients suffering from acute coronary syndrome: - Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA). - ST segment elevation acute myocardial infarction, in combination with ASA in medically treated patients eligible for thrombolytic therapy.
BRU14111612P	Chloramine Tablet 4mg	Treatment of allergic reactions of the skin and mucous membranes, such as acute urticaria, atopic dermatitis, allergic rhinitis, hayfever.
BRU14111613NP	Tolnaderm Cream 1%	The topical treatment of tinea pedis (athlete's foot), tinea cruris (jock itch), tinea corporis (body ringworm), tinea barbae (ringworm of the face and neck) and tinea manuum due to infection with *Trichophyton rubrum, Trichopyton mentagrophytes, Trichopyton tonsurans, Microsporum canis, Microsporum audouini, Epidermophyton floccosum* and tinea versicolor due to *Pityrosporum orbiculare* . Tolnaderm cream is indicated in tinea infections of the skin especially the non-hairy areas of the body and including the groin. The vanishing cream base makes it cosmetically acceptable and there is no staining of the skin or clothing from the preparation. Tolnaftate preparations are not suitable for deep infections of the nailbed and hair follicles but may be applied concomitantly with a systemic agent.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111614P	Medoflucon Capsule 50mg	• Acute or recurrent vaginal candidiasis. • Mucosal candidiasis, including oropharyngeal, oesophageal, non invasive bronchopulmonary infection, candiduria, mucocutaneous and chronic oral atrophic candidiasis. • Tinea pedis, tinea cruris, tinea corporis, tinea versicolor and dermal Candida infection. • Systemic candidiasis such as candidaemia, disseminated candidiasis and invasive candidal infection of the peritoneum, endocardium and urinary and pulmonary tracts. • Cryptococcosis, including pulmonary and cutaneous infections and cryptococcal meningitis. In AIDS patients, as a maintenance therapy to prevent relapse of cryptococcal disease. • Prevention of fungal infection in immunocompromised patients at risk as a result of neutropenia following cytotoxic chemotherapy or radiotherapy.
BRU14111615P	Curam 156.25mg/5ml Powder For Oral Suspension	For the treatment of common bacterial infections where oral therapy is indicated, including: • Upper respiratory tract infections (including ENT): sinusitis, tonsillitis, otitis media. • Skin and soft tissue infections: boils/abscesses, cellulitis, wound infections, intra-abdominal sepsis • Lower respiratory tract infections: acute and chronic bronchitis, pneumonia, lung abscess • Genito-urinary tract infections: cystitis, urethritis, pyelonephritis, septic abortion, pelvic infection • Other infections: osteomyelitis, peritonitis, postoperative infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents.
BRU14111618NP	Strepsils Extra Strong Lozenge	An antiseptic lozenge for relief of sore throat for children and adults.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111621P	Brozil Film Coated Tablet 600mg	Hyperlipidaemias of type IIa, IIb, III, IV and V. It is indicated in patient who has not responded adequately to weight loss and specific dietary, or when other non-drug measures have failed.
BRU14111622NP	Panadol Extra Caplet	Panadol Extra mengandungi paracetamol, sejenis analgesik dan antipiretik, dan kafein, sebagai pembantu kepada kesan analgesik paracetamol. Panadol Extra disyorkan untuk merawat kesakitan ringan dan sederhana serta melegakan demam termasuk: Sakit kepala, migrain, sakit otot, sakit senggugut, sakit muskuloskeletal, demam dan sakit selepas vaksinasi, sakit selepas prosedur pergigian / pencabutan gigi, sakit gigi, sakit osteoartritis serta melegakan gejala-gejala selesema, influenze dan sakit tekak.

BRU14111623P	Botox (Botulinium Toxin, Type A) Injection 100 Units/Vial	BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following therapeutic indications: • BOTOX® is indicated for the treatment of blepharospasm associated with dystonia, including benign essential blepharospasm, hemifacial spasm and VIIth nerve disorders in patients 12 years or older. • BOTOX® is indicated for the correction of strabismus in patients 12 years of age or older. • BOTOX® is indicated for the treatment of spasmodic torticollis (cervical dystonia) in adults. • BOTOX® is indicated for the treatment of dynamic equinus foot deformity due to spasticity in paediatric cerebral palsy patients, two years of age and older. • BOTOX® is indicated in the management of focal spasticity: o including wrist and hand disability due to upper limb spasticity associated with stroke in adults. o Including ankle and foot disability due to lower limb spasticity associated with stroke in adults. • BOTOX® is indicated for the management of severe hyperhidrosis of the axillae which does not respond to topical treatment with antiperspirant or antihidrotics. • BOTOX® is indicated for the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). • BOTOX® is indicated for the treatment of urinary incontinence due to neurogenic detrusor overactivity (NDO) associated with Multiple Sclerosis or Spinal Cord Injury in adults who had an inadequate response to or are intolerant of an anticholinergic medication. • BOTOX® is indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication. BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following cosmetic indications: • BOTOX® is indicated for the temporary improvement in the appearance of upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults. • BOTOX® is indicated for the temporary treatment of glabellar lines associated with corrugator and/or procerus muscle activity in adult patients below 65 years of age.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111624P	Botox (Botulinium Toxin, Type A) Injection 50 Units/Vial	BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following therapeutic indications: • BOTOX® is indicated for the treatment of blepharospasm associated with dystonia, including benign essential blepharospasm, hemifacial spasm and VIIth nerve disorders in patients 12 years or older. • BOTOX® is indicated for the correction of strabismus in patients 12 years of age or older. • BOTOX® is indicated for the treatment of spasmodic torticollis (cervical dystonia) in adults. • BOTOX® is indicated for the treatment of dynamic equinus foot deformity due to spasticity in paediatric cerebral palsy patients, two years of age and older. • BOTOX® is indicated in the management of focal spasticity: o including wrist and hand disability due to upper limb spasticity associated with stroke in adults. o Including ankle and foot disability due to lower limb spasticity associated with stroke in adults. • BOTOX® is indicated for the management of severe hyperhidrosis of the axillae which does not respond to topical treatment with antiperspirant or antihidrotics. • BOTOX® is indicated for the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). • BOTOX® is indicated for the treatment of urinary incontinence due to neurogenic detrusor overactivity (NDO) associated with Multiple Sclerosis or Spinal Cord Injury in adults who had an inadequate response to or are intolerant of an anticholinergic medication. • BOTOX® is indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication. BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following cosmetic indications: • BOTOX® is indicated for the temporary improvement in the appearance of upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults. • BOTOX® is indicated for the temporary treatment of glabellar lines associated with corrugator and/or procerus muscle activity in adult patients below 65 years of age.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111625P	Botox (Botulinium Toxin, Type A) Injection 200 Units/Vial	BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following <u>therapeutic indications</u>: • BOTOX® is indicated for the treatment of blepharospasm associated with dystonia, including benign essential blepharospasm, hemifacial spasm and VIIth nerve disorders in patients 12 years or older. • BOTOX® is indicated for the correction of strabismus in patients 12 years of age or older. • BOTOX® is indicated for the treatment of spasmodic torticollis (cervical dystonia) in adults. • BOTOX® is indicated for the treatment of dynamic equinus foot deformity due to spasticity in paediatric cerebral palsy patients, two years of age and older. • BOTOX® is indicated in the management of focal spasticity: o including wrist and hand disability due to upper limb spasticity associated with stroke in adults. o Including ankle and foot disability due to lower limb spasticity associated with stroke in adults. • BOTOX® is indicated for the management of severe hyperhidrosis of the axillae which does not respond to topical treatment with antiperspirant or antihidrotics. • BOTOX® is indicated for the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine). • BOTOX® is indicated for the treatment of urinary incontinence due to neurogenic detrusor overactivity (NDO) associated with Multiple Sclerosis or Spinal Cord Injury in adults who had an inadequate response to or are intolerant of an anticholinergic medication. • BOTOX® is indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication. BOTOX® (botulinum toxin type A) purified neurotoxin complex is indicated for the following <u>cosmetic indications</u>: • BOTOX® is indicated for the temporary improvement in the appearance of upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults. • BOTOX® is indicated for the temporary treatment of glabellar lines associated with corrugator and/or procerus muscle activity in adult patients below 65 years of age.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111627P; BRU14111627PS2	Cellcept Tablet 500mg	CellCept is indicated for: • prophylaxis of acute organ rejection and treatment of refractory organ rejection in patients receiving allogeneic renal transplants. • prophylaxis of acute organ rejection and increased graft and patient survival in patients receiving allogeneic cardiac transplants. • prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplants. CellCept should be used concomitantly with cyclosporin and corticosteroids.
BRU14111628NP	0.45% Sodium Chloride Intravenous Infusion BP	• Hypertonic dehydration, • Vehicle solution for compatible medicinal products.
BRU14111631NP	Peditrace Concentrate For Solution For Infusion	Peditrace is intended to meet the basal requirement of trace elements during intravenous nutrition of infants and children.
BRU14111633P	Pharmaniaga Salbutamol Respirator Solution 0.5% w/v	Salbutamol Respirator Solution is indicated for the relief of bronchospasm in patients with reversible obstructive airway disease and acute bronchospasm.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111634P	Epimate 50mg Tablet	Topiramate tablets is indicated as adjunctive therapy for adults and pediatric patients ages 2-16 years with partial onset seizures, or primary generalized tonic-clonic seizures, and in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome.
BRU14111635NP	HOE Aqueous Cream 9% w/w	Aqueous cream is suitable for the incorporation of anionic medicaments and for dilution of similar creams. It may be used as an emollient for dry skin conditions.
BRU14111636P	Melomet Cream 0.1% w/w	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
BRU14111637NP	Poro Suspension 250mg/5ml	For the relief of fever and mild to moderate pain.
BRU14111638P	Primovist 0.25mmol/ml Solution For Injection	Primovist is indicated for use in adults for the enhancement of magnetic resonance imaging (MRI) of focal liver lesions.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111641NP	Hoemal Oral Suspension 250mg/5mL	For the relief of most mild to moderate pain including teething pain and symptomatic relief of fever in influenza and feverish cold. It is also a substitute for aspirin for its analgesic or antipyretic uses in patients who allergic to aspirin or when aspirin is contraindicated as in children and patients with peptic ulcer.
BRU14111642P	Manace Injection 5mg/ml (Haloperidol 5mg/ml)	Chronic Therapy: - The management of manifestations of psychotic disorders such as schizophrenia, phase of manic-depressive illness, Gilles de la Tourette syndrome. Short Term Therapy: - The treatment of acute alcoholism for the relief of delusions, hallucinations and confused states and for the control of accompanying tremulousness and aggressiveness behaviour. - In the treatment of intractable nausea and vomiting associated with radiation or malignancy and not responding to other therapy.
BRU14111643NP	Woodward's Gripe Water (Alcohol Free)	For relief from wind pains, digestive upsets, especially during the teething period.
BRU14111644P	Buston Injection 20mg/ml	Buston 20mg/mL Solution for Injection is indicated in acute spasm, as in renal or biliary chronic, in radiology for differential diagnosis of obstruction. It also indicated to reduce spasm and pain in pyelography, and in other diagnostic procedures where spasm may be a problem.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111646NP	Oralite Orange Oral Rehydration Salts	For replacement of body fluids and electrolytes lost in diarrhoea and vomiting.
BRU14111648P	Pharmaniaga Cetirizine 10mg Tablet	It is used for the symptomatic relief of allergic condition including rhinitis and chronic urticaria.
BRU14111649P	Hovid Lipiduce-20 Tablet	Atorvastatin is indicated: As an adjunct therapy to diet to reduce elevated total cholesterol, LDL-cholesterol, apolipoprotein B, triglycerides and increase HDL-cholesterol in patients with: • Primary hypercholesterolemia (heterozygous familial and nonfamilial). • Combined hyperlipidaemias (Fredrickson Types IIa and IIb). • Hypertriglyceridemia (Fredrickson Type IV). • Primary dysbetalipoproteinemia (Fredrickson Type III). As an adjunct therapy with other lipid lowering treatment (e.g. LDL apheresis) in homozygous familial hypercholesterolemia to reduce total cholesterol and LDL cholesterol.

BRU14111650P	Invokana Film-Coated Tablet 100mg	<u>Monotherapy</u> INVOKANA (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance. <u>Combination with Metformin or a Sulfonylurea</u> INVOKANA is indicated in combination with metformin or a sulfonylurea in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise plus monotherapy with one of these agents does not provide adequate glycemic control. <u>Combination with Metformin and either a Sulfonylurea or Pioglitazone</u> INVOKANA is indicated in combination with metformin and either a sulfonylurea or pioglitazone in adult patients with type 2 diabetes mellitus to improve glycemic control when diet, exercise, and dual therapy (with metformin plus either a sulfonylurea or pioglitazone) do not provide adequate glycemic control. <u>Combination with Insulin</u> INVOKANA is indicated as add-on combination therapy with insulin (with or without metformin) in adult patients with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control when diet and exercise, and therapy with insulin (with or without metformin) do not provide adequate glycemic control. <u>Add-On Combination in Patients with Established Cardiovascular Disease</u> INVOKANA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adult with type 2 diabetes mellitus and established cardiovascular disease (CVD). <u>Patients with Diabetic Nephropathy</u> INVOKANA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of end-stage kidney disease, doubling of serum creatinine, and cardiovascular (CV) death in adult patients with type 2 diabetes mellitus and diabetic nephropathy with albuminuria (> 33.9 mg/mmol).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111651P	Axcel Chlorpheniramine-2 Syrup	For allergic conditions including hay fever, urticaria, angioedema, vasomotor rhinitis, allergic eczema, atopic and contact dermatitis, drug and serum reactions, insect bites, pruritus.
BRU14111653P	Asmol 2 Tablet	It is indicated for the relief of bronchospasm in patients with reversible obstructive airway disease.
BRU14111654NPS1; BRU14111654NPS2	Paracetamol Kabi Solution For Infusion 10mg/ml	Paracetamol Kabi is indicated for: - The short-term treatment of moderate pain, especially following surgery, - the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14111655P	Risperdal Solution 1mg/ml	**RISPERDAL TABLET (1MG, 2MG & 3MG) AND RISPERDAL ORAL SOLUTION 1MG/ML** RISPERDAL® is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERDAL® alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERDAL® is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERDAL is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. **RISPERDAL TABLETS (1MG) AND RISPERDAL ORAL SOLUTION 1MG/ML** RISPERDAL is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.
BRU14121661P	Kastipron Tablet 375mg	Aids expectoration by reducing sputum viscosity.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14121663P	Curam 625mg Film-Coated Tablet	For the treatment of common bacterial infections where oral therapy is indicated, including: • Upper respiratory tract infections (including ENT): sinusitis, tonsillitis, otitis media. • Skin and soft tissue infections: boils/abscesses, cellulitis, wound infections, intra-abdominal sepsis. • Lower respiratory tract infections: acute and chronic bronchitis, pneumonia, lung abscess. • Genito-urinary tract infections: cystitis, urethritis, pyelonephritis, septic abortion, pelvic infection. • Other infections: osteomyelitis, peritonitis, postoperative infections.
BRU14121666P	Amoxicap 500 Capsule	For treatment of: 1) Ear, nose and throat infections caused by *streptococci, pneumococci* , non-*penicillinase* -producing *staphylococci* and *H.influenzae* 2) Genitourinary tract infections caused by E.Coli, P.Mirabilis, S.Faecalis 3) Skin and soft-tissues infections caused by *streptococci* , non-*penicillinase* -producing *staphylococci* and E.Coli 4) Anogenital and urethral *gonorrhoea* caused by N.Gonorrhoea
BRU14121667NP	Wintosal Cream	For temporary relief of pain associated with musculoskeletal soreness and discomfort.
BRU14121668NP	50% Glucose Intravenous Infusion B.P.	Parenteral nutrition. High caloric carbohydrate therapy, especially when fluid intake is limited as for example in renal insufficiency. Hypoglycaemia.

BRU14121670P	Medoflucon Capsule 150mg	• Acute or recurrent vaginal candidiasis; • Mucosal candidiasis, including oropharyngeal, oesophageal, non-invasive bronchopulmonary infection, candiduria, mucocutaneous and chronic oral atrophic candidiasis; • Tinea pedis, tinia cruris, tinea corporis, tinea versicolor and dermal Candida infection; • Systemic candidiasis, such as candidaemia, disseminated candidiasis and invasive candidial infection of the peritoneum, endocardium and urinary and pulmonary tracts; • Cryptococcosis, including pulmonary and cutaneous infections and cryptococcal meningitis. In AIDS patients, as a maintenance therapy to prevent relapse of cryptococcal disease; • Prevention of fungal infection in immunocompromised patients at risk as a result of neutropenia following cytotoxic chemotherapy or radiotherapy.
BRU14121671P; BRU14121671PR2	Topamax 100 Tablets 100mg	**Epilepsy** TOPAMAX is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy. TOPAMAX is indicated as adjunctive therapy for adults and children aged 2 and above with partial onset seizures or generalized tonic-clonic seizures. TOPAMAX is also indicated in adults and children as adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome. **Migraine** TOPAMAX is indicated in adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX in the acute treatment of migraine headache has not been studied.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14121673P	Eprex® 40,000 Prefilled Syringe	• Treatment of anemia associated with chronic renal failure in adult hemodialysis, peritoneal dialysis and predialysis patients and pediatric patients on hemodialysis. • Treatment of anemia and reduction of transfusion in adult cancer patients with non-myeloid malignancies receiving chemotherapy. • Treatment of anemia in HIV-infected patients being treated with zidovudine who have endogenous erythropoietin levels ≤ 500 mIU/mL. • To facilitate autologous blood collection within a predeposit program and decrease the risk of receiving allogeneic blood transfusions in patients with hematocrits of 33 - 39%, who are scheduled for major elective surgery and are expected to require more blood than that which can be obtained through autologous blood collection techniques in the absence of Eprex. • Eprex is indicated in adult patients with mild to moderate anemia (hemoglobin > 10 to ≤ 13 g/dL) scheduled for elective surgery with an expected moderate blood loss (2 - 4 units or 900 to 1800 mL) to reduce exposure to allogeneic blood transfusions and to facilitate erythropoietic recovery). • Eprex is indicated for the treatment of anemia (hemoglobin concentration of ≤ 10 g/dL) in adults with low- or intermediate-1-risk myelodysplastic syndromes (MDS) who have low serum erythropoietin (< 200 mU/mL).
BRU14121674P	Milosec Capsule 20mg	Treatment of duodenal ulcer, gastric ulcer, reflux esophagitis and symptomatic gastroesophageal reflux disease. Helicobacter pylori eradication in peptic ulcer disease. Management of Zollinger-Ellison syndrome.
BRU14121675P	Ziagen Oral Solution	ZIAGEN is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and children.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14121677P	Pataday Olopatadine Ophthalmic Solution 0.2%	PATADAY is indicated for the temporary prevention of itching of the eye due to allergic conjunctivitis.
BRU14121681NP	Strepsils Strawberry Sugar Free Children Lozenges	As an antiseptic lozenge for relief of sore throat for children over 6 years.
BRU14121682P	Axcel Sodium Fusidate 250 Tablet	Sodium Fusidate is indicated for the treatment of infections caused by susceptible organisms, especially staphylococci, e.g. Osteomyelitis, septicaemia, endocarditis, superinfected cystic fibrosis, pneumonia, skin and soft tissue infections, surgical and traumatic wound infections.
BRU14121683P	Pencor Tablet 1mg	Hypertension: PENCOR is indicated for the treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. In patients inadequately controlled on single antihypertensive therapy, PENCOR may be used in combination with thiazide diuretic, beta-adrenoceptor blocking agent, calcium antagonist or an angiotensin-converting enzyme inhibitor. Benign prostatic hyperplasia: PENCOR is indicated for the treatment of urinary outflow obstruction and symptoms associated with benign prostatic hyperplasia (BPH). PENCOR may be used in BPH patients who are either hypertensive or normotensive.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14121684P	Pencor 2 Tablet	Hypertension: PENCOR is indicated for the treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. In patients inadequately controlled on single antihypertensive therapy, PENCOR may be used in combination with thiazide diuretic, beta-adrenoceptor blocking agent, calcium antagonist or an angiotensin-converting enzyme inhibitor. Benign prostatic hyperplasia: PENCOR is indicated for the treatment of urinary outflow obstruction and symptoms associated with benign prostatic hyperplasia (BPH). PENCOR may be used in BPH patients who are either hypertensive or normotensive.
BRU14121685P	Pencor 4 Tablet	Hypertension: PENCOR is indicated for the treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. In patients inadequately controlled on single antihypertensive therapy, PENCOR may be used in combination with thiazide diuretic, beta-adrenoceptor blocking agent, calcium antagonist or an angiotensin-converting enzyme inhibitor. Benign prostatic hyperplasia: PENCOR is indicated for the treatment of urinary outflow obstruction and symptoms associated with benign prostatic hyperplasia (BPH). PENCOR may be used in BPH patients who are either hypertensive or normotensive.
BRU14121686P	Decan Injection 2mg/ml	Rheumatic disorders: Acute and subacute rheumatism, rheumatoid arthritis, acute gouty arthritis, post-traumatic osteoarthritis, synovitis of osteoarthritis, epicondylitis, and acute nonspecific tenosynovitis etc. Collagen diseases, dermatologic disease, allergic states and ophthalmic inflammatory diseases.
BRU14121687P	Primodil-10 Tablet	• PRIMODIL is indicated for the first line management of Hypertension, Stable angina, Variant/Prinzmetal's angina. • PRIMODIL may be used alone or in combination with other antihypertensive and/or antianginal drugs for effective management.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14121690P	Seladin 500mg Tablet	For the relief of pain and inflammation in rheumatic disorders, acute gout and other musculoskeletal disorders.
BRU14121691P	Driminate 50mg Suppository	For the prevention and relief of motion sickness and treatment of nausea, vomiting and vertigo.
BRU14121695P	Axcel Fungicort Cream	Treatment of fungal infections of the skin including candidiasis, tinea and pityriasis versicolor, where inflammation of the skin is also present.
BRU14121698P	Edurant Film-Coated 25mg Tablet	EDURANT, in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml.

BRU14121699P	Invokana Film-Coated Tablet 300mg	Monotherapy INVOKANA (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance. Combination with Metformin or a Sulfonylurea INVOKANA is indicated in combination with metformin or a sulfonylurea in adult patients with type 2 diabetes mellitus to improve glycemic control when diet and exercise plus monotherapy with one of these agents does not provide adequate glycemic control. Combination with Metformin and either a Sulfonylurea or Pioglitazone INVOKANA is indicated in combination with metformin and either a sulfonylurea or pioglitazone in adult patients with type 2 diabetes mellitus to improve glycemic control when diet, exercise, and dual therapy (with metformin plus either a sulfonylurea or pioglitazone) do not provide adequate glycemic control. Combination with Insulin INVOKANA is indicated as add-on combination therapy with insulin (with or without metformin) in adult patients with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control when diet and exercise, and therapy with insulin (with or without metformin) do not provide adequate glycemic control. Add-On Combination in Patients with Established Cardiovascular Disease INVOKANA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adult with type 2 diabetes mellitus and established cardiovascular disease (CVD). Patients with Diabetic Nephropathy INVOKANA is indicated as an adjunct to diet, exercise, and standard of care therapy to reduce the risk of end-stage kidney disease, doubling of serum creatinine, and cardiovascular (CV) death in adult patients with type 2 diabetes mellitus and diabetic nephropathy with albuminuria (> 33.9 mg/mmol).

BRU14121701P	Borymycin Capsule 100mg	Borymycin Capsule is indicated in the treatment of the following infections caused by susceptible strains: Respiratory tract infections caused by *Mycoplasma pneumoniae* ; Psittacosis due to *Chlamydia psittaci* ; Trachoma caused by *Chlamydia trachomatis* , although the infection is not always eliminated, as judged by the immunofluorescence; Inclusion conjunctivitis caused by *Chlamydia trachomatis* ; Nongonococcal urethritis in adults caused by *Ureaplasma urealyticum* or *Chlamydia trachomatis* ; Chancroid due to *Haemophilus ducreyi* ; Cholera caused by *Vibrio cholerae* . Minocycline is indicated for treatment of infections caused by the following Gram-negative microorganisms, when bacteriologic testing indicates appropriate susceptibility to the drug: *Escherichia coli; Enterobacter aerogenes; Shigella species; Acinetobacter* species; Respiratory tract infections caused by *Haemophilus influenzae* ; Respiratory tract and urinary tract infections caused by *Klebsiella* species. Minocycline is indicated for treatment of infections caused by the following Gram-positive microorganisms, when bacteriologic testing indicates appropriate susceptibility to the drug: Upper respiratory tract infections caused by *Streptococcus pneumoniae* ; Skin and skin structure infections caused by Minocycline-sensitive organism; Uncomplicated urethritis in men due to *Neisseria gonorrhoeae* and for the treatment of other gonococcal infections when penicillin is contraindicated. Minocycline is an alternative drug in the treatment of the following infections: Infections in women caused by *Neisseria gonorrhoeae* ; Syphilis caused by *Treponema pallidum* ; Listeriosis due to *Listeria monocytogenes* ; Anthrax caused by *Bacillus anthracis* ; Infections caused by *Clostridum* species; In severe acne, Minocycline may be used as an adjunct therapy. Oral Minocycline is indicated in the treatment of asymptomatic carriers of *Neisseria meningitidis* to eliminate meningococci from the nasopharynx. It is recommended that the prophylactic use of Minocycline be reserved for situations in which the risk of meningococcal meningitis is high. Oral Minocycline also has been used in the treatment of infections caused by *Mycobacterium marinum* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU14121702NP	Septi-Sol Solution	For hand disinfection of healthcare personnel. Septi-Sol Solution is to be used as a supplement to handwashing when hands are not visibly soiled or when soap and water are not conveniently or readily available.
BRU14121703P	Atoris Film-Coated Tablet 20mg	<u>Hypercholesterolaemia</u> Atoris is indicated as an adjunct to diet for the reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atoris is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. <u>Prevention of cardiovascular disease</u> Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU14121704NP	Nutrilite OsteGlucosamine 375mg Capsule	As adjuvant therapy for osteoarthritis.
BRU14121705PS2	Ultibro Breezhaler 110/50 mcg Inhalation Powder Hard Capsule	Ultibro Breezhaler is indicated as a once-daily maintenance bronchodilator treatment to relieve symptoms and reduce exacerbations in adult patients with chronic obstructive pulmonary disease (COPD).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15011710P	Klerimed 250mg Film-Coated Tablets	Klerimed is indicated for treatment of infections caused by one or more susceptible organisms. Indications include: • Lower respiratory tract infections for example, acute and chronic bronchitis, and pneumonia. • Upper respiratory tract infections for example, sinusitis and pharyngitis. Klerimed is appropriate for initial therapy in community acquired respiratory infections and has been shown to be active in vitro against common and atypical respiratory pathogens as listed in the microbiology section. Klerimed is also indicated in skin and soft tissue infections of mild to moderate severity. Klerimed in the presence of acid suppression effected by omeprazole is also indicated for the eradication of *H. Pylori* in patients with proven duodenal ulcers.
BRU15011711P	DiSuf-B Cream	Disuf-B Cream is indicated in inflammatory dermatoses where bacterial infection is present or likely to occur. Inflammatory dermatoses include atopic eczema, discoid eczema, stasis eczema, seborrhoeic dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis, discoid lupus erythematosus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15011714P	Ospamox 250mg/5ml Granules For Suspension	Ospamox is useful in the treatment of infections caused by amoxicillin-susceptible organisms: • Acute bacterial sinusitis • Acute otitis media • Acute streptococcal tonsillitis and pharyngitis • Acute exacerbations of chronic bronchitis • Community acquired pneumonia • Acute cystitis • Asymptomatic bacteriuria in pregnancy • Acute pyelonephritis • Typhoid and paratyphoid fever • Dental abscess with spreading cellulitis • Prosthetic joint infections • Helicobacter pylori eradication • Lyme disease Amoxicillin is also indicated for the prophylaxis of endocarditis. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

BRU15011716P	Ospamox 500mg Film-Coated Tablet	Ospamox is useful in the treatment of infections caused by amoxicillin-susceptible organisms. *Respiratory tract infections* • Upper airways and ENT infections • Lower airways infections, e.g. acute and chronic bronchitis, pneumonia, lung abscess, pertussis (incubation period and early stages) *Urogenital infections* • Acute and chronic pyelonephritis, pyelitis, prostatitis, epididymitis • Cystitis, urethritis, symptomatic bacteriuria during pregnancy • Gonorrhoea *Gynaecologic infections* (septic abortion, adnexitis, endometritis, etc.) *Gastro-intestinal infections* • Typhoid fever, parathyphoid, particularly if complicated by septicaemia (incombination with an aminoglycoside antibiotic); control of Salmonella carriers • Shigellosis • Infections of the biliary system (cholangitis, cholecystitis) *Skin and soft tissue infections* *Leptospirosis*

		Acute and latent listeriosis Unless parenteral treatment (e.g. with ampicillin) is required, Ospamox is also active in the conditions below: • Short-term (24 to 48 hours) prophylactic treatment of patients undergoing surgery (e.g. in the oral cavity) • Endocarditis, e.g. enterococal endocarditis (alone or n combination with an aminoglycoside antibiotic); • Bacterial meningitis (pending the outcome of susceptibility tests; particularly in children) • Septicaemias caused by amoxicillin-susceptible pathogens. Infections caused by pathogens with established penicillin G susceptibility should preferentially be treated with penicillin G. Consideration should be given to official guidance on the appropriate use of antibacterial agents.
BRU15011722P	T3 Ada Gel 0.1%	For treatment of acne vulgaris in which comedones, papules and pustules predominate.
BRU15011723P	Clarimycin Film Coated Tablet 250mg	Treatment of infections caused by pathogens sensitive to Clarithromycin. Infections of nose-pharinx tract (tonsillitis, pharyngitis) and of paranasal sinuses. Infections of lower respiratory tract: bronchitis, bacterial pneumonia and atypical pneumonia. Skin Infections: impetigo, erysipelas, folliculitis, furunculosis and septic wounds.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15011724P	Forteo Injection 20mcg/80mcl	FORTEO is indicated in adults. Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. In postmenopausal women, a significant reduction in the incidence of vertebral and non- vertebral fractures but not hip fractures has been demonstrated. Treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk for fracture.
BRU15011727P	Bactigen Eye Drops 0.3% w/v	BACTIGEN is indicated in the topical treatment of infections caused by susceptible bacteria of the external structures of the eyes and their adnexa, such as conjunctivitis, keratitis and keratoconjunctivitis, corneal ulcers, blepharitis and blepharoconjunctivitis, acute meibomianitis and dacryocystitis.
BRU15011728P	Hexaxim Suspension For Injection	Hexaxim (DTaP-IPV-HB-Hib) is indicated for primary and booster vaccination of infants and toddlers from six weeks to 24 months of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b (Hib). The use of this vaccine should be in accordance with official recommendations.
BRU15011730PS1; BRU15011730PS3	Bridion Solution For Injection 100mg/ml	Reversal of neuromuscular blockade induced by rocuronium or vecuronium in patients 2 years of age and older.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15011732NP	Strepsils Soothing Honey & Lemon Lozenge	An antiseptic lozenge for relief of sore throat for children and adults.
BRU15011733NP	Strepsils Max Triple Action	For the relief of sore throat and its associated pain.
BRU15011734P	Implanon NXT Implant 68mg	Contraception.
BRU15011738NP	Bactidol Mouthwash	For the symptomatic relief of mouth and throat infections including mouth ulcers caused by susceptible bacteria and fungus.
BRU15011743P	Pharmaniaga Germacid Cream 2%	Pharmaniaga Germacid Cream is indicated for treatment of skin lesions caused by staphylococci, streptococci, Propionibacterium acnes, Corynebacterium minutissimum, and other organisms sensitive to fusidic acid. The most important indications being: Impetigo, infected wounds, folliculitis, boils, sycosis barbae, carbuncles, hidradenitis, paronychia and erythrasma. Pharmaniaga Germacid Cream is an invisible, non-staining preparation, which is cosmetically acceptable for treatment of face and scalp infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15011744NP	Extraneal Peritoneal Dialysis Solution 75g/l (2L Ultrabag)	Extraneal is recommended as a once daily replacement for a single Dextrose exchange as part of a CAPD or automated peritoneal dialysis (APD) regimen for the treatment of chronic renal failure, particularly for some categories of patients who have lost ultrafiltration on Dextrose solutions, because it canextend time on CAPD therapy in such patients.
BRU15011745P	Seladin Tablet 250mg	For the relief of pain and inflammation in rheumatic disorders, acute gout and other musculoskeletal disorders.
BRU15011746NP	Vitalipid N Adult	Vitalipid N Adult is indicated as a supplement in complete intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D_2, E and K_1.
BRU15011747NP	Vitalipid N Infant	Vitalipid N Adult is indicated as a supplement in complete intravenous nutrition to meet the daily requirements of the fat-soluble vitamins A, D_2, E and K_1. As above Vitalipid N Infant is indicated in paediatric patients up to 11 years of age.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15011750NP	Prismasol BO	As substitution solution in continuous haemofiltration and haemodiafiltration and as dialysis solution in continuous haemodialysis for acute renal failure.
BRU15021754P	Cernevit Multivitamin Powder For Injection	CERNEVIT is indicated for adults and children over 11 years of age. When the daily requirements of vitamins are required to be given to the patient by the parenteral route because oral administration is either contraindicated, impossible or insufficient (eg due to malnutrition, gastrointestinal malabsorption, etc).

BRU15021757P	Simponi Solution For Injection 50mg/0.5ml	*Rheumatoid arthritis (RA):* SIMPONI, by SC administration, in combination with methotrexate (MTX), is indicated for: • the treatment of moderate to severe active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including methotrexate has been inadequate. • the treatment of severe, active, and progressive rheumatoid arthritis in adult patients not previously treated with MTX. SIMPONI, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function. *Psoriatic arthritis (PsA):* SIMPONI, by SC administration, alone or in combination with MTX, is indicated for: • the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate. SIMPONI has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Axial spondyloarthritis* *Ankylosing spondylitis (AS):* SIMPONI, by SC administration, is indicated for: • the treatment of severe, active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA):* SIMPONI, by SC administration, is indicated for the treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

		Ulcerative colitis (UC): SIMPONI, by SC administration, is indicated for: • the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids. and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.
BRU15021760PS1; BRU15021760PS2	Insulatard® 100IU/ml Suspension For Injection (Vial)	Treatment of Diabetes Mellitus.
BRU15021761P	Covapril Tablet 4mg	1. Hypertension: Treatment of hypertension. 2. Heart failure: Treatment of symptomatic heart failure. 3. Stable coronary artery disease: Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularization.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15021762P	Axcel Amlodipine-5mg Tablet	Amlodipine is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin – converting enzyme inhibitor. Amlodipine is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and / or vasospasm / vasoconstriction (Prinzmetal's or variant angina) or coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic / vasoconstrictive component but where vasospasm / vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and / or adequate doses of beta blockers.
BRU15021764P	Miostat Intraocular Solution	Intraocular use for obtaining miosis during surgery. In addition, Miostat reduces the intensity of intraocular pressure elevation in the first 24 hours after cataract surgery.
BRU15021766P	Neulastim Pre-Filled Syringe 6mg/0.6ml	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).
BRU15021767P	Bacitracin-N Ointment	For the prevention or treatment of superficial skin infections caused by susceptible organisms in minor abrasions, burns and cuts.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15021768P	Exelon Patch 15	Treatment of patients with: • Mild to moderately severe dementia of the Alzheimer's type. • Severe dementia of the Alzheimer's type. • Mild to moderately severe dementia associated with Parkinson's disease.
BRU15021769NP	Zellox-II Liquid Antacid	Zellox-II is indicated for relief from gastric acidity, indigestion, heartburn, flatulence and dyspepsia.
BRU15021770NP	Bonjela Gel 15g Tube	For mouth ulcers, teething pain, denture sore spots and cold sores.
BRU15021771P	Gilenya 0.5mg Hard Capsule	Gilenya is indicated for the treatment of adult patients and pediatric patients of 10 years of age and above with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.
BRU15021772P	Presolin 150mg Tablet	Hypertension (treatment) – Irbesartan is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medications.
BRU15021773P	Presolin 300mg Tablet	Hypertension (treatment) – Irbesartan is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medications.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15021774P	Tracidol Injection 50mg/ml	Moderate to severe pain.
BRU15021776P	Apo-Risperidone Tablets 2mg	For the treatment of acute and chronic schizophrenic psychoses, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. Risperidone also alleviate affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. Risperidone is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response.
BRU15021777P	Apo-Megestrol Tablet 160mg	Apo-Megestrol (megestrol acetate) is indicated for adjunctive or palliative treatment of recurrent inoperable or metastatic carcinoma of the breast endometrium. Apo-Megestrol should not be used in lieu of currently accepted procedures such as surgery and radiation. Objective or subjective responses or arrest of tumour growth may occur for one to several months while on therapy. Apo-Megestrol is also indicated in male or female patients for the treatment of anorexia, cachexia or weight loss secondary to metastatic cancer.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15021779P; BRU15021779PS2	Trajenta Duo 2.5mg/500mg Film-Coated Tablet	Trajenta Duo is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate (see *Posology and Method of Administration* and *Clinical Studies*).
BRU15021780P; BRU15021780PS2	Trajenta Duo 2.5mg/850mg Film-Coated Tablet	Trajenta Duo is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate (see *Posology and Method of Administration* and *Clinical Studies*).
BRU15021781P; BRU15021781PS2	Trajenta Duo 2.5mg/1000mg Film-Coated Tablet	Trajenta Duo is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate (see *Posology and Method of Administration* and *Clinical Studies*).
BRU15021783P	Acustop Cataplasma	For the treatment of the sign and symptoms of the following: arthritis demorfans, periarthritis humero-scapularis, tendiitis, peridenitis, humeral epicondylitis (tennis elbow), sore muscle, swelling and pain resulted from trauma.
BRU15021786P	Giotrif 20mg Film-Coated Tablets	GIOTRIF as monotherapy is indicated for the treatment of • Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). • Locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15021787P	Giotrif 30mg Film-Coated Tablets	GIOTRIF as monotherapy is indicated for the treatment of • Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). • Locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.
BRU15021788P	Giotrif 40mg Film-Coated Tablets	GIOTRIF as monotherapy is indicated for the treatment of • Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s). • Locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.
BRU15021793NP	SMOFlipid 20% Emulsion For Infusion	Supply of energy and essential fatty acids and omega-3 fatty acids to patients, as part of a parenteral nutrition regimen, when oral or enteral nutrition is impossible, insufficient or contra-indicated.
BRU15021795P	Ceflour Film Coated Tablet 250mg	For the treatment of the following infections due to susceptible gram-positive and gram-negative microorganisms: upper and lower respiratory tract infections, genitourinary tract infections, gonorrhea, skin and soft tissue infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15021796P	Montelair 10mg Film-Coated Tablet	• For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 6 years of age and older. • Montelukast is indicated in adults and pediatric patients 6 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis.
BRU15021797P	Amlibon 10mg Tablet	*Hypertension* Amlodipine is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha-blocker, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme inhibitor. *Chronic Stable Angina* Amlodipine is indicated for the first line treatment of myocardial ischaemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or beta-blockers.
BRU15021798NP	Dianeal Low Calcium (2.5MEq/L) Peritoneal Dialysis Solution With 4.25% Dextrose (2L Ultrabag)	Dianeal Low Calcium peritoneal dialysis solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

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BRU15021799NP	Dianeal Low Calcium (2.5MEq/L) Peritoneal Dialysis Solution 2.5% Dextrose (2L Ultrabag And 2.5L Ultrabag)	Dianeal Low Calcium peritoneal dialysis solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.
BRU15021800NP	Dianeal Low Calcium (2.5MEq/L) Peritoneal Dialysis Solution 1.5% Dextrose (2L Ultrabag And 2.5L Ultrabag)	Dianeal Low Calcium peritoneal dialysis solutions in ULTRABAG containers are indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.
BRU15021801NP	Calactate Tablet 300mg	Calcium salts are mainly in the treatment of calcium deficiency, hypocalcaemia, post-menopausal osteoporosis, and conditions requiring increased calcium demand in pregnancy lactation, old age, and growth period.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15021802P	Xylid 250mg Tablet	Xylid is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most β (beta)-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for the treatment of infections caused by susceptible bacteria. Susceptibility to Xylid will vary with geography and time and local susceptibility data should be consulted where available. Indications include: • Upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis. • Lower respiratory tract infections for example, pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis. • Genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis. • Skin and soft tissue infections for example, furunculosis, pyoderma and impetigo. • Gonorrhoea, acute uncomplicated gonococcal urethritis and cervicitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15021805P	Serenata Tablets 50mg	Sertaline is indicated for the treatment of symptoms of depression, including accompanied by symptoms of anxiety, in patients with or without history of mania. Following satisfactory response, continuation with Sertraline therapy is effective in preventing relapse of the initial episode of depression or recurrence of further depressive episodes including accompanying symptoms of anxiety. Sertraline is indicated for the treatment of obsessive-compulsive disorder (OCD). Following satisfactory response, continuation with Sertraline therapy is effective in preventing relapse of the initial episode of OCD. Sertraline is indicated for the treatment of post-traumatic stress disorder (PTSD). Following satisfactory response, continuation with Sertraline therapy is effective in preventing relapse of the initial episode of PTSD.
BRU15031809P	Moxiclav Forte Dry Powder For Oral Suspension 312.5mg/5ml	Moxiclav is indicated for the treatment of bacterial infections such as: - Upper Respiratory Tract Infections (including ENT): tonsillitis, sinusitis, otitis media. - Lower Respiratory Tract Infections: acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. - Genito-urinary tract infections: cystitis, urethritis, pyelonephritis. - Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections. - Bone and joint infections e.g. osteomyelitis. - Other infections e.g. septic abortion, puerperal sepsis, intraabdominal sepsis. A comprehensive list of susceptible organisms is provided in the *Pharmacodynamics section* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15031810P	Moxiclav 625mg Tablets	Moxiclav is indicated for the treatment of bacterial infections such as: • Upper Respiratory Tract Infections (including ENT): tonsillitis, sinusitis, otitis media. • Lower Respiratory Tract Infections: acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. • Genito-urinary tract infections: cystitis, urethritis, pyelonephritis. • Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections. • Bone and joint infections e.g. osteomyelitis. • Other infections e.g. septic abortion, puerperal sepsis, intraabdominal sepsis. A comprehensive list of susceptible organisms is provided in the *Pharmacodynamics* section.
BRU15031811P	Zemplar Injection	Paricalcitol injection is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal insufficiency.

BRU15031812P; BRU15031812PS2	Lamotrix 100mg Tablets	*EPILEPSY* **• Adults and children (over 12 years of age)** Lamotrigine is indicated as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. **• Children (2 to 12 years of age)** Lamotrigine is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalised seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti-epileptic drugs (AEDs) may be withdrawn and patients continued on lamotrigine monotherapy. *BIPOLAR DISORDER* **• Adults (18 years of age and over)** Lamotrix is indicated for the prevention of depressive episodes in patients with bipolar disorder. Safety and efficacy of lamotrigine in the acute treatment of mood episodes has not been established. The physician who elects to use lamotrigine for periods extending beyond 18 months should periodically re-evaluate the long term usefulness of the drug for the individual patient.

BRU15031813P; BRU15031813PS2	Lamotrix 50mg Tablets	*EPILEPSY* **• Adults and children (over 12 years of age)** Lamotrigine is indicated as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. **• Children (2 to 12 years of age)** Lamotrigine is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalised seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome. Initial monotherapy treatment in newly diagnosed paediatric patients is not recommended. After epileptic control has been achieved during adjunctive therapy, concomitant anti-epileptic drugs (AEDs) may be withdrawn and patients continued on lamotrigine monotherapy. *BIPOLAR DISORDER* **• Adults (18 years of age and over)** Lamotrix is indicated for the prevention of depressive episodes in patients with bipolar disorder. Safety and efficacy of lamotrigine in the acute treatment of mood episodes has not been established. The physician who elects to use lamotrigine for periods extending beyond 18 months should periodically re-evaluate the long term usefulness of the drug for the individual patient.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15031814P	Nimenrix™ (Meningococcal Polysaccharide Serogroups A,C,W-135, Y) Vaccine	Active immunization of individuals from 6 weeks of age against invasive meningococcal diseases caused by Neisseria meningitidis group A, C, W-135, and Y.
BRU15031816P	Cialis 5mg Tablet	Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required. Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males. CIALIS is not indicated for use by women.
BRU15031817P	Cialis 20mg Tablet	Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective, sexual stimulation is required. CIALIS is not indicated for use by women.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15031820NP	SmofKabiven Peripheral Emulsion for Infusion	Parenteral nutrition for adults and children aged 2 years and above when oral enteral nutrition is impossible, insufficient or contraindicated.
BRU15031821P	Ometac Capsule 20mg	Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy. Treatment of reflux oesophagitis, *Zollinger-Ellison syndrome* . Prophylactic treatment in patients with an increased risk of NSAID–associated gastric ulcers, duodenal ulcers, gastro-duodenal erosions or dyspeptic symptoms.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15031825P	Saizen® Liquid 12mg (8mg/ml)	Saizen® (6 mg, 12 mg, and 20 mg) is indicated in the treatment of: • Growth failure in children caused by decreased or absent secretion of endogenous growth hormone. • Growth failure in girls with gonadal dysgenesis (Turner Syndrome), confirmed by chromosomal analysis. • Growth disturbance (current height SDS < -2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS <0 during the last year) by 4 years of age or later. • Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency. Patients must also fulfill the following criteria: Childhood Onset: Patients who were diagnosed as growth hormone deficient during childhood, must be retested and their growth hormone deficiency confirmed before replacement therapy with Saizen is started. Adult Onset: Patients must have growth hormone deficiency as a result of hypothalamic or pituitary disease and at least one other hormone deficiency diagnosed (except for prolactin) and adequate replacement therapy instituted, before replacement therapy using growth hormone may begin. Saizen® (Only for 6 mg and 12 mg) is indicated in the treatment of: • growth failure in prepubertal children due to chronic renal failure (CRF). • growth disturbance due to idiopathic short stature (ISS).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15031826P	Saizen® Liquid 6mg (5.83mg/ml)	Saizen® (6 mg, 12 mg, and 20 mg) is indicated in the treatment of: • Growth failure in children caused by decreased or absent secretion of endogenous growth hormone. • Growth failure in girls with gonadal dysgenesis (Turner Syndrome), confirmed by chromosomal analysis. • Growth disturbance (current height SDS < -2.5 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS <0 during the last year) by 4 years of age or later. • Replacement therapy in adults with pronounced growth hormone deficiency as diagnosed by a single dynamic test for growth hormone deficiency. Patients must also fulfill the following criteria: Childhood Onset: Patients who were diagnosed as growth hormone deficient during childhood, must be retested and their growth hormone deficiency confirmed before replacement therapy with Saizen is started. Adult Onset: Patients must have growth hormone deficiency as a result of hypothalamic or pituitary disease and at least one other hormone deficiency diagnosed (except for prolactin) and adequate replacement therapy instituted, before replacement therapy using growth hormone may begin. Saizen® (Only for 6 mg and 12 mg) is indicated in the treatment of: • growth failure in prepubertal children due to chronic renal failure (CRF). • growth disturbance due to idiopathic short stature (ISS).
BRU15031827P	Torpezil Tablets 10mg	Torpezil is indicated for the treatment of mild, moderate and severe dementia in Alzheimer's disease.
BRU15031828P	Torpezil Tablets 5mg	Torpezil is indicated for the treatment of mild, moderate and severe dementia in Alzheimer's disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15031830NP	Gaviscon Liquid Sachet	Gaviscon Liquid sachets bring relief from the pain and discomfort of heartburn and acid indigestion which, for example can occur after meals or during pregnancy.

BRU15041834P	Rotaqor 20mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (*Fredrickson* Types IIa and IIb), elevated serum triglyceride levels (*Fredrickson* Type IV), and for patients with dysbetalipoproteinemia (*Fredrickson* Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia when response to diet and other non-pharmacological measures are inadequate. *Prevention of Cardiovascular Disease* In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • reduce the risk of non-fatal myocardial infarction, • reduce the risk of fatal and non-fatal stroke, • reduce the risk for revascularization procedures, • reduce the risk of hospitalization for CHF, • reduce the risk of angina.

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dL or b. LDL-C remains ≥ 160 mg/dL and: • there is a positive family history of premature cardiovascular disease or • two or more other CVD risk factors are present in the pediatric patient
BRU15041835P	Jakavi 20mg Tablet	<u>Myelofibrosis (MF)</u> Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. <u>Polycythaemia vera (PV)</u> Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. <u>Graft versus host disease (GvHD)</u> Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15041836P	Jakavi 15mg Tablet	<u>Myelofibrosis (MF)</u> Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. <u>Polycythaemia vera (PV)</u> Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. <u>Graft versus host disease (GvHD)</u> Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).
BRU15041837P	Jakavi 5mg Tablet	<u>Myelofibrosis (MF)</u> Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. <u>Polycythaemia vera (PV)</u> Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. <u>Graft versus host disease (GvHD)</u> Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15041839P	Archifar 500mg Powder For Injection/Infusion	Archifar IV is indicated for the treatment of the following infections in adults and children over 3 months of age: • Pneumonias, including community acquired pneumonia and nosocomial pneumonia • Broncho-pulmonary infections in cystic fibrosis • Complicated urinary tract infections • Complicated intra-abdominal infections • Intra- and post-partum infections • Complicated skin and soft tissue infections • Acute bacterial meningitis Archifar may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15041840P	Ciproflo 2mg/ml Solution For IV Infusion	Ciproflo 2mg/ml solution for infusion is indicated in the treatments of uncomplicated and complicated infections caused by ciprofloxacin sensitive pathogens: - Infections of the respiratory tract In the treatment of outpatients with pneumonia due to Pneumococcus ciprofloxacin should not be used as a first choice of drug. Ciprofloxacin can be regarded as advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E.Coli, Pseudomonas, Haemophilus, Branhamella, Legionella and Staphylococcus. - Infections of the middle ear (otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by gram negative organisms including Pseudomonas or by Staphylococcus. - Infections of the eyes - Infections of the kidneys and/or the efferent urinary tract - Infections of the genital organs, including adnexitis, gonorrhea, prostatitis - Infections of the abdominal cavity (eg. Infections of the gastrointestinal tract or of the biliary tract, peritonitis) - Infections of the skin and soft tissue - Infections of the bones and joints - Sepsis - Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (eg, patients on immunosuppressants or have neutropenia) - Selective intestinal decontamination in immunosuppressed patients
BRU15041841P	Omezole 20mg Capsule	Omezole 20mg capsule is indicated for: • Treatment of reflux oesophagitis • Duodenal ulcer; benign gastric ulcer • Long term treatment of pathologic gastric hypersecretion associated with Zollinger-Ellison syndrome

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15041842P	B-Mycin Cream	Treatment of impetigo, ecthyma and other localized primary bacterial skin infection with a gram-negative component and also for secondary bacterial infections complicating other pre-existing dermatoses.
BRU15041843P	Mucodin Syrup 250mg/5ml	It is indicated as adjuvant therapy for patients with abnormal, viscid or inspissated mucous secretions in such conditions: - chronic/acute broncho-pulmonary disease - pulmonary complications of cystic fibrosis - tracheostomy care - pulmonary complications associated with surgery - post-traumatic chest conditions - atelectasis due to mucous obstruction - diagnostic bronchial studies
BRU15041844P	Pharmaniaga Loratadine Tablet 10mg	Loratadine is indicated for the relief of symptoms associated with allergic rhinitis e.g. Sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. Also indicated for the relief of symptoms and signs of chronic urticaria and other allergic dermatological disorders.
BRU15041846P	Vancotex Injection 500mg	Vancomycin is indicated in the serious or severe infections caused by susceptible strains of beta-lactam resistant staphylococci for penicillin-allergic patients, for infections caused by Vancomycin susceptible organism that are resistant to other antimicrobial drugs.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15041847P	Sunadine Tablet 10mg	Loratadine is indicated for the relief of nasal as well as non-nasal symptoms of seasonal allergic rhinitis, chronic urticaria and other allergic dermatological disorders.
BRU15041848NP	Soluvit N Powder For Solution For Infusion	Soluvit N is indicated in adult patients and children as a supplement in intravenous nutrition to meet the daily requirements of watersoluble vitamins.
BRU15041849NP	SW Folic Acid Tablet 5mg	It is indicated for the treatment of megaloblastic anaemia caused by deficiency of folic acid. It is also indicated in pregnancy to supply a maintenance dosage of folic acid.
BRU15041850P	Estelle-35 Tablet	For the treatment of androgen-dependent diseases in women, such as moderate to severe acne, and mild forms of hirsutism. When used for the treatment of acne, Estelle-35 should only be used after topical therapy or systemic antibiotic treatments have failed. If the hirsutism has only recently appeared or has lately intensified to a considerable extent, the cause (androgen-producing tumour or an adrenal enzyme defect) must be clarified by differential diagnosis. Estelle-35 should not be prescribed for the purpose of contraception alone.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15041852PS1; BRU15041852PS2	Glucophage® XR 1000mg Extended-Release Tablet	• Reduction in the risk or delay of the onset of type 2 diabetes mellitus in adult, overweight patients with IGT* and/or IFG* who are: - at high risk for developing overt type 2 diabetes mellitus (see section 5.1) and - not suitable for intensive lifestyle modifications. Treatment with Glucophage XR must be based on a risk score incorporating appropriate measures of glycaemic control and including evidence of high cardiovascular risk (see section 5.1). *IGT: Impaired Glucose Tolerance; IFG: Impaired Fasting Glucose • Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. Glucophage XR may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.
BRU15041854NP	Voluven Solution For Infusion 6%	Treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient.
BRU15041860NP	Fisherman's Friend Sugar Free Cherry Lozenges With Menthol 6.9mg	Fisherman's Friend Sugar Free Cherry Lozenges refreshes breath, helps soothe the throat and provides symptomatic relief of cough and nasal congestion due to colds.

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BRU15041861NP	ChlorHex 5% Concentrate Solution	ChlorHEX 5% is an antimicrobial agent for general antiseptic purposes. Chlorhexidine gluconate is effective against a wide range of bacteria and inhibits some viruses and is active against some fungi.
BRU15041862P	Salmax CR Tablet 4mg	Salbutamol is indicated for the symptomatic treatment of bronchial asthma. It is also indicated for the treatment of reversible bronchospasm associated with bronchitis, pulmonary emphysema, bronchiestasis and other obstructive pulmonary disease.
BRU15051867NP	Kabiven Peripheral Emulsion For Infusion	KABIVEN is indicated for parenteral nutrition for patients and children above 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.
BRU15051868NP	Kabiven Emulsion For Infusion	KABIVEN is indicated for parenteral nutrition for patients and children above 2 years of age when oral or enteral nutrition is impossible, insufficient or contraindicated.
BRU15051869P	Dopatab M250 Tablet	For treatment of moderate to severe hypertension.
BRU15051870P	Fenagesic Tablet 250mg	Mefenamic acid is indicated for the treatment of primary dysmenorrhoea and the relief of moderate pain when therapy will not exceed one week.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15051871P	Metta SR Tablets 500mg	METFORMIN as monotherapy is indicated as an adjunct to diet and exercise to improve glycaemic control in patients with type II diabetes. METFORMIN may be used concomitantly with a sulfonylurea or insulin to improve glycaemic control.
BRU15051872P	Diamitex Tablet 80mg	Diabetes mellitus of the maturity onset type, which cannot be controlled by diet alone.
BRU15051873NP	Calamine Lotion	For relief of discomfort due to pruritis, insect bites, rashes and sunburn.
BRU15051874NP	Fisherman's Friend Original Lozenges	For the symptomatic relief of coughs due to colds.
BRU15051878P	Loratyn-10	For relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, and ocular itching and burning).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15061880P	Keppra® Oral Solution 100mg/ml	Keppra is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Keppra is indicated as adjunctive therapy: • in the treatment of partial onset seizures with or without secondary generalisation in adults and children from 4 years of age with epilepsy; • in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • in the treatment of primary generalised tonic-clonic seizures in adults and children from 12 years of age with Idiopathic Generalised Epilepsy. Keppra Concentrate is an alternative for patients (adults and children from 4 years of age) when oral administration is temporarily not feasible.

BRU15061881P	Norditropin FlexPro Injection 5mg/1.5ml Pre-Filled Pen, Solution For Injection	<u>Children:</u> Growth failure due to growth hormone deficiency (GHD) Growth failure in girls due to gonadal dysgenesis (Turner syndrome) Growth retardation in prepubertal children due to chronic renal disease. Growth disturbance (current height standard deviation score (SDS) < -2.5 and parental adjusted height SDS < -1) in short children born small for gestational age (SGA), with a birth weight and/or length below -2 standard deviation SD, who failed to show catch-up growth (height velocity standard deviation (HV SDS) < 0 during the last year) by 4 years of age or later. <u>Adults:</u> <u>Childhood onset growth hormone deficiency:</u> Patients with childhood onset GHD should be re-evaluated for growth hormone secretory capacity after growth completion. Testing is not required for those with more than three pituitary hormone deficits, with severe GHD due to a defined genetic cause, due to structural hypothalamic pituitary abnormalities, due to central nervous system tumours or due to high-dose cranial irradiation, or with GHD secondary to a pituitary/hypothalamic disease or insult, if measurements of serum insulin-like growth factor 1 (IGF-1) is <-2 SDS after at least four weeks off growth hormone treatment. In all other patients an IGF-1 measurement and one growth hormone stimulation test is required.

		<u>Adult onset growth hormone deficiency:</u> Pronounced GHD in known hypothalamic-pituitary disease, cranial irradiation and traumatic brain injury. GHD should be associated with one other deficient axis, other than prolactin. GHD should be demonstrated by one provocative test after institution of adequate replacement therapy for any other deficient axis. In adults, the insulin tolerance test is the provocative test of choice. When the insulin tolerance test is contraindicated, alternative provocative tests must be used. The combined arginine-growth hormone releasing hormone is recommended. An arginine or glucagon test may also be considered; however, these tests have less established diagnostic value than the insulin tolerance test.
BRU15061883NP	Povidone Iodine Solution 10% w/v	Use as a disinfectant and antiseptic for the treatment of contaminated wounds and pre-operative preparation of the skin.
BRU15061884P	Pharmaniaga Cephalexin Suspension 250mg	Cephalexin is used to treat septicaemia, bone and joint infections, including burn wound infections, and urinary tract infections caused by susceptible bacterial organisms. They are not effective in treating meningitis. Cephalexin is used as a possible alternative to the penicillins for staphylococcus and nonenterococcal streptococcal infections including pneumonia, bone and joint infections, and bacterial endocarditis.
BRU15061885P	Zorax Suspension 200mg/5ml	It is indicated for the treatment of viral infections due to herpes simplex virus (type 1 & 2) and varicella-zoster virus (zoster and chickenpox).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15061886P	Ganaton 50mg Tablet	Treatment of gastrointestinal symptoms caused by gastric dysmotility and delayed gastric emptying, like sensation of bloating, early satiety, postprandial fullness, upper abdominal pain or discomfort, anorexia, heartburn, nausea and vomiting. ; functional (non-ulcer) dyspepsia or chronic gastritis.
BRU15061887NP	PVP Iodine Solution	Disinfectant and antiseptic for the treatment of contaminated wounds, cuts and burns, and also for pre-operative preparation of the skin and mucous membrane.

BRU15061888PS1; BRU15061888PS2	Herceptin Powder For Injection 440mg/Vial	*Metastatic Breast Cancer (MBC)* Herceptin is indicated for the treatment of patients with metastatic breast cancer who have tumors that overexpress HER2: a) as monotherapy for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease b) in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease c) in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer, not previously treated with Herceptin. This indication is based on data from one Phase III trial which studied the use of Herceptin in combination with anastrozole (see 3.1.2 Clinical/ Efficacy Studies). Experience with other aromatase inhibitors is limited. *Early Breast Cancer (EBC)* Herceptin is indicated for the treatment of patients with HER2 positive early breast cancer. - following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable) (see section 3.1). - following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel. - in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin. - in combination with neoadjuvant chemotherapy followed by adjuvant Herceptin therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter (see sections 2.4 and 3.1). Herceptin should only be used in patients whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay.

		Metastatic Gastric Cancer (MGC) Herceptin in combination with capecitabine or 5-fluorouracil and cisplatin is indicated for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-esophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Herceptin should only be used in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.
BRU15061892P	Perindosyl 4mg Tablets	<u>Hypertension</u> Treatment of hypertension. <u>Heart failure</u> Treatment of symptomatic heart failure. <u>Stable coronary artery disease</u> Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation.
BRU15061893NP	Mentholatum Deep Heating Rub	For the temporary relief of minor aches and pains of muscles, simple backache, strains, and sprains.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15061894NP	Oxy Cover Cream	OXY COVER acne pimples medication contains 10% Benzoyl Peroxide to treat the more stubborn pimples/acnes that do not respond to mild acne treatments: - Kills acne bacteria that causes pimples - Helps dry up excessive oil - Helps unclog pores - Hide pimples. Enhance with skin tone colour; it covers as it treats.
BRU15061896NP	Hocodin Lozenge 250mcg	For the relief of minor infections of the mouth and throat.
BRU15061897NP	Gaviscon Advance Peppermint	Gaviscon Advance Peppermint Flavour provides fast relief from heartburn and acid indigestion. It can also be used to relieve the symptoms of conditions such as hiatus hernia and reflux oesophagitis (inflamed food pipe).
BRU15071899P	Cavumox 625mg Tablet	- Upper Respiratory Tract Infections eg. Otitis media, sinusitis, tonsillitis. - Lower Respiratory Tract Infections eg. Lobar and bronchopneumonia, acute and chronic bronchitis, lung abscess, emphysema. - Skin and Soft Tissue Infections eg. Boils/abscess, cellulitis, wound infections. - Genito-Urinary Tract Infections eg. Cystitis, urethritis, pyelonephritis, septic abortion, puerperal sepsis, pelvic infections, gonorrhea. - Other infections eg. Osteomyelitis, septicaemia, peritonitis, post-operative infections, prophylaxis against infections associated with major surgery.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15071900NP	Gaviscon Liquid	For the symptomatic relief of upset stomach or dyspepsia associated with hyperacidity. Gaviscon alleviates the painful conditions resulting from the reflux of gastric acid and bile into the oesophagus, by suppressing the reflux itself. It is indicated in dyspepsia associated with gastric reflux, reflux oesophagitis, heartburn, hiatus hernia, flatulence associated with gastric reflux, heartburn of pregnancy, regurgitation and in all cases of epigastric and retrosternal distress where the underlying cause is gastric reflux.
BRU15071901P	Zapine 100mg Tablet	Treatment with clozapine is indicated in treatment-resistant schizophrenic patients only, i.e. schizophrenic patients who are non-responsive to or intolerant of classic neuroleptics. Non-responsiveness is defined as lack of satisfactory clinical improvement despite the use of adequate doses of at least two marketed neuroleptics prescribed for adequate durations. Intolerance is defined as the impossibility of achieving adequate clinical benefit with classic neuroleptic drugs because of severe and untreatable neurological adverse reactions (extrapyramidal side effects or tardive dyskinesia).
BRU15071902P	Alendronate Sandoz 70mg Film-Coated Tablet	Treatment of post-menopausal osteoporosis. Alendronate reduces the risk of vertebral and hip fractures.
BRU15071903NP	Chlorhex 4% Antiseptic Solution	ChlorHEX 4% Antiseptic Solution is an antimicrobial solution, containing 4% chlorhexidine gluconate which ahs antibacterial and bacteriostatic properties. It is effective against a wide range of bacteria and inhibits some viruses and is active against some fungi.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15071904P	Resolor Film-Coated Tablet 2mg	RESOLOR® is indicated for symptomatic treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief.
BRU15071905P	Proglutrol 500 Extended Release Tablets	Treatment of type 2 diabetes mellitus in adults, when dietary management and exercise alone does not result in adequate glycaemic control. PROGLUTROL 500 may be used as monotherapy or in combination with other oral antidiabetic agents or with insulin.
BRU15071906NP	Gaviscon Double Action Liquid	Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy, and for symptoms of excess stomach acid (hyperacidity).
BRU15071907NP	Gaviscon Double Action Tablet	Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy, and for symptoms of excess stomach acid (hyperacidity).
BRU15071909NP	Oxy 10 Lotion	Kills acne bacteria, helps dry excessive oil and unclog pores.
BRU15071910NP	Oxy 5 Lotion	Kills acne bacteria, helps dry excessive oil and unclog pores.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15071911P	Hydrogen Peroxide Solution 6%	Topical antiseptic cleansing solution, mouthwash or gargle.
BRU15081913NP	Zentel Suspension 400mg/10ml	Treatment of single or mixed infestations of intestinal parasites.
BRU15081914P	Xalacom Eye Drops	Reduction of intraocular pressure (IOP) in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers.
BRU15081916P	Unihepa 5000IU/ml Injection (5ml Vial)	Heparin is indicated for prophylaxis and treatment of venous thrombosis and pulmonary embolism; in the treatment of myocardial infarction and arterial embolism; for prevention of clotting in arterial and heart surgery and for prevention of cerebral thrombosis. Heparin may also be used as an anticoagulant in blood transfusions, extra-corporal circulation, dialysis procedures, and for laboratory purposes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15081920P	Metrogyl Injection 5mg/ml	Metronidazole IV is an isotonic formulation, composed of a superior grade of injectable metronidazole specially developed by Unique's R & D division in India, for intravenous administration in susceptible life threatening infections. It is particularly suited for patients who cannot retain oral medication and for patients in whom desired serum concentrations have to be attained rapidly and reliably. Metronidazole IV is thus indicated for I. Treatment of infections caused by Bacteroides fragilis and other species of bacteroides like Fusobacteria, Eubacteria and Anaerobic cocci such as (a) Intra abdominal infections-appendicitis, cholecystitis, peritonitis, liver abscess and post-operative wound infection. (b) Gynaecological and obstetrical infections-puerperal sepsis, pelvic pellulitis, pelvic peritonitis. (c) Respiratory infections-necrotising pneumonia, empyema, lung abscess. (d) Central nervous system infections-meningitis, brain abscess. (e) Miscellaneous infections-septicaemia, gas gangrene, osteomyelitis. II. Prevention of post operative infections due to anaerobic bacteria. III. Treatment of amoebic abscess of the liver and in moribund or toxic cases of fulminating intestine.
BRU15081921P	Pharmaniaga Dermapro Ointment 0.05% w/w	Clobetasol is indicated for short-term treatment of inflammation and/or pruritus associated with acute and chronic corticosteroid-responsive skin disorders.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15081923P	Risperdal Tablet 1mg	**RISPERDAL TABLET (1MG, 2MG & 3MG) AND RISPERDAL ORAL SOLUTION 1MG/ML** RISPERDAL® is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERDAL® alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERDAL® is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERDAL is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. **RISPERDAL TABLETS (1MG) AND RISPERDAL ORAL SOLUTION 1MG/ML** RISPERDAL is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15081924P	Risperdal Tablet 2mg	**RISPERDAL TABLET (1MG, 2MG & 3MG) AND RISPERDAL ORAL SOLUTION 1MG/ML** RISPERDAL® is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERDAL® alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERDAL® is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERDAL is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders.
BRU15081925P	Apo-Clopidogrel Tablet 75mg	Clopidogrel is indicated for the prevention of atherothrombotic events in: • Patients suffering from myocardial infacrtion (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease; • Patients suffering from acute coronary syndrome; • Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention; • ST segment elevation acute myocardial infarction, in combination with acetylsalicylic acid (ASA) in medically treated patients eligible for thrombolytic therapy.
BRU15081926NP	Win-Aqueous Cream	Protectant and emollient cream with moisturizing effects on dry skin conditions.
BRU15091928P	Acular Ophthalmic Solution 0.5%	Acular ophthalmic solution is indicated for the short-term relief of ocular itching due to seasonal allergic conjunctivitis and for the prophylaxis and reduction of inflammation and associated symptoms following ocular surgery.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15091929P	Dilantin Capsule 30mg	Clinical evidence indicates phenytoin is effective in controlling epilepsy, particularly of the generalised tonic-clonic type (grand mal) and psychomotor seizures. It will prevent or greatly decrease the incidence and severity of convulsive seizures in a substantial percentage of cases, and patients exhibit little tendency to become resistant to treatment.
BRU15091931P	Klerimed 500mg Film-Coated Tablets	Klerimed is indicated for treatment of infections caused by one or more susceptible organisms. Indications inclue: - Lower respiratory tract infections for example, acute and chronic bronchitis, and pneumonia. - Upper respiratory tract infections for example, sinusitis and pharyngitis. Klerimed is appropriate for initial therapy in community acquired respiratory infections and has been shown to be active in vitro against common and atypical respiratory pathogens as listed in the microbiology section. Klerimed is also indicated in skin and soft tissue infections of mild to moderate severity. Klerimed in the presence of acid suppression effected by omeprazole is also indicated for the eradication of *H. Pylori* in patients with proven duodenal ulcers.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15091932P	Gadovist Injection 1.0mmol/ml Prefilled Syringe 5.0ml	This medicinal product is for diagnostic use only. Gadovist is indicated in adults, and children of all ages (including term neonates) for • Contrast enhancement in cranial and spinal magnetic resonance imaging (MRI). Gadovist is particularly suitable for cases where the exclusion or demonstration of additional pathology may influence the choice of therapy or patient management for detection of very small lesions and for visualization of tumours that do not readily take up contrast media. Gadovist is also suited for perfusion studies for the diagnosis of stroke, detection of focal cerebral ischaemia and tumour perfusion. • Contrast enhanced MRI of liver or kidneys in patients with high suspicion or evidence of having focal lesion to classify these lesions as benign or malignant. • Contrast enhancement in Magnetic Resonance Angiography (CE-MRA). Gadovist can also be used for MR Imaging of pathologies of the whole body. It facilitates visualisation of abnormal structures or lesions and helps in the differentiation between healthy and pathological tissue.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15091933P	Gadovist Injection 1.0mmol/ml	This medicinal product is for diagnostic use only. Gadovist is indicated in adults, and children of all ages (including term neonates) for • Contrast enhancement in cranial and spinal magnetic resonance imaging (MRI). Gadovist is particularly suitable for cases where the exclusion or demonstration of additional pathology may influence the choice of therapy or patient management for detection of very small lesions and for visualization of tumours that do not readily take up contrast media. Gadovist is also suited for perfusion studies for the diagnosis of stroke, detection of focal cerebral ischaemia and tumour perfusion. • Contrast enhanced MRI of liver or kidneys in patients with high suspicion or evidence of having focal lesion to classify these lesions as benign or malignant. • Contrast enhancement in Magnetic Resonance Angiography (CE-MRA). Gadovist can also be used for MR Imaging of pathologies of the whole body. It facilitates visualisation of abnormal structures or lesions and helps in the differentiation between healthy and pathological tissue.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15091935NP	Cardiprin 100 Tablet	As a platelet aggregation inhibitor in patients following aortocoronary by-pass surgery, to prevent graft occlusion. Conditions where modification of platelet behavior is considered beneficial, including ischaemic attacks, secondary prevention of myocardial infarction and for prophylaxis against stroke, occlusion and deep vein thrombosis. On PIL: Cardiprin 100 reduces the stickiness of platelets (the clot-forming part of blood), making them less likely to form a clot and helping to prevent blocking of blood vessels. Each tablet contains 100mg of aspirin, a low dose shown by medical studies to effectively lower the risk of stroke and heart attacks. Cardiprin 100 has also been specially formulated to dissolve on the tongue for rapid absorption. Some scientists believe that aspirin which is rapidly absorbed may be more effective in the prevention of strokes and heart attacks.
BRU15091936P	Calact 300mg Tablets	Used as dietary and health supplement.
BRU15091939NP	Hoe Zinc Cream	As a mild astringent for the skin, a soothing and protective application in eczema and a protective to slight excoriation.
BRU15091940P	Pirimat Injection 10mg/ml (1ml Ampoule)	For all conditions requiring antihistamines therapy such as hay fever, vasomotor rhinitis, urticarial, angioneurotic oedema, food allergies, drug and serum reactions, atopic and contact dermatitis, allergic eczema, pruritus ani et vulvae, insect bites, and some cases of asthma.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15091946P	Axcel Bromhexine (Children) Syrup	Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport.
BRU15101947P	Cetyrol 10mg Film-Coated Tablet	Adults and children of 6 years and above: symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticaria of allergic origin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15101948P	Archifar 1g Powder For Solution For Injection/Infusion	Archifar is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem: • Pneumonias and Nosocomial Pneumonias • Urinary Tract Infections • Intra-abdominal Infections • Gynaecological Infections, such as endometritis and pelvic inflammatory disease • Skin and Skin Structure Infections • Meningitis • Septicaemia • Empiric treatment, for presumed infections in adult patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents. Meropenem has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections. There is no experience in paediatric patients with neutropenia or primary or secondary immunodeficiency.
BRU15101949P	Antismine Syrup 2mg/5ml	To be used therapeutically for palliative treatment in allergic reactions including hay fever, vasomotor rhinitis, urticaria, itching skin conditions including hay fever, vasomotor rhinitis, itching skin conditions including pruritus of drug rashes, contact dermatitis and insect bites.
BRU15101952NP	Flexijoint Glucosamine 1500mg Powder	**Flexijoint Glucosamine 1500mg Powder** is indicated as adjunctive therapy for osteoarthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15101953NP	Colin Cough Syrup	For the relief of cough. Reduce the viscosity of sputum and expectorate thick phlegm.
BRU15101954P	Tystatin Oral Suspension	Tystatin Oral Suspension is indicated for the treatment of candidal infection of the oral cavity.
BRU15101955P	Ezede Tablet 10mg	Ezede tablet is indicated for the relief of symptoms associated with allergic rhinitis, including sneezing, nasal discharge and itching, as well as ocular itching. It is also indicated for the relief of symptoms associated with chronic urticaria and other allergic dermatologic disorders.
BRU15101956P	Pred Forte Sterile Ophthalmic Suspension 1%	Steroid-responsive inflammation of the palpebral & bulbar conjunctiva, cornea & anterior segment of the globe.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15111957P	Stivarga Tablet 40mg	**Colorectal Cancer** Stivarga is indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild type, an anti-EGFR therapy. **Gastrointestinal Stromal Tumors** Stivarga is indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate. **Hepatocellular Carcinoma** Stivarga is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.
BRU15111958P	A Scabs Lotion	For the treatment of scabies.
BRU15111959P; BRU15111959PS2	Insugen-N (NPH)	Treatment of diabetes mellitus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15111961NP	Infusol® NS (Ampoule)	• Plasma isotonic fluid replacement. • Sodium and chloride depletion. • Hypochloremic alkalosis. • Vehicle solution for supplementary medication.
BRU15111962NP	INFUSOL® W (Sterilised Water For Injection BP)	Sterilised water for injection is generally used as diluents for other drugs.
BRU15111964P	Valparin XR 500mg Tablet	In the treatment of generalized or partial epilepsy, particularly with the following patterns or seizures: • Absence, Myoclonic, Tonic-clonic, Atonic, Mixed As well as for partial epilepsy: • Simple or complex seizures • Secondary generalized seizures • Specific syndromes (West, Lennox-Gastaut)
BRU15111965P	Axcel Betamethasone Cream	For the treatment of eczema, including atopic, infantile, discoid and stasis eczema; prurigo; psoriasis; neurodermatoses, including lichen simplex; lichen planus; seborrhoiec dermatitis; intertrigo; contact sensitivity reactions; discoid lupus erythematosus; generalized erythroderma; insect bites; otitis externa.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15111966P	Freederm Gel	Once daily antifungal treatment for tinea and other fungal skin infections – athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis), Pityriasis versicolor and fungal nail infection (cutaneous candidiasis).
BRU15111967P	Cough-En Linctus	**Cough-en Linctus** is indicated for the relief of dry irritating coughs such as those associated with common cold, upper respiratory tract infections, allergic (seasonal) rhinitis, vasomotor (perennial) rhinitis and hayfever. **Cough-en Linctus** helps dry up running nose and opens congested bronchi to aid clear breathing.
BRU15121972PS1; BRU15121972PS2	Varivax (Refrigerated)	Refrigerator-stable VARIVAX is indicated for vaccination against varicella in individuals 12 months of age and older.
BRU15121974P	Paracetamol Codeine Tablet	It is indicated for the symptomatic relief of pain, aches and pyresis.
BRU15121976NP	Mentholatum Deep Cold Ice Gel Therapy	Mentholatum Deep Cold ice gel provides icy pain relief right where it hurts. It helps to reduce pain and relieve muscle aches & pains.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU15121977NP	Axcel Urea Cream	It is used in ichthyosis and hyperkeratotic skin disorders i.e. dry, scaling and itchy skin conditions, such as: - Contact irritant dermatitis (housewife dermatitis) which is caused by detergent, shampoo, highly alkaline soap or chemicals, - Acute and chronic allergic eczemas, - Infantile eczema, - 'winter itch' and 'winter chapping'
BRU15121979P	Medocef 1g Powder For Solution For Injection Or Infusion	Indicated for the treatment of the following infections caused by susceptible bacteria: Respiratory tract infections, skin and soft tissue and wound infections, biliary tract infections, urinary tract infections, Gonorrhoea, gynaecological infections, intra-abdominal infections, peritonitis, prophylaxis of abdominal/biliary tract surgery and septicaemia.
BRU15121980NP	Axcel Dexxon Lozenges	Minor infection of the mouth and throat. Anginous infection: Angina catarrhalis, as adjuvant in angina lacunaris and Plaut-Vincent's angina. Catarrhal infections: Pharyngitis, laryngitis. Inflammation of the mucous membrane and gums: Gingivitis, ulceration stomatitis, aphthous stomatitis.
BRU15121981NP	Oragel Pain Relief	For the relief of pain and inflammation caused by ulceration, abrasion and oral infections. It is used for the healing of mouth ulcers, infant teething, denture irritation, sore gums, cold sores and discomfort due to braces in children.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16011982NP; BRU16011982NPS2; BRU16011982NPS3	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. It is also indicated for use as a priming solution in hemodialysis procedures.
BRU16011983P	Amlibon 5mg Tablet	<u>Hypertension</u> Amlodipine is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha-blocker, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme inhibitor. <u>Chronic Stable Angina</u> Amlodipine is indicated for the first line treatment of myocardial ischaemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or beta-blockers.
BRU16011987P	Zenalb® 20, Human Albumin Solution 20%	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16011990P	Gastrografin Solution	This medicinal product is for use by oral or rectal administration only. • Gastrografin is a contrast medium for the radiological examination of the gastrointestinal tract (also in combination with barium sulfate). • Treatment of uncomplicated meconium ileus. • Computerized tomography in the abdominal region.
BRU16011991P	Rabotide 20 Capsule	**Healing of Erosive or Ulcerative Gastroes-ophageal Reflux Disease (GERD):** Rabeprazole is indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative gastroesophageal reflux disease (GERD). **Maintenance of Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD):** Rabeprazole is indicated for maintaining healing and reduction in relapse rates of heartburn symptoms in patients with erosive or ulcerative gastroesophageal reflux disease (GERD Maintenance). **Healing of Duodenal Ulcers:** Rabeprazole is indicated for short-term (up to four weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Most patients heal within four weeks. **Treatment of Pathological hypersecretory Conditions, including Zollinger-Ellison Syndrome:** Rabeprazole is indicated for the long-term treatment of pathological hypersecretory conditions including Zollinger-Ellison Syndrome.
BRU16011992P	Pharmaniaga Gliclazide Tablet 80mg	Non-insulin-dependent diabetes mellitus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16011997P	Soluwax Ear Drops	Docusate sodium is indicated for softening wax in the ear.
BRU16021998P; BRU16021998PS2	Insugen-R (Regular)	Treatment of diabetes mellitus.
BRU16022000P	Glimicron 80mg Tablet	Gliclazide is indicated in non-insulin dependent diabetes mellitus.
BRU16022001NP	Hovid-Liquid Paraffin	hovid-Liquid Paraffin is indicated for the symptomatic relief of constipation. Long-term use of this medication is not recommended.
BRU16022002NP	Noxworm Suspension (Chocolate) 400mg	Noxworm is indicated for the treatment of single or mixed intestinal helmintic infestations, including pinworm, whipworm, roundworm, hookworm, tapeworm, trichinosis and threadworm (strongyloides).
BRU16022003PS2	Mircera Pre-Filled Syringe 100mcg/0.3ml	Treatment of anaemia associated with chronic kidney disease (CKD). The safety and efficacy of MIRCERA therapy in other indications has not been established, therefore such use is not recommended.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16022007P	Adezio Oral Suspension 1mg/ml	Adezio is indicated for the relief of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis in adult and children over 2 years of age such as sneezing, rhinorrhea, postnasal discharge, nasal pruritus, ocular pruritus, tearing and redness of the eyes. Adezio is also indicated for the treatment of the uncomplicated skin manifestations of chronic urticarial in adults and children over 2 years of age. It significantly reduces the occurrence, severity and duration of hives and significantly reduces pruritus.
BRU16022008P	Zarin Cream 2% w/w	Zarin is indicated for the topical treatment of skin infections due to susceptible fungi (dermatophytes and yeasts) such as tinea pedis (athletes foot), tinea cruris, tinea corporis (ringworm), tinea versicolor (white spots) and candidiasis.
BRU16022010P	Bena® Expectorant	Bena is indicated for the relief of chest congestion and coughs with thick phlegm. It clears nasal passages, liquefies and loosens stubborn phlegm and soothes tiresome coughing.
BRU16032014P	Tinazol Cream 2% (15g)	For the topical treatment of tinea pedis, tinea cruris and tinea corporis, and in the topical treatment of cutaneous candidiasis, tinea and pityriasis versicolor.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16032015PS1; BRU16032015PS2	M-M-R II® Vaccine	M-M-R II is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older. There is some evidence to suggest that infants who are born to mothers who had wild-type measles and who are vaccinated at less than one year of age may not develop sustained antibody levels when later revaccinated. The advantage of early protection must be weighed against the chance for failure to respond adequately on reimmunization. Infants who are less than 12 months of age may fail to respond to the measles component of the vaccine due to presence in the circulation of residual measles antibody of maternal origin; the younger the infant, the lower the likelihood of seroconversion. In geographically isolated or other relatively inaccessible populations for whom immunization programs are logistically difficult, and in population groups in which wild-type measles infection may occur in a significant proportion of infants before 15 months of age, it may be desirable to give the vaccine to infants at an earlier age. Infants vaccinated under these conditions at less than 12 months of age should be revaccinated after reaching 12 to 15 months of age.
BRU16032016P; BRU16032016PS2	Insugen-30/70 (Biphasic)	Treatment of diabetes mellitus.
BRU16032017P	Natrixam 1.5mg/10mg Modified-Release Tablet	Natrixam is indicated as substitution therapy for treatment of essential hypertension in patients already controlled with indapamide and amlodipine given concurrently at the same dose level.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16032018P	Natrixam 1.5mg/5mg Modified-Release Tablet	Natrixam is indicated as substitution therapy for treatment of essential hypertension in patients already controlled with indapamide and amlodipine given concurrently at the same dose level.
BRU16032020NP	Mifuko Ointment	For ringworm, athlete's foot, eczema, psoriasis, seborrheic dermatitis, scabies, warts and corns.
BRU16032023NP	Bacidin Antiseptic Cream 1% w/w	Bacidin™ Antiseptic Cream is used as a disinfectant for wounds, burns, abrasions and minor skin infections.
BRU16032024P	Axcel Oxymetazoline 0.05% Nasal Spray	Symptomatic relief of nasal & nasopharyngeal congestion.
BRU16042027NP	Potassium Chloride Injection Demo 10% w/v	Prevention and treatment of moderate or severe potassium deficit when oral replacement therapy is not feasible.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16042028P	Oratane 20mg Capsules	ORATANE is indicated for the treatment of severe forms of nodulo-cystic acne which are resistant to therapy, particularly cystic acne and acne conglobate, especially when the lesions involve the trunk. ORATANE should only be prescribed by physicians who are experienced in the use of systemic retinoids, preferably dermatologists, and understand the risk of teratogenicity if ORATANE is used during pregnancy.
BRU16042029P	Oratane 10mg Capsules	ORATANE is indicated for the treatment of severe forms of nodulo-cystic acne which are resistant to therapy, particularly cystic acne and acne conglobate, especially when the lesions involve the trunk. ORATANE should only be prescribed by physicians who are experienced in the use of systemic retinoids, preferably dermatologists, and understand the risk of teratogenicity if ORATANE is used during pregnancy.
BRU16042030NP	Osteoactiv 3 In 1 Joint Formula Powder	As adjuvant therapy for osteoarthritis.
BRU16042031NP	Osteoactiv 3 In 1 Joint Formula Tablet	As adjuvant therapy for osteoarthritis.
BRU16042032P	Sedilix®-DM Linctus	**Sedilix-DM** is indicated for the relief of dry irritating coughs such as those associated with common cold or upper respiratory tract infections. **Sedilix-DM** helps to relieve nasal congestion, sneezing and rhinorrhoea associated with allergy and the common cold.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16042034P	Taver Tablet 200mg	• Epilepsy – generalised tonic-clonic and partial seizures. Note: Carbamazepine is not usually effective in absences (petit mal) and myoclonic seizures. Moreover, anecdotal evidence suggests that seizure exacerbation may occur in patients with atypical absences. • The paroxysmal pain of trigeminal neuralgia. • For the prophylaxis of manic-depressive psychosis in patients unresponsive to lithium therapy.
BRU16042035NP	Axcel B Complex Tablet	For prevention and treatment of Vitamin B complex deficiency.
BRU16042036P	Pharmaniaga Allopurinol Tablet 300mg	Allopurinol is used to treat primary or secondary hyperuricaemia associated with chronic gout, uric acid nephropathy, recurrent uric acid stone formation, certain enzyme disorders and neoplastic disease with high cell turnover rates in which high urate levels occur either spontaneously or after cytotoxic therapy.
BRU16042037NP	Povidin Solution 10%	Povidin Solution is indicated for the treatment of contaminated wounds, cuts, abrasions and minor skin infections.
BRU16052039NP	Noxworm Chewtab	For the treatment of single or mixed intestinal helmintic infestations, including roundworms, threadworms, hookworms, whipworms and tapeworms.
BRU16052042P	Axcel Oxymetazoline 0.025% Nasal Drop	Relief of nasal congestion in acute colds, paranasal sinusitis and otitis media.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16052044P; BRU16052044PS2	Zometa Solution For Infusion 4mg/100ml	• Treatment of osteolytic, osteoblastic, and mixed bone metastases of solid tumours and osteolytic lesions of multiple myeloma, in conjunction with standard antineoplastic therapy. • Treatment of hypercalcemia of malignancy (HCM).
BRU16052045P	Novomin Tablet 50mg	Novomin has anti-emetic properties and is used for the prevention and treatment of nausea and vomiting, such as in travel or motion sickness.
BRU16062049PS2	Seebri Breezhaler 50mcg Inhalation Powder Hard Capsules	Seebri Breezhaler is indicated as a once-daily maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
BRU16062052P	Tidact Injection 150mg/ml	For the treatment of serious infections due to susceptible strains of Staphylococci, Streptococci, Pneumococci, and anaerobic bacteria.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16072058P	Noxafil 100mg Tablet	NOXAFIL Delayed Release Tablets and Oral Suspension are indicated for prophylaxis of invasive *Aspergillus* and *Candida* infections, including both yeasts and molds, in patients, 13 years of age and older, who are at high risk of developing these infections, such as patients with prolonged neutropenia or hematopoietic stem cell transplant (HSCT) recipients. NOXAFIL Delayed Release Tablets and Oral Suspension are indicated for use in the treatment of the following fungal infections in patients 13 years of age or older: • Refractory Invasive Fungal infections/Intolerant Patients with IFI: Fusariosis, zygomycosis, cryptococcosis, coccidioidomycosis, chromoblastomycosis, and mycetoma in patients with disease refractory to other therapy, or patients who are intolerant of other therapy. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy. NOXAFIL Oral Suspension is also indicated for use in the treatment of the following fungal infections in patients 13 years of age or older: • Oropharyngeal candidiasis in patients who have severe disease or who are immunocompromised, including in patients with disease that is refractory to itraconazole and fluconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16072059P	Onegaba 300mg Capsules	**Epilepsy** Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children age 3 years and above. Safety and effectiveness for adjunctive therapy in pediatric patients below the age of 3 years have not been established. **Neuropathic pain** Gabapentin is indicated for the treatment of neuropathic pain which includes diabetic neuropathy, post-herpetic neuralgia and trigeminal neuralgia in adults age 18 years and above. Safety and effectiveness in patients below the age of 18 years have not been established.
BRU16072060P	Pethidine-Hameln Solution For Injection 50mg/ml	Severe pain.
BRU16072062P	Prednisolone Syrup 5mg/5ml	Prednisolone is a synthetic corticosteroid with predominantly glucocorticoid activity. It allows for a greater margin of safety than more potent agents. It is indicated for treatment of various disorders in which corticosteroids are indicated, such as asthmatic cough. However, it is not indicated for adrenal deficiency state.
BRU16082063P	Zenalb® 4.5, Human Albumin Solution 4.5%	Zenalb 4.5 is indicated in all patients for the restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16082064P	Axcel Lamivudine 100mg Tablet	To be used only for the treatment of Human Immunodeficiency Virus (HIV) infection.
BRU16082065P	Calpo Suspension	For the treatment of single or mixed worm infestations, including threadworm, roundworm, whipworm and hookworm.
BRU16082067P	Anoro Ellipta 62.5/25 Micrograms Inhalation Powder, Pre-Dispensed	ANORO is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
BRU16092069P; BRU16092069PS2	Sifrol Extended Release 0.375mg Tablet	Sifrol® extended-release tablet is indicated in the treatment of signs and symptoms of advanced idiopathic Parkinson's disease. It may be used as monotherapy or in combination with levodopa.
BRU16092070P; BRU16092070PS2	Sifrol Extended Release 1.5mg Tablet	Sifrol® extended-release tablet is indicated in the treatment of signs and symptoms of advanced idiopathic Parkinson's disease. It may be used as monotherapy or in combination with levodopa.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16092071NP	Mentholatum Deep Heating Rub Extra Strength Cream	For the temporary relief of minor aches and pains of muscles, simple backache, strains, and sprains.
BRU16092075P	Amphotret For Injection U.S.P. 50mg	**AMPHOTRET** Intravenous should be administered primarily to patients with progressive, potentially life-threatening fungal infections. This potent drug should not be used to treat noninvasive fungal infections, such as oral thrush, vaginal candidiasis and esophageal candidiasis in patients with normal neutrophil counts. **AMPHOTRET** Intravenous is specifically intended to treat potentially life-threatening fungal infections: aspergillosis, cryptococcosis (torulosis), North American blastomycosis, systemic candidiasis, coccidioidomycosis, histoplasmosis, zygomycosis including mucormycosis due to susceptible species of the genera Absidia, Mucor and Rhizopus, and infections due to related susceptible species of Conidiobolus and Basidiobolus, and sporotrichosis.
BRU16092076NP	Alumag Plus Tablet	As antacid in dyspepsia, peptic ulcer, gastritis; use in the relief of abdominal distension and treatment of flatulence, and oesophageal reflux with heartburn.
BRU16102079P	Baxter Chlorhexidine Acetate 0.1% w/v Antiseptic Solution	Chlorhexidine Acetate (0.1% antiseptic solution is used as a general antiseptic. It is used for the cleaning and disinfecting of wounds and the antiseptic treatment of burns.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16102080P	Magurol Tablet 2mg	Magurol is indicated for the treatment of hypertension where it can be administered alone or in combination with other antihypertensive agents such as diuretics, beta-blockers, calcium antagonist or ACE inhibitors. Magurol is indicated for the treatment of urinary outflow obstruction and symptoms associated with benign prostatic hyperplasia.
BRU16102081P	Magurol 4mg Tablet	Magurol is indicated for the treatment of hypertension where it can be administered alone or in combination with other antihypertensive agents such as diuretics, beta-blockers, calcium antagonist or ACE inhibitors. Magurol is indicated for the treatment of urinary outflow obstruction and symptoms associated with benign prostatic hyperplasia.
BRU16102084P	Bilaxten 20mg Tablet	Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. BILAXTEN 20mg Tablet is indicated in adults and adolescents (12 years of age and over).
BRU16102085P	Loxin Injection (5ml Amp)	Dopamine hydrochloride is indicated for the correction of haemodynamic imbalances present in the shock syndrome due to myocardial infarctions, trauma, endotoxic septicaemia, open heart surgery, renal failure and chronic cardiac decompensation as in congestive failure.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16102087P	Vaxcel Fluconazole 2mg/ml IV Infusion	Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. 1. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g. pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. 2. Systemic candidiasis including candidemia, disseminated candidiasis & other forms of invasive candidal infection. These include infections of the peritoneum, endocardium, eye and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 3. Mucosal candidiasis. These include oropharyngeal, non-invasive bronchopulmonary infections, candidura, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of orpharyngela candidiasis in patients with AIDS. 4. Genital candidiasis. Vaginal candidiasis, acute or recurrent; and prophylaxis to reduce the incidence or recurrent vaginal candidiasisi (3 or more episodes a year). Candida balanitis. 5. Prevention of fungal infections in patients malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy. 6. Dermatomycosis including tinea pedis, tinea corporis, tinea cruris, tinea versicolor and dermal candida infections.
BRU16102088P	Sellon Shampoo 2.5%	In the management of simple dandruff and seborrheic dermatitis of the scalp.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16102090NP	Three Legs Cough Relief	As an expectorant for the symptomatic relief of cough due to colds.
BRU16112092P	Risperidone Orally Disintegrating Tablet 3mg	Risperidone orally disintegrating tablet is indicated for the treatment of schizophrenia. Risperidone orally disintegrating tablet is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. Risperidone orally disintegrating tablet is indicated for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. Risperidone orally disintegrating tablet is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16112093P	Risperidone Orally Disintegrating Tablet 2mg	Risperidone orally disintegrating tablet is indicated for the treatment of schizophrenia. Risperidone orally disintegrating tablet is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. Risperidone orally disintegrating tablet is indicated for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. Risperidone orally disintegrating tablet is indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.
BRU16112098NP	Calamine Lotion With Menthol	Antipruritic with cooling effect.
BRU16112099P	Toujeo 300 Units/ml Solution For Injection In Pre-Filled Pen	Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16112102NP	Three Legs White Balsem	For symptomatic relief of muscle pain, rheumatic pain and sprain.
BRU16112103NP	Three Legs Tinea Skin Solution	For ringworm, athletes foot and tinea versicolor.
BRU16112104NP	Three Legs Yellow Lotion	As an antiseptic for treatment of skin lesions, cuts, abrasions, infected wounds and burns.
BRU16112105P	Furosemide-Hameln 10mg/ml Injection	Furosemide is a potent diuretic with a rapid action. It is used in the treatment of: - Oedema associated with heart failure including pulmonary oedema, renal and hepatic disorder, nephritic syndrome and may be effective in patients unresponsive to thiazide diuretics. Furosemide is particularly useful when an agent with greater diuretic potential than that of the more commonly used agent is desired. - Hypertensive crises. - Acute or chronic renal failure.
BRU16112106NP	Three Legs Tolnaftate Cream	For the treatment of fungal infections including Ringworm, Athlete's Foot, Tinea Capitis, Tinea Corporis, Tinea Barbae, Tinea Versicolor and Tinea Cruris.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16112107NP	Three Legs Medicinal Powder Aspirin 600mg/Sachet	For relief of headache, fever, toothache and minor pain.
BRU16112109NP	5% Dextrose In 0.9% Sodium Chloride Solution For Intravenous Infusion	1. For replacement or maintenance of fluid and electrolytes. 2. As a vehicle for compatible drugs used in therapy or in diagnostic procedures.
BRU16112110P	Zylovaa Tablet 100mg	• Hypertension Zylovaa is indicated for treatment of hypertension. • Hypertensive patients with left ventricular hypertrophy Zylovaa is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. • Nephropathy in Type 2 Diabetic Patients Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio 300 mg/g or more) in patients with type 2 diabetes and a history of hypertension. In this population, Zylovaa reduces the rate of progression of nephropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation) or death.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16122112P	Ziagen Tablet	*ZIAGEN* is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and children.
BRU16122113P	Apo-Alendronate 70mg Tablet	Apo-Alendronate is indicated for the treatment of osteoporosis in postmenopausal women.
BRU16122114P	Tensiber Film Coated Tablet 300mg	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen.
BRU16122116P	Apo-Quetiapine 25mg Tablet	• Treatment of depressive episodes associated with bipolar disorder. • Treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct to lithium or divalproex. • Treatment of schizophrenia.
BRU16122117P	Apo-Quetiapine 100mg Tablet	• Treatment of depressive episodes associated with bipolar disorder. • Treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct to lithium or divalproex. • Treatment of schizophrenia.
BRU16122118P	Apo-Quetiapine 200mg Tablet	• Treatment of depressive episodes associated with bipolar disorder. • Treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct to lithium or divalproex. • Treatment of schizophrenia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU16122119NP	Actimax 500 Tablet	For the relief of fever and mild to moderate pain including headache, migraine, symptoms of colds and flu, dental pain, period pain, back pain, muscular pain and osteoarthritis.
BRU16122121NP	Flanil Analgesic Cream	For temporary relief of minor ache and pains of muscle s and joints associated with arthritis, strains, sprains and rheumatism.
BRU16122124P	Ferriprox 500mg Tablet	Ferriprox is indicated for the treatment of iron overload in patients with thalassemia major when deferoxamine therapy is contra-indicated or inadequate.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17012130PS2; BRU17012130PS3	Tarceva Tablet 100mg	**Non-small cell lung cancer**: Tarceva is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer with EGFR activating mutations. Tarceva is also indicated for switch maintenance treatment in patients with locally advanced or metastatic NSCLC with EGFR activating mutations and stable disease after first-line chemotherapy. Tarceva is also indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with Epidermal Growth Factor Receptor (EGFR)- negative tumours. **Pancreatic cancer**: Tarceva in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17012131PS2; BRU17012131PS3	Tarceva Tablet 150mg	**Non-small cell lung cancer**: Tarceva is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer with EGFR activating mutations. Tarceva is also indicated for switch maintenance treatment in patients with locally advanced or metastatic NSCLC with EGFR activating mutations and stable disease after first-line chemotherapy. Tarceva is also indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with Epidermal Growth Factor Receptor (EGFR)- negative tumours. **Pancreatic cancer**: Tarceva in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.
BRU17012137P	Tussidex Forte Linctus	Tussidex Forte Linctus is indicated for the relief of resistant, dry and unproductive cough for adults and children. It is non-sedative and free of alcohol. As it does not contain sugar, it may be suitable for diabetic use.
BRU17012138P	Floctil 250mg Capsule	Azithromycin is indicated for the treatment of bronchitis, community-acquired pneumonia, sinusitis, pharyngitis/tonsillitis, otitis media, skin and soft tissue infections, and uncomplicated genital infections due to Chlamydia trachomatis. Considerations should be given to official guidance regarding the appropriate use of antibacterial agents.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17012141P	Dyna Metformin Tablet 500mg	Control of hyperglycaemic of maturity onset diabetes mellitus. It is used in non Insulin-dependant diabetes mellitus when diet control fails. It is sometimes given to patients no longer responding to the sulphonylureas.
BRU17022146P	Azarga 10mg/ml + 5mg/ml Eye Drops, Suspension	Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.
BRU17022147P	Pharmaniaga Dermasole Cream 0.1% w/w	Betamethasone is a potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following: - Atopic dermatitis (including infantile atopic dermatitis) - Nummular dermatitis (discoid eczema) - Prurigo nodularis - Psoriasis (excluding widespread plaque psoriasis) - Lichen simplex chronicus (neurodermatitis) and lichen planus - Seborrhoeic dermatitis - Irritant or allergic contact dermatitis - Discoid lupus erythematosus - Adjunct to systemic steroid therapy in generalized erythroderma - Insect bite reactions - Miliara (prickly heat)

BRU17022148P; BRU17022148PS2	Jardiance 10mg Film-Coated Tablet	**Type 2 diabetes mellitus** ***Glycaemic control*** Jardiance is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as: Monotherapy When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. Add-on combination therapy In combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. ***Prevention of cardiovascular death*** Jardiance is indicated in patients with type 2 diabetes mellitus and established cardiovascular disease to reduce the risk of cardiovascular death. To prevent cardiovascular deaths, Jardiance should be used in conjunction with other measures to reduce cardiovascular risk in line with the current standard of care. **Heart failure** Jardiance is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV). **Chronic kidney disease** Jardiance is indicated in adults for the treatment of chronic kidney disease.

BRU17022149P; BRU17022149PS2	Jardiance 25mg Film-Coated Tablet	**Type 2 diabetes mellitus** ***Glycaemic control*** Jardiance is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults as: Monotherapy When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. Add-on combination therapy In combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. ***Prevention of cardiovascular death*** Jardiance is indicated in patients with type 2 diabetes mellitus and established cardiovascular disease to reduce the risk of cardiovascular death. To prevent cardiovascular deaths, Jardiance should be used in conjunction with other measures to reduce cardiovascular risk in line with the current standard of care. **Heart failure** Jardiance is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV). **Chronic kidney disease** Jardiance is indicated in adults for the treatment of chronic kidney disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17022154P	Targin Prolonged Release Tablets 10mg/5mg	The management of moderate to severe chronic pain unresponsive to non-narcotic analgesics. The opioid antagonist naloxone in the fixed combination is added to counteract and/or prevent opioid-induced constipation. Second line symptomatic treatment of patients with severe to very severe idiopathic Restless Legs Syndrome (RLS) after failure of dopaminergic therapy.
BRU17022157P	Pristine Shampoo 2% w/w	Pristine shampoo is used for the treatment and prophylaxis of infections such as pityriasis capitis (dandruff), seborrheic dermatitis and pityriasis versicolor (white spots).
BRU17022159P	Salmol Expectorant	It is used for prophylactic treatment and relief of asthma, chronic bronchitis, emphysema, and other bronchopulmonary disorders involving bronchospasm in adults and children 2 years of age and older. It may be useful for the symptomatic relief of respiratory conditions characterized and in the presence of mucus in the respiratory tract because of guaiphenesin.
BRU17022164P	Cef-4® 1G Injection	CEF-4® is used in the treatment of susceptible infections including:- -Lower Respiratory Tract Infections -Urinary Tract Infections -Skin and Soft Tissue Structure Infections -Bacterial Septicemia -Bone and Joint infections -Gynecological infections, including endometritis, pelvic cellulitis and other infections of the female genital tract -Intraabdominal infections -CNS infections -Severe and life-threatening infections

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17032165P	Asthator 4mg Chewable Tablet	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 2 years of age and older. ASTHATOR is indicated in adults and pediatric patients 2 years of age and older for the relief day time and night time symptoms of allergic rhinitis.
BRU17032166P	Asthator 5mg Chewable Tablet	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 2 years of age and older. ASTHATOR is indicated in adults and pediatric patients 2 years of age and older for the relief day time and night time symptoms of allergic rhinitis.
BRU17032167P	Asthator 10mg Tablet	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 2 years of age and older. ASTHATOR is indicated in adults and pediatric patients 2 years of age and older for the relief day time and night time symptoms of allergic rhinitis.
BRU17032168NP	Oliclinomel N7-1000E Emulsion For Infusion	Parenteral nutrition for adults and children greater than two years of age, when oral or enteral nutrition is impossible, insufficient or contraindicated.
BRU17032169P	Pharmaniaga Ziconal Cream 2% w/w	Ketoconazole cream is indicated for the topical treatment of tinea corporis, tinea cruris and tinea pedis caused by Trichophyton rubrum, T. mentagrophytes and Epidermophyton floccosum; in the treatment of tinea versicolor caused by Malassezia furfur; in the treatment of cutaneous candidiasis caused by Candida spp. and the treatment of seborrheic dermatitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17032170P	Zolennic Concentrate For Solution For IV Infusion	1) An adjunct to antineoplastic therapy for the treatment of bone metastases of solid tumors and osteolytic lesions of multiple myeloma. 2) Paget's disease of bone. 3) Hypercalcemia of malignancy (HCM).
BRU17032171P	Dynadryl Syrup	Irritating coughs, nasal stuffiness and bronchial congestion associated with common cold and allergy.
BRU17032172P	Depo Geston Injection 50mg/ml	For contraception (ovulation suppression).
BRU17032173P	Axcel Valacyclovir-500 Tablet	Axcel Valacyclovir-500 is indicated for the treatment of herpes zoster (shingles). Axcel Valacyclovir-500 accelerates the resolution of pain; it reduces the duration, and the proportion of patients with zoster-associated pain, which includes acute and post-herpetic neuralgia. Axcel Valacyclovir-500 is indicated for the treatment of herpes simplex infections of the skin and mucous membranes, including initial and recurrent genital herpes. Axcel Valacyclovir-500 can prevent lesion development when taken at the first signs and symptoms of an HSV recurrence. Axcel Valacyclovir-500 is indicated for the prevention (suppression) of recurrent herpes simplex infections of the skin and mucous membranes, including genital herpes. Axcel Valacyclovir-500 can reduce transmission of genital herpes when taken as suppressive therapy and combined with safer sex practices (particularly the use of condoms).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17032174P	Pharmaniaga Lidocaine Hydrochloride 2% w/v Injection	Lidocaine can be used for most major nerve blocks, e.g. sciatic and retrobulbar. Lidocaine can be used for local or regional anaesthesia and nerve block.
BRU17032175NP	Axcel Paracetamol-250 Suspension (Strawberry)	For the relief of fever, symptoms of cold and influenza, teething pain and headache.
BRU17042176NP	Oliclinomel N4-550E Emulsion For Infusion	Parenteral nutrition for adults and children greater than two years of age, when oral or enteral nutrition is impossible, insufficient or contraindicated.
BRU17042177NP	Huachi Enema	The product is indicated for the relief of constipation.
BRU17042179P	Glumet XR Tablet 500mg	Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate, glycaemic control. Glumet XR may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17042181P	Zimmex 20 Tablet	Coronary Heart Disease: Reduce risk of death, coronary death & non-fatal Myocardial Infarction; Reduce risk of undergoing myocardial revascularization procedures (CABG & PTCA); slow progression of coronary atherosclerosis, including reducing development of new lesions & new total occlusions. Hyperlipidaemia: As an adjunct to diet to reduce elevated total-C, LDL-C, Apo B & TG, LDL-C/HDL-C & total-C/HDL-C ratios & to increase HDL-C in primary hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet & other nonpharmacological measures is inadequate.
BRU17042182P	KOP 2.5% Gel (Ketoprofen BP)	For inflammatory non-articular musculoskeletal conditions and mild trauma due to sport injuries, sprains, tendinitis, musculotendinous contusion and oedema.
BRU17042183P	Dextracin Eye/Ear Drops	**EYE** Treatment of inflammatory conditions of the anterior segment of the eye complicated by infection caused by organisms sensitive to neomycin. **EAR** Treatment of inflammatory conditions of the external ear complicated by infection caused by organisms sensitive to neomycin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17042185P	Triplixam 5mg/1.25mg/5mg Film-Coated Tablets	Triplixam indicated as substitution therapy for treatment of essential hypertension in patients already controlled with perindopril / indapamide fixed dose combination and amlodipine, taken at the same dose level.
BRU17042186P	Triplixam 5mg/1.25mg/10mg Film-Coated Tablets	Triplixam indicated as substitution therapy for treatment of essential hypertension in patients already controlled with perindopril / indapamide fixed dose combination and amlodipine, taken at the same dose level.
BRU17042187P	Triplixam 10mg/2.5mg/5mg Film-Coated Tablets	Triplixam indicated as substitution therapy for treatment of essential hypertension in patients already controlled with perindopril / indapamide fixed dose combination and amlodipine, taken at the same dose level.
BRU17042188P	Triplixam 10mg/2.5mg/10mg Film-Coated Tablets	Triplixam indicated as substitution therapy for treatment of essential hypertension in patients already controlled with perindopril / indapamide fixed dose combination and amlodipine, taken at the same dose level.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17042189P	Cotren Vaginal Tablet 500mg	Vaginal infections caused by fungi-mainly candida and/or trichomonas.
BRU17042190P	Axcel Bromhexine Tablet	For the reduction of sputum viscosity.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17042192P	Zocol 150mg Capsule	Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g., pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. Systemic candidiasis including candidemia, disseminated candidiasis and other forms of invasive candidal infection. These include infections of the peritoneum, endocardium and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. Mucosal candidiasis including oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of oropharyngeal candidiasis in patients with AIDS. Genital candidiasis, vaginal candidiasis, acute or recurrent; and prophylaxis to reduce the incidence of recurrent vaginal candidiasis (=3 episodes a year). Candidal balanitis. Prevention of fungal infections in patients with malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy. Dermatomycosis including tinea pedis, tinea corporis, tinea cruris, pityriasis versicolor and candida infections.
BRU17042193NP	Anucare Ointment	For the relief of itching, burning and soreness of haemorrhoids and minor rectal inflammations and irritations.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17052195P	Pamorelin 3.75mg Powder For Suspension For Injection	Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg is indicated for the treatment of locally advanced or metastatic, hormone-dependent prostate cancer. Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg are indicated as concomitant to and following radiotherapy in patients with high-risk localized or locally advanced prostate cancer. Pamorelin 3.75 mg is indicated for the treatment of endometriosis. Pamorelin 3.75 mg is indicated for the pituitary down-regulation in the context of assisted reproduction technology. Pamorelin 3.75 mg is indicated as adjuvant treatment, in combination with tamoxifen or an aromatase inhibitor, of hormone receptor positive early stage breast cancer in women at high risk of recurrence who are confirmed as premenopausal after completion of chemotherapy. Pamorelin 22.5 mg is indicated for the treatment of central precocious puberty (CPP) in children of 2 years of age and older with an onset of CPP before 8 years in girls and 10 years in boys.
BRU17052196P	Pamorelin 11.25mg Powder For Suspension For Injection	Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg is indicated for the treatment of locally advanced or metastatic, hormone-dependent prostate cancer. Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg are indicated as concomitant to and following radiotherapy in patients with high-risk localized or locally advanced prostate cancer. Pamorelin 3.75 mg is indicated for the treatment of endometriosis. Pamorelin 3.75 mg is indicated for the pituitary down-regulation in the context of assisted reproduction technology. Pamorelin 3.75 mg is indicated as adjuvant treatment, in combination with tamoxifen or an aromatase inhibitor, of hormone receptor positive early stage breast cancer in women at high risk of recurrence who are confirmed as premenopausal after completion of chemotherapy. Pamorelin 22.5 mg is indicated for the treatment of central precocious puberty (CPP) in children of 2 years of age and older with an onset of CPP before 8 years in girls and 10 years in boys.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17052197P	Pamorelin 22.5mg Powder For Suspension For Injection	Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg is indicated for the treatment of locally advanced or metastatic, hormone-dependent prostate cancer. Pamorelin 3.75 mg, 11.25 mg, and 22.5 mg are indicated as concomitant to and following radiotherapy in patients with high-risk localized or locally advanced prostate cancer. Pamorelin 3.75 mg is indicated for the treatment of endometriosis. Pamorelin 3.75 mg is indicated for the pituitary down-regulation in the context of assisted reproduction technology. Pamorelin 3.75 mg is indicated as adjuvant treatment, in combination with tamoxifen or an aromatase inhibitor, of hormone receptor positive early stage breast cancer in women at high risk of recurrence who are confirmed as premenopausal after completion of chemotherapy. Pamorelin 22.5 mg is indicated for the treatment of central precocious puberty (CPP) in children of 2 years of age and older with an onset of CPP before 8 years in girls and 10 years in boys.
BRU17052198NP	Weng Heng Tablet Paracetamol 500mg	For the relief of fever, headache, toothache and mild to moderate pain including dysmenorrhea, condicitons involving musculoskeletal pain, myalgias, neuralgias, analgesic after tooth extraction and in teething, and earache.
BRU17052199P	MST Continus 10mg Prolonged Release Tablets	Prolonged relief of severe pain.
BRU17052200P	MST Continus 30mg Prolonged Release Tablets	Prolonged relief of severe pain.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17052204P	Oxair Chewable Tablet 5mg	1) For the prophylaxis and chronic treatment of asthma in adults and children ≥ 2 years of age. 2) It is indicated in adults ≥ 15 years of age for the relief of daytime and night-time symptoms of seasonal allergic rhinitis.
BRU17052205P	Anacaine Injection 1%	Local or regional anaesthetic solution for use in infiltration anaesthetia.
BRU17052206P	Anacaine Injection 2%	Local or regional anaesthetic solution for use in infiltration anaesthetia.
BRU17052207NP	Ferromed Tablet 200mg	Indicated in the prevention and treatment of iron deficiency anemia, which may result from inadequate diet, malabsorption, pregnancy, rapid growth during childhood, and/or blood loss. Iron deficiency may lead to defective erythropoiesis that may eventually result in a hypochromic anaemia (low haemoglobin concentrations); the red blood cells in iron-deficiency anaemia may be either normocytic (normal size) or microcytic (small in size). Note: Deficiency of iron may lead to fatigue, shortness of breath, decreased physical performance, impaired learning in children and adults, altered body temperature, and altered immune function.
BRU17052208NP	Calazite Lotion	A soothing and protecting lotion for the relief of skin irritations due to insect bites, prickly heat, sunburn, cosmetic, nappy rash and other minor skin irritation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17052209P	Acipan Injection 1mg/ml (1ml Ampoule)	1) Pre-anaesthetic medication to inhibit excessive salivary and bronchial secretion and to diminish the risk of vagal inhibition of the heart. 2) Management of patients with acute myocardial infarction and sinus bradycardia who have associated hypotension and increased verticular irritability. 3) In conjunction with morphine or other drugs for the relief of biliary or renal colic. 4) Administered concurrently with anticholinesterase agents (eg. neostigmine, physostigmine) to block the adverse muscarinic effects of these latter agents when they are used after surgery to terminate curarization. 5) Concomitant with a cholinesterase reactivator (eg.: pralidoxime) to reverse muscarinic effects associated with toxic exposure to anticholinesterase compounds (eg.: organophosphate pesticides).
BRU17062211P	SW Hyoscine Butylbromide Tablets	It is indicated for gastrointestinal spasm hypermotility, biliary dyskinesia and spasm of the urinary tract, delayed relaxation of the lower uterine segment and dysmenorrhea.
BRU17062212NP	SMOFKABIVEN Emulsion For Infusion	Parenteral nutrition for adult patients when oral or enteral nutrition is impossible, insufficient or contraindicated.

BRU17062214P	Cosentyx 150mg Solution For Injection In Pre-Filled Syringe	**Plaque psoriasis** Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy. **Hidradenitis Suppurativa (HS)** Cosentyx is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Psoriatic arthritis** Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Axial spondyloarthritis (axSpA)** **Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)** Cosentyx is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA)** Cosentyx is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).

		Juvenile idiopathic arthritis (JIA) **Enthesitis-related arthritis (ERA)** Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active enthesitis-related arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. **Juvenile psoriatic arthritis (JPsA)** Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active juvenile psoriatic arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.

BRU17062215P	Fraizeron 150mg Solution For Injection In Pre-Filled Pen	**Plaque psoriasis** Fraizeron is indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy. **Hidradenitis Suppurativa (HS)** Fraizeron is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Psoriatic arthritis** Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Axial spondyloarthritis (axSpA)** **Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)** Fraizeron is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA)** Fraizeron is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).

		Enthesitis-related arthritis (ERA) Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active enthesitis-related arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. **Juvenile psoriatic arthritis (JPsA)** Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active juvenile psoriatic arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.
BRU17062216P	Morphine-Hameln 10mg/ml Injection, 1mL	Analgesic for severe and very severe pain.
BRU17062217P	Xtandi Soft Capsules 40mg	Xtandi is indicated for : • the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC). • the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC). • the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. • the treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17062218P	PRAXBIND Solution For Injection/Infusion 50mg/ml	Praxbind is a specific reversal agent for dabigatran and is indicated in patients treated with Pradaxa when rapid reversal of the anticoagulant effects of dabigatran is required: • For emergency surgery/ urgent procedures • In life-threatening or uncontrolled bleeding
BRU17062219NP	Zam-Buk Ointment	Indicated for temporary relief of pain and itch associated with minor wounds, burns, scalds, chapped hands, mosquitoes and insect bites.
BRU17062220P	Axcel Sildenafil-100mg Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.
BRU17072223P	Monoclox 500mg Powder For Solution For Injection Or Infusion	• Cloxacillin is indicated for the treatment of sensitive staphylococcal infections: respiratory infections, otorhinolaryngologic infections, urogenital infections, neuro-meningeal infection, bone and joint infections, endocarditis and treatment of skin infections caused by sensitive staphylococci and/or streptococci. • Cloxacilliln is also indicated as preventive treatment of postoperative infections in neurosurgery.
BRU17072225P	Gluvecron MR 30mg Tablet	Gluvecron MR is recommended in adults for non-insulin-dependent diabetes (type 2), in association with dietary measures and with physical exercise, when these measures alone are not sufficient to obtain normal blood glucose levels (levels of sugar in blood).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17072226NP	Restors Oral Powder	Helps to restore fluid and electrolyte loss and prevent dehydration due to diarrhoea, vomiting and gastroenteritis.
BRU17072227P	Flumazenil-Hameln 0.1mg/ml Injection	Flumazenil-hameln 0.1mg/ml injection is indicated for the complete or partial reversal of the central sedative effects of benzodiazepines. It may therefore be used in anaesthesia and in intensive care in the following situations: *In anaesthesia* -Termination of hyposedative effects in general anaesthesia induced and/or maintained with benzodiazepines in hospitalised patients. -Reversal of benzodiazepines sedation in short-term diagnostic and therapeutic procedures in ambulatory patients and hospitalised patients. -For the reversal of conscious sedation induced with benz odiazepines in children > 1 year of age. *In intensive care situations* -For diagnosis and treatment of intoxication s or overdose with only or mainly benzodiazepines . (see special warnings and precautions for use). -For the specific reversal of the central effects of benzodiazepines in order to restore spontaneous respiration.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17082232P	Xeljanz Film-Coated Tablet 5mg	**Rheumatoid Arthritis** XELJANZ is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs). Limitations of Use: Use of XELJANZ in combination with biologic DMARDs or with potent immunosuppressants, such as azathioprine and cyclosporine is not recommended. **Psoriatic Arthritis** XELJANZ is indicated for the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other disease modifying antirheumatic drugs (DMARDs). Limitations of Use: Use of XELJANZ in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **Ulcerative Colitis** XELJANZ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have an inadequate response or who are intolerant to TNF blockers. Limitations of Use: Use of XELJANZ in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17082233P	Amoxicap 250 Capsule	For treatment of: 1) Ear, nose and throat infections caused by streptococci, pneumococci, non-penicillinase-producing staphylococci and H.influenzae 2) Genitourinary tract infections caused by E.Coli, P.Mirabilis, S.Faecalis 3) Skin and soft-tissues infections caused by streptococci, non-penicillinase-producing staphylococci and E.Coli 4) Anogenital and urethral gonorrhoea caused by N.Gonorrhoea

BRU17082234P	Forxiga 5mg Film-Coated Tablet	**<u>Type 2 diabetes mellitus</u>** Forxiga is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: **Monotherapy** When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. **Add-on combination therapy** In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations). **Initial Combination** Forxiga is indicated for use as initial combination therapy with metformin, as an adjunct to diet and exercise, to improve glycaemic control in patients with type 2 diabetes mellitus when diet and exercise have failed to provide adequate glycaemic control and there are poor prospects for response to metformin monotherapy (for example, high initial HbA1c levels). To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors. For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1. **<u>Heart failure</u>** Forxiga is indicated in adults for the treatment of symptomatic chronic heart failure. **<u>Chronic kidney disease</u>** Forxiga is indicated in adults for the treatment of chronic kidney disease.

BRU17082235P	Forxiga 10mg Film-Coated Tablet	**<u>Type 2 diabetes mellitus</u>** Forxiga is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as: **Monotherapy** When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance. **Add-on combination therapy** In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations). **Initial Combination** Forxiga is indicated for use as initial combination therapy with metformin, as an adjunct to diet and exercise, to improve glycaemic control in patients with type 2 diabetes mellitus when diet and exercise have failed to provide adequate glycaemic control and there are poor prospects for response to metformin monotherapy (for example, high initial HbA1c levels). To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors. For study results with respect to combination of therapies, effects on glycaemic control, cardiovascular and renal events, and the populations studied, see sections 4.4, 4.5 and 5.1. **<u>Heart failure</u>** Forxiga is indicated in adults for the treatment of symptomatic chronic heart failure. **<u>Chronic kidney disease</u>** Forxiga is indicated in adults for the treatment of chronic kidney disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17082236P	Motigut Suspension 1mg/ml	Domperidone is indicated for the relief of the symptoms of nausea and vomiting. This includes: • Nausea and vomiting of functional, organic, infectious or dietary origin • Nausea and vomiting induced by: -Radiotherapy or drug therapy -Dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson's disease
BRU17082239P	Shrizine Injection 25mg/ml	Psychotic disorders including schizophrenia. It is not intended for use in non-psychotic disorders or for short term therapy.
BRU17082240P	Canesten HC Cream	Treatment of skin infections with co-existing symptoms of inflammation, eg. Itching, requiring rapid relief: - Dermatomycoses caused by dermatophytes (eg. Athlete's foot), yeasts (eg. Candida intertrigo), moulds and other fungi - Infections of the labia and adjacent areas caused by yeast fungi (candida vulvitis); inflammation of the glans and prepuce of the sexual partner caused by yeast fungi (candidal balanitis) - Skin diseases superinfected with organisms sensitive to clotrimazole
BRU17082242P; BRU17082242PS2	Losartan Hexal 50mg Film-Coated Tablets	• Losartan is indicated for the treatment of hypertension. • Losartan is indicated for the reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy (see section 5.1). • Losartan is indicated to delay the progression of renal disease as measured by a reduction in the incidence of doubling of serum creatinine and end stage renal disease (need for dialysis or renal transplantation), and to reduce proteinuria (see section 5.1).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17082243P; BRU17082243PS2	Losartan Hexal 100mg Film-Coated Tablets	• Losartan is indicated for the treatment of hypertension. • Losartan is indicated for the reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy (see section 5.1). • Losartan is indicated to delay the progression of renal disease as measured by a reduction in the incidence of doubling of serum creatinine and end stage renal disease (need for dialysis or renal transplantation), and to reduce proteinuria (see section 5.1).
BRU17092244P	Relvar Ellipta 100/25 Micrograms Inhalation Powder, Pre-Dispensed	Asthma Relvar Ellipta is indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: • patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists. COPD (Chronic Obstructive Pulmonary Disease) Relvar Ellipta is indicated for the symptomatic treatment of adults with COPD with a FEV1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.
BRU17092245P	Relvar Ellipta 200/25 Micrograms Inhalation Powder, Pre-Dispensed	Asthma Relvar Ellipta is indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: • patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists. **Note: 200/25mcg strength is not indicated for COPD

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17092246P	Hiprogin Injection 250mg/ml (1ml Ampoule)	1. Habitual abortion, when associated with proven progesterone-deficiency. 2. Primary and secondary amenorrhoea. 3. Infertility due to corpus luteum insufficiency, primary and secondary amenorrhoea.
BRU17092247P	Phebra Magnesium Sulfate Heptahydrate 50% 2.5g/5mL	•Treatment of acute hypomagnesaemia. •To prevent hypomagnesaemia in patients receiving total parenteral nutrition. •The prevention and treatment of life-threatening seizures in the treatment of toxaemias of pregnancy (pre-eclampsia and eclampsia). • For emergency treatment of some arrhythmias such as Torsade de Pointes and those associated with hypokalemia.
BRU17092249NP	Three Legs Yellow Balsem	For symptomatic relief of muscle pain, rheumatic pain and sprain
BRU17092251NP	ORS PLUS	For replacement of water and electrolytes lost during moderate to severe diarrhoea.
BRU17092252NP	Axe Brand Universal Oil	Provides temporary relief of headaches, colds and blocked noses, muscular and joint pains, stomach discomforts and wind, giddiness or travel sickness and soothes itching from insect bites.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17092253NP	Vitabiotics Pregnacare Breast-Feeding Tablet/Capsule	For the prevention and correction of vitamin and mineral deficiency states.
BRU17092254P	Ravimed Tablet 5mg	1. Carcinoma: Palliative treatment of recurrent and or metastatic breast or renal cell cancer and of inoperable recurrent or metastatic endometrial carcinoma. 2. Endometriosis: For use in the treatment of visually proven (laparoscopy) endometriosis where the required end-point of treatment is pregnancy, or for the control of symptoms when surgery is contraindicated or has been unsuccessful. 3. Secondary amenorrhoea proven not due to pregnancy. In amenorrhoea associated with a poorly developed proliferative endometrium, conventional oestrogen therapy may be employed in conjunction with Medroxyprogesterone Acetate. 4. Abnormal uterine bleeding in the absence of organic pathology. 5. Adjunct to cyclic oestrogen therapy.
BRU17092255P	T.O. Prazosin 2mg Tablet	Prazosin tablet is indicated in the treatment of hypertension and left ventricular heart failure.
BRU17092256P	Vaxcel Acyclovir 250mg I.V. For Infusion	Vaxcel Acyclovir 250mg I.V. for Infusion is indicated: 1. For the treatment of Herpes simplex infections. 2. For the prophylaxis of Herpes simplex infections in immune-compromised patients. 3. In the treatment of Varicella zoster infections. 4. For the treatment of Herpes simplex infections in the neonate.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17112257P	Azithromycin Tablets 250mg	Azithromycin tablets can be applied in situations where micro-organisms sensitive to azithromycin have caused: - Upper respiratory tract infections: sinusitis, pharyngitis, tonsillitis - Acute otitis media - Lower respiratory tract infections: acute bronchitis and mild to moderately severe community acquired pneumonia - Skin and soft tissue infections - Uncomplicated Chlamydia trachomatis urethritis and cervicitis Considerations should be given to official guidance on the appropriate use of antibacterial agents.
BRU17112258P	Fybogel Orange Sachet	For relief of constipation including constipation in pregnancy and maintenance of regularity; for the management of bowel function in patients with colostomy, ileostomy haemorrhoids, anal fissure, chronic diarrhea associated with diverticular disease, irritable bowel syndrome and ulcerative colitis.
BRU17112259NP	Paracetamol Osteo-Tab Modified Release Tablets	Paracetamol osteo-tab is effective for the relief of fever and relief of mild to moderate pain including: headache, migraine, toothache, pain after dental procedures, neuralgia, muscular aches and joint pains, pain of osteoarthritis, rheumatic pain, period pain, pain after vaccination, sore throat and the discomfort from colds and influenza.
BRU17112260P	Phenadryl Syrup	Phenadryl syrup is indicated for control of cough and alleviation of nasal stuffiness, bronchial congestion and lachrymation.
BRU17112261P	Dermosone Cream 0.1%	For topical treatment of corticosteroid-responsive skin conditions. It provides symptomatic relief of itch, allergy and inflammation in eczema, dermatitis, psoriasis, neurodermatoses and pruritus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17112263PS1; BRU17112263PS2	Octagam 5%, Solution For Infusion	**Replacement therapy in adults, and children and adolescents (0-18 years) in**: • Primary immunodeficiency syndromes with impaired antibody production. • Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia, in whom prophylactic antibiotics have failed. • Hypogammaglobulinaemia and recurrent bacterial infections in plateau phase multiple myeloma patients who have failed to respond to pneumococcal immunisation. • Hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation (HSCT). • Congenital AIDS with recurrent bacterial infections. **Immunomodulation in adults, and children and adolescents (0-18 years) in**: • Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count. • Guillain Barré syndrome • Kawasaki disease

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122264P	Ceficad 1000mg Injection	Ceficad injection (Cefepime Hydrochloride) is indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms: Pneumonia (moderate to severe) caused bystreptococcus pneumoniae, including cases associated with concurrent bacteremia, pseudomonas aeruginosa, klebsiella pneumonia, or Enterobacter species. Empiric therapy for febrile neutropenic patients Cefepime as monotherapy is indicated for empiric treatment of febrile neutropenic patients. In patients at high risk for severe infection (including patients with a history of recent bone marrow transplantation, with hypotension at presentation, with an underlying hematologic malignancy, or with severe or prolonged neutropenia), antimicrobial monotherapy may not be appropriate. Insufficient data exist to support the efficacy of cefepime monotherapy in such patients. Urinary tract infections Uncomplicated and complicated Urinary Tract Infections (including pyelonephritis) caused by Escherichia coli, Klebsiella pneumonia, or Proteus mirabilis, when the infection is mild to moderate, including cases associated with concurrent bacteremia with these microorganisms. Skin and Skin Structure infections Uncomplicated Skin and Skin Structure infections caused by Staphylococcus aureus (methicillin susceptible strains only) or Streptococcus pyogenes. Intra-abdominal infections Complicated Intra-abdominal infections caused by Escherichia coli, pseudomonas aeruginosa or Bacteroides fragilis. To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefepime hydrochloride and other antibacterial drugs, cefepime hydrochloride should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122265P	Probitor Capsule 20mg	• Treatment of duodenal and benign gastric ulcers including those complicating NSAID therapy; • Treatment of NSAIDs associated peptic and gastro-duodenal erosions • Prophylactic treatment in patients with an increased risk of NSAIDs associated peptic ulcer, gastro-duodenal erosions or dyspeptic symptoms • Helicobacter pylori associated peptic ulcer disease • Reflux oesophagitis • Zollinger-Ellison syndrome
BRU17122266P	Solbid Tablet 10mg	Isosorbide dinitrate is used prophylactically in the treatment of angina pectoris.
BRU17122268P; BRU17122268PS2; BRU17122268PS3	Converium 300mg Tablet	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.
BRU17122269P	Salazine Enteric Coated Tablet 500mg	SALAZINE Tablets is indicated for the management of mild to moderate and severe ulcerative colitis, Crohn's Disease and rheumatoid arthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122270P	Axcel Metronidazole-200 Tablet	Treatment of protozoal infection, intestinal and extra-intestinal amoebiasis, lambliasis, acute ulcerative gingivitis, urogenital trichomoniasis, glardiasis, and Vincent's infection.
BRU17122271NP	Dermorub Liniment Muscle & Joint	For the relief of aches and pains including rheumatism, arthritis, backache, bruises, sprains and strains due to sports injuries.
BRU17122272P	Tenof 300mg Tablet	HIV-1 Infection Tenofovir is indicated in combination with other antiretroviral agents for the treatment of HIV-1infection in adults and pediatric patients 12 years of age and older. The following points should be considered when initiating therapy with tenofovir for the treatment of HiV-1 infection: • TENOF should not be used in combination with other products containing tenofovir disoproxil fumarate. Chronic Hepatitis B Tenofovir is indicated for the treatment of chronic hepatitis B in adults. The following points should be considered when initiating therapy with tenofovir for the treatment of HBV infections: • This indication is based primarily on data from treatment of subjects who were nucleoside-treatment-naïve and a smaller number of subjects who had previously received lamivudine or adefovir dipivoxil. Subjects were adult with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease. • Tenofovir was evaluated in a limited number of subjects with chronic hepatitis B and decompensated liver disease. • The numbers of subjects in clinical trials who had lamivudine- or adefovir associated substitutions at baseline were too small to reach conclusions of efficacy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122273NP	Bisacodyl Tablets 5mg	Bisacodyl is used for the treatment of constipation for evacuation of the colon before radiological examination of the abdomen or endoscopy, and before or after surgical operations.
BRU17122274P	Alfutor ER Tablets 10mg	Treatment of the functional symptoms of benign prostatic hypertrophy (BPH). Adjuvant Treatment to a catheter in acute urinary retention related to benign prostatic hypertrophy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122275P	Venlift ER 37.5mg Capsule	Venlift ER is indicated for the treatment of depression, including depression with associated anxiety, in hospitalized patients. Treatment of anxiety or Generalized Anxiety Disorder (GAD), including long-term treatment. For prevention of relapse of an episode of depression or for prevention of the recurrence of new depressive episodes. Venlift ER is indicated for the treatment of Social Anxiety Disorder, also known as Social Phobia, as defined in DSM-IV. Social Anxiety Disorder (DSM-IV) is characterised by a marked and persistent fear of 1 or more social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. Exposure to the feared situation almost invariably provokes anxiety, which may approach the intensity of a panic attack. The feared situations are avoided or endured with intense anxiety or distress. The avoidance, anxious anticipation, or distress in the feared situation(s) interferes significantly with the person's normal routine, occupational or academic functioning, or social activities or relationships, or there is a marked distress about having the phobias. Lesser degrees of performance anxiety or shyness generally do not require psychopharmacological treatment. Panic disorder, including prevention of relapse.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122276P	Venlift ER 75mg Capsule	Venlift ER is indicated for the treatment of depression, including depression with associated anxiety, in hospitalized patients. Treatment of anxiety or Generalized Anxiety Disorder (GAD), including long-term treatment. For prevention of relapse of an episode of depression or for prevention of the recurrence of new depressive episodes. Venlift ER is indicated for the treatment of Social Anxiety Disorder, also known as Social Phobia, as defined in DSM-IV. Social Anxiety Disorder (DSM-IV) is characterised by a marked and persistent fear of 1 or more social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. Exposure to the feared situation almost invariably provokes anxiety, which may approach the intensity of a panic attack. The feared situations are avoided or endured with intense anxiety or distress. The avoidance, anxious anticipation, or distress in the feared situation(s) interferes significantly with the person's normal routine, occupational or academic functioning, or social activities or relationships, or there is a marked distress about having the phobias. Lesser degrees of performance anxiety or shyness generally do not require psychopharmacological treatment. Panic disorder, including prevention of relapse.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122277P	Venlift ER 150mg Capsule	Venlift ER is indicated for the treatment of depression, including depression with associated anxiety, in hospitalized patients. Treatment of anxiety or Generalized Anxiety Disorder (GAD), including long-term treatment. For prevention of relapse of an episode of depression or for prevention of the recurrence of new depressive episodes. Venlift ER is indicated for the treatment of Social Anxiety Disorder, also known as Social Phobia, as defined in DSM-IV. Social Anxiety Disorder (DSM-IV) is characterised by a marked and persistent fear of 1 or more social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. Exposure to the feared situation almost invariably provokes anxiety, which may approach the intensity of a panic attack. The feared situations are avoided or endured with intense anxiety or distress. The avoidance, anxious anticipation, or distress in the feared situation(s) interferes significantly with the person's normal routine, occupational or academic functioning, or social activities or relationships, or there is a marked distress about having the phobias. Lesser degrees of performance anxiety or shyness generally do not require psychopharmacological treatment. Panic disorder, including prevention of relapse.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122279P; BRU17122279PS2	Medaxonum (Ceftriaxone) 1g Powder For Injection/Infusion	Medaxonum is indicated for the treatment of the following infections caused by susceptible organisms. For details of susceptible organisms, see Pharmacodynamics. Therapy may be initiated prior to the results of susceptibility testing being known. Bones, skin and soft tissue infection Gonorrhoea Infections in patients with impaired defence mechanisms Meningitis (bacterial), including meningococcal meningitis prophylaxos Pneumonia Septicaemia It is also indicated for use peri-operatively in the prophylaxis of infection associated with surgical procedures.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122282P	Vaxcel Cefobactam-1g Injection	**Monotherapy**: Sulbactam / cefoperazone is indicated for the treatment of the following infections when caused by susceptible organism: Respiratory tract infections (upper and lower) Urinary tract infections (upper and lower) Peritonitis, cholecystitis, cholangitis and other intra-abdominal infections Septicaemia Meningitis Skin and soft tissue infections Bone and joint infections Pelvic inflammatory disease, endometritis, gonorrhoea and other infections of the genital tract **Combination therapy**: Because of the broad spectrum of activity of sulbactam / cefoperazone, most infections can be treated adequately with this antibiotic alone. However, sulbactam / cefoperazone may be used concomitantly with other antibiotics if such combinations are indicated. If an aminoglycoside is used (see interaction with other medicaments) renal function should be monitored during the course of therapy (see Recommended Dose Use in Renal Function)
BRU17122283P	Ibuspan Tablet 200mg	Ibuprofen is used in the management of mild to moderate pain in conditions such as dysmenorrhoea, migraine, postoperative pain, ankylosing spondylitis, osteoarthritis, and rheumatoid including juvenile rheumatoid arthritis, and in other musculoskeletal and joint disorders such as sprains and strains.
BRU17122284NP	Three Legs Lemon Sweet Purgative	For the relief of constipation and difficulty in bowel movement due to hardened faeces.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU17122285P	Fucithalmic Eye Drops 1%	Bacterial eye infections caused by susceptible organisms in conjunctivitis, blepharitis, sty, keratitis, dacryocystitis and in connection with removal of foreign bodies.
BRU17122286NP	SM Calamine Lotion	Calamine is indicated for the topical relief of itching, pain and discomfort of minor skin irritations, such as those caused by eczemas, insect bites, prickly heat, sunburn and napkin rash.
BRU17122287P	Pivakan 0.5% w/v (Plain) Injection (20ml Vial)	It is indicated for the production of local or regional anaesthesia and analgesia in individuals as follows: Surgical anaesthesia: Epidural block for surgery, Field block (minor and major nerve blocks and infiltration). Analgesia: Continuous epidural infusion or intermittent bolus epidural administration for analgesia in postoperative pain or labour pain, Field block (minor nerve block and infiltration).
BRU18012288P	Irbesartan Tablets 150mg	• Treatment of essential hypertension. • Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.
BRU18012289P	Irbesartan Tablets 300mg	• Treatment of essential hypertension. • Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18012291P	Spiolto Respimat Inhalation Solution 2.5µg/2.5µg Per Actuation	Spiolto Respimat is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).
BRU18012292P	Zykadia™ 150mg Hard Capsule	Zykadia as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive-advanced non-small cell lung cancer (NSCLC). ZYKADIA as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.
BRU18012294NP	Ketosteril Film-Coated Tablet	Prevention and therapy of damages, due to faulty or deficient protein metabolism in chronic renal insufficiency in connection with limited protein in food of 40g per day (for adults) and less, i.e. generally in patients with glomerular filtration rate (GFR) between 5 and about 15 ml/minutes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18012295PS2	Kadcyla Powder For Concentrate For Solution For Infusion 100mg/Vial	**Breast Cancer** *Metastatic Breast Cancer (MBC)* Kadcyla, as a single agent, is indicated for the treatment of patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with trastuzumab and a taxane, separately or in combination. Patients should have either: - Received prior therapy for advanced or metastatic disease, or - Developed disease recurrence during or within six months of completing adjuvant therapy. *Early Breast Cancer (EBC)* Kadcyla, as a single agent, is indicated for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease, after neoadjuvant trastuzumab and taxane-based treatment.
BRU18012296PS2	Kadcyla Powder For Concentrate For Solution For Infusion 160mg/Vial	**Breast Cancer** Metastatic Breast Cancer (MBC) Kadcyla, as a single agent, is indicated for the treatment of patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with trastuzumab and a taxane, separately or in combination. Patients should have either: - Received prior therapy for advanced or metastatic disease, or - Developed disease recurrence during or within six months of completing adjuvant therapy. Early Breast Cancer (EBC) Kadcyla, as a single agent, is indicated for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease, after neoadjuvant trastuzumab and taxane-based treatment.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18012297NP	5% Dextrose In Water Solution For Intravenous Infusion	1. For fluid and caloric maintenance. 2. As a vehicle for compatible drugs used in therapy or in diagnostic procedures.
BRU18012298NP	10% Dextrose In Water Solution For Intravenous Infusion	1. For fluid and caloric maintenance. As a vehicle for compatible drugs used in therapy or in diagnostic procedures.
BRU18012299P	Three Legs Tinea-Kare Anti-Fungal Cream 1% w/w	For treatment of fungal infections including ringworm, athletes foot, jock itch and white spot.
BRU18012301NP	Gascoal Tablet 50mg	For the relief of flatulence and gas expellation for (gastroscopic) gastrodiagraphic and X-ray examination.
BRU18012302NP	Vitabiotics Pregnacare Original Tablet	For the prevention and correction of vitamin and mineral deficiency states.
BRU18022303NP	Glycophos Concentrate For Solution For Infusion 216mg/ml	Glycophos is indicated in adults patients as a supplement in intravenous nutrition to meet the requirements of phosphate.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18022304NP	Nutrilite Daily Tablet	As dietary supplement.
BRU18022308P	Jakavi 10mg Tablet	Myelofibrosis (MF) Jakavi is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis. Polycythaemia vera (PV) Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea. Graft versus host disease (GvHD) Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).
BRU18022309P	Zycort Injection 100mg	Replacement therapy for adrenal-cortical failure or hypopituitarism. In patients with known or suspected adrenal insufficiency, intravenous or intra-muscular administration of a rapidly acting corticosteroid (such as hydrocortisone) is indicated prior to surgery, including dental surgery, or if shock, severe trauma, illness, or other stress conditions occur. Patients already receiving replacement therapy require supplemental pharmacologic doses; Congenital adrenal hyperplasia; Status asthmaticus; Allergic and anaphylactic reactions; Ulcerative colitis; Soft tissue or joint inflammation; Collagen diseases; Dermatological diseases; Hypercalcaemia associated with cancer.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18022310PS2	Opsumit 10mg Film-Coated Tablet	Opsumit, as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU18022311P	Uractonum 25mg Tablet	Hepatic cirrhosis: Oedema in hepatic cirrhosis Hypertension: Congestive heart failure. Long-term treatment of primary aldosteronism Nephrotic syndrome
BRU18022312P	Perjeta Concentrate For Solution For Infusion 420mg/14ml	<u>Metastatic Breast Cancer (MBC)</u> Perjeta is indicated for use in combination with Herceptin and docetaxel for the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. <u>Early Breast Cancer</u> Perjeta is indicated for use in combination with Herceptin and chemotherapy for the: • neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival. • adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18022318NP	Sangobion Capsule	Iron deficiency anaemia. Prophylaxis and therapy of anaemia due to deficiency or increased requirements of the active agents, e.g. in: haemorrhage of traumatic or endogenous origin, pregnancy, growth, convalescence and senility, poor nutrition and blood donation.
BRU18022319P	Talgesil Injection 0.1mg/2ml (Amp)	Short duration analgesia during pre-medication induction and maintenance of anaesthesia, and in the immediate post-operative period.
BRU18032320P	Norfox Tablet	Indicated for the oral treatment of adults with complicated and uncomplicated urinary tract infections that are caused by susceptible strains of microorganisms.
BRU18032321P	Domil Suspension 5mg/5ml	Domperidone is indicated for the relief of symptoms of nausea and vomiting. This includes: • Nausea and vomiting of functional, organic, infectious or dietary origin • Nausea and vomiting induced by: - Radiotherapy or drug therapy - Dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson's disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18032322P	Latanostill 50mcg/ml Eye Drops Solution	Latanostill is indicated for the reduction of elevated intra-ocular pressure in patients suffering from open-angle glaucoma and from ocular hypertension.
BRU18032323P	Gardasil 9, Suspension For Injection	GARDASIL 9 is a vaccine indicated in girls and women from 9 through 45 years of age for the prevemtion of cervical, vulvar, vaginal, and anal cancer; premalignant genital lesions (cervical, vulvar and vaginal); premalignant anal lesions; HPV infections; cervical adenocarcinoma in situ (AIS); and external genital warts (condyloma acuminata) causally related to Human Paillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58. GARDASIL 9 is indicate in boys and men from 9 through 45 years of age for the prevention of premalignant lesions and HPV infections caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58; anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58 and genital warts (condyloma acuminata) caused by HPV types 6 and 11.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18032324P	Entresto 50mg Film-Coated Tablets	**Heart failure** Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat [see Clinical efficacy and safety (section 5.1)]. Entresto is administered in combination with other heart failure therapies (e.g. beta blockers, diuretics and mineralocorticoid antagonists) as appropriate, in place of an ACE inhibitor or ARB [see Clinical efficacy and safety (section 5.1)]. **Hypertension** Entresto is indicated for the treatment of essential hypertension. Entresto should not be used as a first-line drug for the treatment of hypertension because of the risk of excessive decrease in blood pressure.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18032325P	Entresto 100mg Film-Coated Tablets	**Heart failure** Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat [see Clinical efficacy and safety (section 5.1)]. Entresto is administered in combination with other heart failure therapies (e.g. beta blockers, diuretics and mineralocorticoid antagonists) as appropriate, in place of an ACE inhibitor or ARB [see Clinical efficacy and safety (section 5.1)]. **Hypertension** Entresto is indicated for the treatment of essential hypertension. Entresto should not be used as a first-line drug for the treatment of hypertension because of the risk of excessive decrease in blood pressure.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18032326P	Entresto 200mg Film-Coated Tablets	**Heart failure** Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. LVEF is a variable measure, so use clinical judgment in deciding whom to treat [see Clinical efficacy and safety (section 5.1)]. Entresto is administered in combination with other heart failure therapies (e.g. beta blockers, diuretics and mineralocorticoid antagonists) as appropriate, in place of an ACE inhibitor or ARB [see Clinical efficacy and safety (section 5.1)]. **Hypertension** Entresto is indicated for the treatment of essential hypertension. Entresto should not be used as a first-line drug for the treatment of hypertension because of the risk of excessive decrease in blood pressure.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18032327P	Dyna Amoxycillin 125mg/5ml	Infections e.g. otitis media, sinusitis, pharyngitis, pneumonia, bronchitis caused by sensitive gram-positive organisms, including Streptococcus pneumonia, and other streptococci and Listeria monocytogenes. Gram-negative microorganism including some of strains of Bordetella pertussis, Haemophilus influenzae and some Enterobacteriaceae such as Escherichia coli, Proteus mirabilis, Salmonella and Shigella spp. ENT infections: otitis media, sinusitis, tonsillitis, pharyngitis, laryngitis, epiglottis. Lower respiratory tract infections: acute and chronic bronchitis, pneumonia, pleuritis. Urinary tract infections: acute and recurrent cystitis, acute and chronic pyelonephritis, asymptomatic bacteriuria, prostitis. Skin and soft tissue infections: erysipelas, impetigo
BRU18032328P	Winofen Suspension 2% w/v	Winofen suspension is indicated for its analgesic and anti-inflammatory effects in the treatment of juvenile rheumatoid arthritis and soft-tissue injuries such as sprains and strains. It is also indicated for its analgesic effect in the relief of mild to moderate pain such as dental pain and for symptomatic relief of headache. Winofen suspension is indicated in short-term use for the treatment of pyrexia in children over one year of age.
BRU18032329P	Wincort 1% Cream	Symptomatic relief of allergic disorders, localised itch and inflammatory conditions of the skin.
BRU18032330P	Acugesic Tablet 50mg	Severe acute and chronic pain.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18032332P	Defuzin Cream 2% w/w	Defuzin Cream 2% w/w is indicated for treatment of skin infections caused by staphylococci, streptococci, Propionibacterium acnes, Corynebacterium minutissimum, and other organisms sensitive to fusidic acid. The most important indications are impetigo, infected wounds, folliculitis, boils, sycosis barbae, carbuncles, hidradenitis, paronychia and erythrasma.
BRU18032333P	Hydrochlorzide-50 Tablet	Hydrochlorzide is indicated for the treatment of oedema and hypertension.
BRU18032334P	SIMBRINZA* 10 mg/ml + 2 mg/ml Eye Drops, Suspension	SIMBRINZA* eye drops contains brinzolamide, a carbonic anhydrase (CA-II) inhibitor, and brimonidine tartrate, an alpha-2 adrenergic agonist. Decrease of elevated intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.
BRU18032335NP	Hexidin Cream 1%	As a disinfectant cream. It can be used for disinfection or lubricating during gynaecological and obstetric procedures or childbirth.
BRU18032336NP	Three Legs Green Balsem	For symptomatic relief of muscular pain and joint pain.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18042338P	Novatretin™ 25mg Capsules	Severe forms of psoriasis including - erythrodermic psoriasis; - local or generalized pustular psoriasis; Severe disorders of keratinization, such as - congenital ichthyosis; - pityriasis rubra pilaris; - Darier's disease; - other disorders of keratinization which may be resistant to other therapies
BRU18042339P	Novatretin™ 10mg Capsules	Severe forms of psoriasis including - erythrodermic psoriasis; - local or generalized pustular psoriasis; Severe disorders of keratinization, such as - congenital ichthyosis; - pityriasis rubra pilaris; - Darier's disease; - other disorders of keratinization which may be resistant to other therapies

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18042340P	Axcel Metoclopramide Tablet	<u>Adult population</u>: Axcel Metoclopramide Tablet is indicated in adults for: - Symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting. - Prevention of delayed chemotherapy induced nausea and vomiting (CINV) - Prevention of radiotherapy induced nausea and vomiting (RINV) <u>Age 9-18 years patient</u>: Axcel Metoclopramide Tablet is indicated in patient (aged 9-18 years) for: Prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second line option.
BRU18042341P	TADIM Colistimethate Sodium 1 Million IU Powder For Nebuliser Solution Vial	Tadim powder for nebuliser solution is indicated for the treatment of colonisation and infections of the lung due to susceptible Pseudomonas aeruginosa in patients with cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18042342P	Clovix 75mg Tablet	Clopidogrel is indicated in adults for the prevention of atherothrombotic events as follows: • Recent Myocardial Infarction, Recent Stroke or Established Peripheral Arterial Disease -patients suffering from Myocardial Infarction (from a few days until less than 35 days), Ischaemic Stroke (from 7 days until less than 6 months) or established peripheral arterial disease. • Acute Coronary Syndrome -Non-ST segment elevation acute coronary syndrome (unstable angina/non-Q-wave myocardial infarction), including patients undergoing a stent replacement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA). -ST segment elevation acute myocardial infarction, in combination with ASA in medically treated patients eligible for thrombolytic therapy.
BRU18042343P	Axcel Cetirizine Tablet	Adults and children of 3 years or above; symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticarial of allergic reaction.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18042344P; BRU18042344PS2	Zarzio 30 MU/0.5ml Solution For Injection Or Infusion In Pre-Filled Syringe	- Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) and reduction in the duration of neutropenia in patients undergoing myeloablative therapy followed by bone marrow transplantation considered to be at increased risk of prolonged severe neutropenia. - The safety and efficacy of filgrastim are similar in adults and children receiving cytotoxic chemotherapy. - Mobilisation of peripheral blood progenitor cells (PBPC). - In children and adults with severe congenital, cyclic or idiopathic neutropenia with an absolute neutrophil count (ANC) of ≤ 0.5 x 10^9/l, and a history of severe or recurrent infections, long term administration of filgrastim is indicated to increase neutrophil counts and to reduce the incidence and duration of infection-related events. - Treatment of persistent neutropenia (ANC ≤ 1.0 x 10^9/l) in patients with advanced HIV infection, in order to reduce the risk of bacterial infections when other therapeutic options are inappropriate.
BRU18042345P	Ibrance Capsules 75mg	IBRANCE is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: □ an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or □ fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18042346P	Ibrance Capsules 100mg	IBRANCE is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.
BRU18042347P	Ibrance Capsules 125mg	IBRANCE is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18042348P	Tulip® 40mg Film-Coated Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Fredrickson Type IV), and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also intended for the decrease of increased total or LDL cholesterol in patients suffering from homozygous familial hypercholesterolemia, when response to diet and other nonpharmacological measures are inadequate. Prevention of Cardiovascular Disease In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • reduce the risk of non-fatal myocardial infarction, • reduce the risk of fatal and non-fatal stroke, • reduce the risk for revascularization procedures, • reduce the risk of hospitalization for CHF, • reduce the risk of angina.

		Pediatric Patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dL or b. LDL-C remains ≥ 160 mg/dL and: • there is a positive family history of premature cardiovascular disease or • two or more other CVD risk factors are present in the pediatric patient
BRU18062349P	Victoza® 6mg/ml, Solution For Injection In Pre-Filled Pen	Victoza® is indicated for the treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications. • in addition to other medicinal products for the treatment of diabetes. Prevention of cardiovascular events Victoza is indicated as an adjunct to diet, exercise and standard care therapy to reduce the risk of major cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or nonfatal stroke) in patients with type 2 diabetes mellitus and established cardiovascular disease who have inadequate glycaemic control.
BRU18062350P	Axcel Clindamycin Topical Solution 1% w/v	Treatment of acne vulgaris.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18062351P	Flucon Solution For IV Infusion 2mg/ml	FLUCON is indicated for the treatment of the following conditions: Use in Adults: 1. Cryptococcosis, including cryptococcal meningitis and infections of other sites (eg. pulmonary, cutaneous) Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. 2. Systemic candidiasis, including candidemia, disseminated candidiasis and other forms of invasive candidal infection. These include infections of the peritoneum, endocardium, eye and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 3. Mucosal candidiasis These include oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated.
BRU18062352P	Analpan Injection 75mg/3ml	1. Inflammatory and degenerative forms of rheumatism 2. Rheumatoid arthritis 3. Ankylosing spondylitis 4. Osteoarthritis, spondylarthritis 5. Non-articular rheumatism 6. Painful inflammatory conditions of non-rheumatic origin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18062353P	ELIGARD® Powder And Solvent For Solution For Injection 7.5mg	ELIGARD is indicated for the palliative treatment of hormone dependent advanced prostate cancer.
BRU18062354P	ELIGARD® Powder And Solvent For Solution For Injection 22.5mg	ELIGARD is indicated for the palliative treatment of hormone dependent advanced prostate cancer.
BRU18062355P	ELIGARD® Powder And Solvent For Solution For Injection 45mg	ELIGARD is indicated for the palliative treatment of hormone dependent advanced prostate cancer.
BRU18062356P	Three Legs Tinea-Kare Anti-Fungal Spray 1% w/v	- All dermatomycoses due to dermatophytes (Trichophyton species) e.g. athlete's foot (Tinea pedis), jock itch (Tinea cruris) and ringworm (Tinea corporis) - All dermatomycoses due to yeast (Candida species) e.g. Candida vulvitis, Candida balanitis - Dermatomycosis due to moulds and other fungi - Skin diseases showing secondary infection with these fungi.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18062357NP	Potrelease TR Tablet 600mg	i. Hypokalaemia, (treatment) – Potassium supplements are indicated in patients with hypokalaemia with or without metabolic alkalosis, in digitalis intoxication, and in patients with hypokalaemic familial periodic paralysis. ii. Hypokalaemia (prophylaxis) - Potassium supplements are indicated to prevent hypokalaemia in patients whose dietary intake of potassium is inadequate and who are taking digitalis and diuretics. Potassium supplements are also indicated in patients who suffer from hepatic cirrhosis with ascites, aldosterone excess with normal renal function, severe diarrhoea, and potassium-losing nephropathy.
BRU18062359P	Encardil Tablet 10mg	Treatment of hypertension: Enalapril is indicated alone or in combination with a thiazide diuretic, in the treatment of hypertension. Also used for treatment of renovascular hypertension (except in patients with bilateral renal artery stenosis or renal artery stenosis in a solitary kidney). Treatment of congestive heart failure: Also indicated, in combination with diuretics and digitalis therapy, for treatment of congestive heart failure not responding to other measures. In patients with symptomatic heart failure, Enalapril is indicated to improve survival, retard the progression of heart failure and reduce hospitalization for heart failure. Prevention of symptomatic heart failure: In asymptomatic patients with left ventricular dysfunction, it is indicated to: - Retard the development of symptomatic heart failure - Reduce hospitalization for heart failure Prevention of Coronary Ischemic Events in Patients with Left Ventricular Dysfunction: Enalapril may reduce the incidence of myocardial infarction and reduce hospitalization for unstable angina pectoris.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18062362P	Apo-Carvedilol 6.25mg Tablet	Hypertension: APO-CARVEDILOL (carvedilol) is indicated primarily for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents (e.g. calcium channel blockers, diuretics). Treatment of angina pectoris. Treatment of symptomatic chronic heart failure (CHF): APO-CARVEDILOL (carvedilol) is indicated for the treatment of symptomatic CHF to reduce mortality and cardiovascular hospitalizations, improve patient well-being and slow the progression of the disease. APO-CARVEDILOL may be used as adjunct of standard therapy, but may also be used in those patients unable to tolerate an ACE inhibitor, or those who are not receiving digitalis, hydralazine or nitrate therapy.
BRU18062363P	Apo-Carvedilol 25mg Tablet	Hypertension: APO-CARVEDILOL (carvedilol) is indicated primarily for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents (e.g. calcium channel blockers, diuretics). Treatment of angina pectoris. Treatment of symptomatic chronic heart failure (CHF): APO-CARVEDILOL (carvedilol) is indicated for the treatment of symptomatic CHF to reduce mortality and cardiovascular hospitalizations, improve patient well-being and slow the progression of the disease. APO-CARVEDILOL may be used as adjunct of standard therapy, but may also be used in those patients unable to tolerate an ACE inhibitor, or those who are not receiving digitalis, hydralazine or nitrate therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18062364P	Cef-3 Injection IM (500mg)	Ceftriaxone is used for treatment infections caused by susceptible bacteria. - Respiratory tract infections, pneumonia, otitis media - Renal and urinary tract infection - Septicemia - Meningitis in pediatric - Bone, joint and skin infection - Intra-abdominal infection - Uncomplicated gonorrhea infection

BRU18062365P	Simponi Solution For Injection 100mg/1.0ml	*<u>Rheumatoid arthritis (RA):</u>* SIMPONI, by SC administration, in combination with methotrexate (MTX), is indicated for: • the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate. • the treatment of severe, active, and progressive rheumatoid arthritis in adults not previously treated with MTX. SIMPONI, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function. *<u>Psoriatic arthritis (PsA):</u>* SIMPONI, by SC administration, alone or in combination with MTX, is indicated for: • the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate. SIMPONI has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Axial spondyloarthritis* *<u>Ankylosing spondylitis (AS):</u>* SIMPONI, by SC administration, is indicated for: • the treatment of severe, active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. *<u>Non-radiographic axial spondyloarthritis (nr-Axial SpA):</u>* SIMPONI, by SC administration, is indicated for: • the treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

		Ulcerative colitis (UC): SIMPONI, by SC administration, is indicated for: • the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18062366P	Apo-Atorvastatin 20mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Frederickson levels type IV), and for patients with dysbetalipoproteinemia (Fredrickson type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia when response to diet and other non-pharmacological measures are inadequate. *Prevention of cardiovascular disease* In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk for revascularization procedures • Reduce the risk of hospitalization for CHF • Reduce the risk of angina

		Pediatric patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains more than 190mg/dl or b. LDL-C remains more than 160mg/dl and; • There is a positive family history or premature cardiovascular disease or • Two or more other CVD risk factors are present in the pediatric patient

BRU18062367P	Apo-Atorvastatin 40mg Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Frederickson levels type IV), and for patients with dysbetalipoproteinemia (Fredrickson type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia when response to diet and other non-pharmacological measures are inadequate. *Prevention of cardiovascular disease* In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke • Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk for revascularization procedures • Reduce the risk of hospitalization for CHF • Reduce the risk of angina

		Pediatric patients (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains more than 190mg/dl or b. LDL-C remains more than 160mg/dl and; • There is a positive family history or premature cardiovascular disease or • Two or more other CVD risk factors are present in the pediatric patient
BRU18062368NP	Sodium Chloride Parenteral Solution 0.9%	1. Parenteral Uses: • For volume and electrolyte replacement and maintenance • As vehicle/solvent for compatible drugs used in therapy or in diagnostic procedures 2. Non-Parenteral Uses: • As a surgical washing solution • For wound irrigation and moistening of wound dressings • As solution for nebulization
BRU18062369NP	Lactated Ringer's Solution	- For replacement of fluid and electrolytes. - Substitute for 5% Dextrose in Lactated Ringer's in cases where dextrose is not indicated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18062370NP	Optrex Refreshing Eye Drops	Soothe and revitalise tired, sore, uncomfortable eyes. For the relief of minor eye irritations caused by dusty or smoky atmospheres, driving or close work.
BRU18062371P	Codipront® Capsules	Symptomatic treatment of dry cough (non-productive cough) such as during bronchitis, influenza as well as inflammations of the respiratory tract due to allergic and infectious causes.
BRU18062372PS1; BRU18062372PS2; BRU18062372PS3	Mixtard® 30 Penfill® 100 IU/ml, 3ml Cartridge Suspension For Injection	To treat diabetes mellitus.
BRU18072375P	Dynalexin Dry Syrup 125mg/5ml	Cephalexin is a semi-synthetic cephalosporin antibiotic for oral administration. It is indicated in the treatment of the following infections due to susceptible microganisms: • Respiratory tract infections • Otitis media • Skin and soft tissue infections • Bone and joint infections • Genito-urinary tract infections, including acute prostatitis Dental infections

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18072376P	Aspira Tablet 10mg	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older. Montelukast is indicated in adults and pediatric patients 2 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis. ***Note:*** *As the package insert for Aspira 10mg Tablet is shared with Aspira Chewable Tablet 4 mg and 5 mg as well as Aspira Oral Granules 4mg, general indication stated includes usage of montelukast on pediatric patients. However the use of Aspira 10mg Tablet in specific age group is stated under the Recommended Dosage.*
BRU18072377P	Terbin Cream 1%	Fungal infections of the skin and nails caused by dermatophytes, eg. Trichophyton (eg. T. rubrum, T.mentagrophytes, T.verrucosum, T.violaceum), Microsporum canis and Epidermophyton floccosum. Yeast infections of the skin caused by the genus Candida (eg. Candida albicans). Pityriasis (tinea) versicolor due to Pityrosporum orbiculare (also known as Malassezia furfur). Note: In contrast to topical Terfin, oral Terfin is not effective in Pityriasis versicolor.
BRU18072379P	Eye Glo Plus Eye Drops	Eye Glo Plus is an ophthalmic solution designed to comfort and cool eyes that are irritated and strained. Eye Glo Plus formula serves not only to cool eyes, but its mild antiseptic property means that it is suitable for the treatment of mild inflammatory conditions of the eye due to irritation and strain. Comforts strained and trained eyes.

BRU18072380NP	Crotocort Cream 10% w/w	i) Pruritis (itching) of varying origin. ii) Scabies (infestation of the skin by mites).
BRU18072381P	MabThera® Solution For Subcutaneous Injection 1400mg	***MabThera IV and MabThera SC*** **Non-Hodgkin's Lymphoma**: MabThera IV and MabThera SC are indicated for the treatment of: • patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) chemotherapy. • previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. MabThera IV and MabThera SC maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.
BRU18082382P	Tolanz ODT Tablets 5mg	Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuing therapy in patients who have shown initial treatment response. Olanzapine is indicated for short-term treatment of acute manic episode associated with Bipolar I Disorder. Olanzapine is indicated for preventing recurrence of manic, mixed or depressive episodes in Bipolar I Disorder.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18082383P	Tolanz ODT Tablets 10mg	Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuing therapy in patients who have shown initial treatment response. Olanzapine is indicated for short-term treatment of acute manic episode associated with Bipolar I Disorder. Olanzapine is indicated for preventing recurrence of manic, mixed or depressive episodes in Bipolar I Disorder.
BRU18082385P	Midazolam-Hameln 5mg/ml Injection, 1ml	Midazolam is a short-acting sleep-inducing drug that is indicated as follows: *In adults* • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia - Induction of anaesthesia - As a sedative component in combined anaesthesia. • SEDATION IN INTENSIVE CARE UNITS *In Paediatrics* • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of Anaesthesia • SEDATION IN INTENSIVE CARE UNITS

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18082386P	Optimol Eye Drops 0.5%	Timolol Opthalmic Drops is indicated in the reduction of elevated intraocular pressure. In clinical trials it has been shown to reduce intraocular pressure in: • Patients with ocular hypertension • Patients with chronic open-angle glaucoma • Aphakic patients with glaucoma
BRU18082387P	Niferin SR 30mg Tablet	1. Treatment of coronary heart disease -Chronic stable angina pectoris (angina of effort) 2. Treatment of hypertension
BRU18082388P	Pharmaniaga Pethidine Hydrochloride 50mg/1ml Injection	Moderate to severe pain, obstetric analgesia, pre-operative analgesia, enhancement of anaesthesia, for basal narcosis with Phenothiazines.
BRU18082389P	Pharmaniaga Pethidine Hydrochloride 100mg/2ml Injection	Moderate to severe pain, obstetric analgesia, pre-operative analgesia, enhancement of anaesthesia, for basal narcosis with Phenothiazines.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18082390P	Tagrisso 40mg Film-Coated Tablets	TAGRISSO as monotherapy is indicated for: • the adjuvant therapy after tumour resection in adult patients with non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. • the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. • the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive (NSCLC) whose disease has progressed on or after EGFR TKI therapy. TAGRISSO is indicated in combination with: • pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.
BRU18082391P	Tagrisso 80mg Film-Coated Tablets	TAGRISSO as monotherapy is indicated for: • the adjuvant therapy after tumour resection in adult patients with non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. • the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. • the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive (NSCLC) whose disease has progressed on or after EGFR TKI therapy. TAGRISSO is indicated in combination with: • pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18082392P	Adezio Tablet 10mg	Adezio is indicated for the relief of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis in adults and children over 2 years of age such as sneezing, rhinorrhea, postnasal discharge, nasal pruritis, ocular pruritis, tearing and redness of the eyes. Adezio is also indicated for the treatment of the uncomplicated skin manifestations of chronic urticarial in adults and children over 2 years of age. It significantly reduces the occurrence, severity and duration of hives and significantly reduces pruritis.
BRU18082393P	Enapril Tablet 20mg	Essential and renovascular hypertension; congestive heart failure; prevention of symptomatic heart failure and coronary ischemic events in patient with left ventricular dysfunction.
BRU18082394P	Xalkori 200mg Hard Capsules	**ALK- or ROS1-Positive Metastatic Non-Small Cell Lung Cancer** Crizotinib is indicated for the treatment of patients with advanced non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive.
BRU18082395P	Xalkori 250mg Hard Capsules	**ALK- or ROS1-Positive Metastatic Non-Small Cell Lung Cancer** Crizotinib is indicated for the treatment of patients with advanced non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18082396P	Normaten Tablet 100mg	Normaten is indicated for the control of hypertension and management of angina pectoris. It is also used as oral maintenance therapy for cardiac dysrhythmias after the acute attacks has been controlled by intravenous therapy and for long-term prophylaxis of myocardial infarction after recovery.
BRU18082397P	Brilinta 60mg Film-Coated Tablet	**History of Myocardial Infarction (at least one year ago)** Brilinta, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events (cardiovascular death, myocardial infarction and stroke) in adult patients with a history of myocardial infarction (MI) (MI occurred at least one year ago), and a high risk of developing an atherothrombotic event. **Coronary Artery Disease, Type 2 Diabetes Mellitus and History of Percutaneous Coronary Intervention** Brilinta, co-administered with low-dose acetylsalicylic acid (ASA: 75-150mg), is indicated to reduce the risk of a first myocardial infarction or stroke in patients with Coronary Artery Disease (CAD), Type 2 Diabetes Mellitus (DM) and a history of percutaneous coronary intervention (PCI), who are also at high risk of developing an atherothrombotic events.
BRU18082400P	Normaten Tablet 50mg	Normaten is indicated for the control of hypertension and management of angina pectoris. It is also used as oral maintenance therapy for cardiac dysrhythmias after the acute attacks has been controlled by intravenous therapy and for long-term prophylaxis of myocardial infarction after recovery.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18082401P	Adroten Tablet 5mg	• Treatment of high blood pressure (hypertension) • Treatment of coronary heart disease (angina pectoris). • Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.
BRU18092402P	Mapenem (1G Injection)	Mapenem 1gm is indicated for infections caused by pathogens sensitive to Meropenem including:- 1. Intra-abdominal infection 2. Skin and skin structure infection 3. Lower respiratory tract infections including bronchitis, pneumonia and Hospital-acquired pneumonia 4. Meningitis 5. Urinary tract infections 6. Gynaecological infections including endometritis and pelvic inflammatory disease 7. Bacterial septicemia 8. Empiric therapy in febrile neutropenia
BRU18092404P	Apo-Fluvoxamine 50mg Tablet	Major depressive episode, obsessive compulsive disorder.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18092405P	Ultiva Injection 5mg	Ultiva is indicated as an analgesic agent for use during induction and/or maintenance of general anaesthesia during surgical procedures including cardiac surgery, and also for continuation of analgesia into the immediate post-operative period under close supervision, during transition to longer acting analgesia. Ultiva is indicated for provision of analgesia and sedation in mechanically ventilated intensive care patients.
BRU18092406P	Ultravist 300 Injection 300mg/ml	This medicinal product is for diagnostic use only. Ultravist 300: Contract enhancement in computerized tomography (CT), digital subtraction angiography (DSA), intravenous urography, phlebography of the extremities, venography, arteriography, visualization of body cavities (e.g. arthrography, hysterosalpingography, fistulography) with the exception of myelography, ventriculography, cisternography.
BRU18092407P	Ultravist 370 Injection 370mg/ml	This medicinal product is for diagnostic use only. Ultravist 370: Contract enhancement in computerized tomography (CT), digital subtraction angiography (DSA), intravenous urography, arteriography and especially angiocardiography, visualization of body cavities (e.g. arthrography, fistulography) with the exception of myelography, ventriculography, cisternography.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18092408P	Halaven 0.5mg/ml Solution For Injection	<u>Breast cancer</u> HALAVEN® monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease (see CLINICAL STUDIES). Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments. HALAVEN® is indicated as monotherapy for the treatment of locally advanced or metastatic HER2 negative breast cancer after failure of one chemotherapeutic regimen for advanced disease. Patients should have received an anthracycline and a taxane unless these treatments were not suitable. <u>Soft Tissue Sarcoma (Liposarcoma)</u> HALAVEN® is indicated for the treatment of inoperable liposarcoma after progression following prior chemotherapy for advanced or metastatic disease in adults. Patients should have received two previous chemotherapy treatments, one of which should have included an anthracycline, unless this treatment is unsuitable.

BRU18092409P	Sivkort® Sterile Suspension For Injection 40mg/1ml	<u>Intramuscular</u> Where oral therapy is not feasible or is temporarily undesirable in the judgement of the physician, SIVKORT® INJECTION is indicated for intramuscular use as follows: 1. Endocrine disorders Nonsuppurative thyroiditis. 2. Rheumatic disorders As adjunctive therapy for short-term administration in: post-traumatic osteoarthritis; synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; epicondylitis; acute non-specific tenosynovitis; acute gouty arthritis; psoriatic arthritis; ankylosing spondylitis; juvenile rheumatoid arthritis. 3. Collagen diseases During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus; acute rheumatic carditis 4. Dermatologic diseases Pemphigus; severe erythema multiforme (Stevens-Johnson syndrome); exfoliative dermatitis; bullous dermatitis herpetiformis; severe seborrheic dermatitis; severe psoriasis. 5. Allergic states Control of severe incapacitating allergic conditions intractable to adequate trials of conventional treatment in bronchial asthma; contact dermatitis; atopic dermatitis; seasonal or perennial allergic rhinitis. 6. Ophthalmic diseases Severe chromic allergic, and inflammatory processes involving the eye; such as herpes zoster ophthalmicus; iritis; iridocyclitis; chorioretinitis: diffuse posterior uveitis and choroiditis; optic neuritis; sympathetic ophthalmia; anterior segment inflammation. 7. Gastrointestinal diseases Critical phase requiring systemic therapy in ulcerative colitis, regional enteritis 8. Respiratory diseases Symptomatic sarcoidosis; berylliosis; aspiration pneumonitis

		9. Hematologic diseases Acquired (autoimmune) hemolytic anemia 10. Neoplastic disorders For palliative management of leukemias and lymphomas in adults; acute leukemia of childhood. 11. Edema To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus. <u>Intra-Articular</u> SIVKORT® INJECTION is indicated for intra-articular or intra-bursal administration, and for injections into tendon sheaths, as adjunctive therapy for short-term administration in the following conditions: Synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; acute gouty arthritis; epicondylitis; acute nonspecific tenosynovitis; posttraumatic osteoarthritis.
BRU18092410P	Dotarem 0.5 mmol/mL, Solution For Injection	This medicinal product is for diagnostic use only. Dotarem should be used only when diagnostic information is essential and not available with unenhanced magnetic resonance imaging (MRI). Magnetic resonance for: • cerebral and spinal disease, • diseases of the vertebral column, and other whole body pathologies (including angiography).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18092411P	Polytet Eye Ointment	It is indicated for the treatment of superficial ocular infection involving the conjunctiva and/or cornea caused by Oxytetracycline with Polymyxin B Sulphate susceptible organisms. It may be administered topically alone, or as an adjunct to systemic therapy. It is effective in infections caused by susceptible strains of staphylococci, streptococci, pneumococci, *Haemophilus influenza* , *pseudomonas aeruginosa* , kochweeks bacillus, and Proteus.
BRU18092412P	IOPROST Latanoprost Eye Drops Solution 0.005% w/v	Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, chronic angle closure glaucoma and ocular hypertension.
BRU18092413NP	Eye Glo Relief Eye Drops 0.25% w/v	Eye Glo Relief is formulated to be used when your eyes are sore, swollen and watery eyes. The eye drops help to calm eyes that have become sore due to exposure to harsh conditions such as dust, strong wind, or when your eyes have been unprotected from chemicals like chlorine from swimming; or prolonged rubbing of the eyes.
BRU18092414NP	SW Aqueous Cream	It may be used as an emollient cream by itself or to serve as vehicle for other drugs.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18092415P	Axcel Cefuroxime-125 For Oral Suspension (125mg/5ml)	Upper respiratory tract infections (for example: ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis). Lower respiratory tract infections (for example: pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis). Genito-urinary tract infections (for example: pyelonephritis, cystitis and urethritis). Gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis. Skin and soft tissue infections (for example: furunculosis, pyoderma and impetigo). Treatment of early Lyme disease and subsequent prevention of late Lyme disease in adults and children over 12 years old.
BRU18092416P	Horf Lozenges	For the prophylaxis of stomatitis, gangrenous stomatitis, pharyngitis, laryngitis, tonsillitis, gingivitis, post-tonsillectomy and post tooth extraction secondary bacterial infections. For the temporary local relief of pain associated with dental conditions and sore throats.
BRU18092417NP; BRU18092417NPS2	Tiger Balm White Ointment	For the relief of headache, nasal congestion, insect bites, itchiness and flatulence.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18092418P	Prolia Solution For Injection 60mg/mL (Prefilled Syringe)	***Treatment of postmenopausal women with osteoporosis at high risk for fracture*** Prolia is indicated for the treatment of postmenopausal women with osteoporosis at high risk of fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures. ***Treatment of men with osteoporosis at high risk of fracture*** Prolia is indicated for the treatment of men with osteoporosis at high risk of fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other osteoporosis therapy. ***Treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer*** Prolia is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures. ***Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer*** Prolia is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for nonmetastatic breast cancer. ***Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.***
BRU18102420P	Simulect Lyophilisate For Injection 20mg Per Vial	Simulect is indicated for the prophylaxisof acute organ rejection in de novo renal transplantation in combination with ciclosporin and corticosteroid-based immunosuppression (in adults and children), or in combination with long-term immunosuppressive triple therapy with ciclosporin, corticosteroids and either azathioprine or mycophenolate mofetil (adults only).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18102421NP	SW Calcium Lactate Tablet 300mg	It is indicated as dietary calcium supplement in: a) Growing adolescents b) Pregnant women c) Post-menopausal women threatened with osteoporosis d) Elderly persons who are bedridden and thus facing slow calcium loss from the bones
BRU18102422P	Sulpin F.C. Tablets 200mg	For the treatment of acute and chronic schizophrenia.
BRU18102423P	Quetiapine Fumarate Tablets 25mg	Quetiapine tablet is indicated for the treatment of: Schizophrenia Bipolar disorder including: - manic episodes associated with bipolar disorder - major depressive episodes in bipolar disorder - preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18102424P	Quetiapine Fumarate Tablets 200mg	Quetiapine tablet is indicated for the treatment of: Schizophrenia Bipolar disorder including: - manic episodes associated with bipolar disorder - major depressive episodes in bipolar disorder - preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment.
BRU18102425P	Quetiapine Fumarate Tablets 100mg	Quetiapine tablet is indicated for the treatment of: Schizophrenia Bipolar disorder including: - manic episodes associated with bipolar disorder - major depressive episodes in bipolar disorder - preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to quetiapine treatment.
BRU18102427P	Hydrogen Peroxide Solution 6% w/v	It is used as a disinfectant, antiseptic and mouthwash.
BRU18102428P	Axcel Prednisolone-5mg EC Tablets	Rheumatic fever, rheumatoid arthritis, allergic diseases, nephritic syndrome, bronchial asthma and other corticosteroid-indicated conditions.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18102433P	Udoxan Injection (1ml Amp)	Induction of labour; inadequate uterine effort; management of third stage of labour; post-partum haemorrhage.
BRU18102435P	Ceftrex Injection 1g IV Ceftriaxone	CEFTREX is used for the treatment of infections caused by pathogens sensitive to ceftriaxone e.g.: • Lower respiratory tract infections • Skin and skin structure infections • Bone and joint infections • Intra-abdominal infections • Urinary tract infections • Meningitis, septicaemia and gonorrhoea caused by susceptible organisms
BRU18102437NP	Optrex Multi Action Eye Wash	Washes, soothes and cleanse to relieve tired, uncomfortable and irritated eyes.
BRU18102438NP	Optrex Rehydrating Eye Drops	Optrex Rehydrating Eye Drops: o Specially formulated to instantly rehydrate and lubricate dry eyes o Suitable for everyday use, even while using contact lenses

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18102439P	Candesartan Sandoz Tablet 8mg	Treatment of hypertension. Treatment of patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction ≤ 40%) as add-on therapy to ACE inhibitors or when ACE inhibitors are not tolerated.

		Melanoma KEYTRUDA (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma. KEYTRUDA is indicated for the treatment of adult and pediatric (12 years and older) patients with Stage IIB or IIC melanoma who have undergone complete resection. KEYTRUDA is indicated for the adjuvant treatment of patients with melanoma with lymph node involvement who have undergone complete resection. *Non-Small Cell Lung Carcinoma* KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic non-squamous non-small cell lung carcinoma (NSCLC), with no EGFR or ALK genomic tumor aberrations. KEYTRUDA, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of patients with metastatic squamous NSCLC. KEYTRUDA as monotherapy is indicated for the first-line treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 with a ≥1% tumor proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations. KEYTRUDA as monotherapy is indicated for the treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 with a ≥1% TPS as determined by a validated test and who have received platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have received prior therapy for these aberrations prior to receiving KEYTRUDA. KEYTRUDA as monotherapy is indicated for the adjuvant treatment of patients with Stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC who have undergone complete resection.

BRU18102440P; BRU18102440PS2	Keytruda 25mg/mL	*Head and Neck Cancer* KEYTRUDA, as monotherapy or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy, is indicated for the first-line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC). KEYTRUDA, as monotherapy, is indicated for the treatment of patients with metastatic or unresectable recurrent HNSCC with disease progression on or after platinum-containing chemotherapy. *Classical Hodgkin Lymphoma* KEYTRUDA is indicated for the treatment of adult and pediatric patients with relapsed or refractory classical Hodgkin lymphoma (cHL). *Urothelial Carcinoma* KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by a validated test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status. KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have received prior platinum-containing chemotherapy. KEYTRUDA is indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in-situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

		Esophageal Cancer KEYTRUDA, in combination with platinum and fluoropyrimidine based chemotherapy, is indicated for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or gastroesophageal junction. KEYTRUDA, as monotherapy, is indicated for the treatment of patients with recurrent locally advanced or metastatic esophageal cancer whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by a validated test, and who have received one prior line of systemic therapy. KEYTRUDA, as monotherapy, is indicated for the treatment of patients with recurrent locally advanced or metastatic esophageal cancer who have received two or more prior lines of systemic therapy. *Microsatellite Instability-High Cancer* KEYTRUDA is indicated for the treatment of patients with advanced microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, as determined by a validated test, who have received prior therapy. *Colorectal Cancer* KEYTRUDA is indicated for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) as determined by a validated test. *Hepatocellular Carcinoma* KEYTRUDA is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with an anti-angiogenic tyrosine kinase inhibitor (TKI) or oxaliplatin-based chemotherapy.

		Cervical Cancer KEYTRUDA, in combination with chemotherapy with or without bevacizumab, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer. *Renal Cell Carcinoma* KEYTRUDA, in combination with axitinib, is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC). KEYTRUDA, in combination with lenvatinib, is indicated for the first-line treatment of patients with advanced RCC. KEYTRUDA, as monotherapy, is indicated for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. *Endometrial Carcinoma* KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation. *Triple-Negative Breast Cancer* KEYTRUDA is indicated for the treatment of patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery. KEYTRUDA, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥ 10) as determined by a validated test.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18112441NP	African Sea Coconut Brand Cough MIxture	• Relieve cough due to o Cold o Flu o Tickling throat • Loosen phlegm • Soothes sore throat & irritated throat
BRU18112442P	Fresofol 2% MCT/LCT Emulsion For Injection Or Infusion	Fresofol 2% MCT/LCT is a short-acting intravenous general anaesthetic agent for - induction and maintenance of general anaesthesia - sedation of artificially ventilated patients in the Intensive Care Unit (ICU)
BRU18112443P	Fresofol 1% MCT/LCT Emulsion For Injection Or Infusion	Fresofol 1% MCT/LCT is a short-acting intravenous general anaesthetic agent for - induction and maintenance of general anaesthesia - sedation of artificially ventilated patients in the Intensive Care Unit (ICU)
BRU18112444NP	Surgical Spirit	As antiseptic and disinfectant of the skin before injections.
BRU18112445P	Androz 100 Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil to be effective, sexual stimulation is required.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18112446P	Androz 50 Tablet	Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil to be effective, sexual stimulation is required.
BRU18112447P	Verapime Powder For Solution For Injection 1g/Vial	Treatment of the following infections when caused by susceptible strains of bacteria: Lower respiratory tract infections (including pneumonia and bronchitis), urinary tract infections (both complicated, including pyelonephritis and uncomplicated infections), skin and skin structure infections; intra-abdominal infections (including peritonitis and biliary tract infections), gynecologic infections, septicemia, empiric treatment in febrile neutropenic patients. In pediatric patients for treatment of infections when caused by susceptible bacteria: Pneumonia, urinary tract infections (both complicated and uncomplicated, including pyelonephritis), skin and skin structure infections, septicemia, empiric treatment in febrile neutropenia.
BRU18112450PS1; BRU18112450PS2	Rebif Solution For Injection In Pre-Filled Cartridge 22mcg/0.5ml	Rebif is indicated for the treatment of relapsing multiple sclerosis. In clinical trials, this was characterised by two or more acute exacerbations in the previous two years. Efficacy has not been demonstrated in patients with secondary progressive multiple sclerosis without ongoing relapse activity.
BRU18112451PS1; BRU18112451PS2	Rebif Solution For Injection In Pre-Filled Cartridge 44mcg/0.5ml	Rebif is indicated for the treatment of • patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing relapsing multiple sclerosis • patients with relapsing multiple sclerosis. In clinical trials, this was characterised by two or more acute exacerbations in the previous two years Efficacy has not been demonstrated in patients with secondary progressive multiple sclerosis without ongoing relapse activity.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18112452P	Nelin 150mg/1.5mL Injection	NELIN injection is indicated in the treatment of infections caused by susceptible strains of the above microorganisms (refer to section of package insert under PHARMACODYNAMICS). Clinical studies have shown NELIN to be effective in: - Bacteremia, septicemia - Serious infections of the respiratory tract - Kidney and genitourinary tract infections - Skin, soft tissue infections - Bone, joint infections - Burns, wounds, peri-operative infections - Intra-abdominal infection (including peritonitis) - Infections of gastrointestinal tract NELIN injection is recommended as initial therapy in suspected or confirmed gram-negative infection. In serious infections when the causative organisms are unknown. NELIN injection may be administered as initial therapy in conjunction with a penicillin or cephalosporin type drug before, obtaining results of susceptibility testing. If anaerobic organisms are suspected suitable anti-microbial therapy in conjunction with NELIN injection should be given. Following identification of the organism and its susceptibility, NELIN injection or other appropriate antibiotic therapy should then be continued.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18112453P	Midazolam-Hameln 5mg/ml Injection, 3ml	Midazolam is a short-acting sleep-inducing drug that is indicated as follows: *In adults* • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia - Induction of anaesthesia - As a sedative component in combined anaesthesia. • SEDATION IN INTENSIVE CARE UNITS *In Paediatrics* • CONSCIOUS SEDATION before and during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of Anaesthesia • SEDATION IN INTENSIVE CARE UNITS
BRU18112454P	Apo-Atenidone Tablets 100/25mg	Management of hypertension.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18112459P	Ificipro 250mg Tablets	Consideration should be given to available official guidance on the appropriate use of antibacterial agents. Uncomplicated and complicated infections caused by ciprofloxacin susceptible pathogens. Infections of the respiratory tract: Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, E.coli, Pseudomonas, Haemophilus, Moraxella, catarrhalis, Legionella and Staphylococcus. Infections of the middle ear (otitis media)*, of the paranasal sinuses (sinusitis)*, especially if these are caused by Gram-negative organisms including Pseudomonas aeruginosa or by staphylococci. Infections of the eyes Infections of the kidneys and/or the efferent urinary tract Infections of the genital organs, including adnexitis, gonorrhea, prostatitis Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or of the biliary tract, peritonitis) Infections of the skin and soft tissue Infections of the bones and joints Sepsis Infections or imminent risk of infection (prophlaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or have neutropenia) Selective intestinal decontamination in immunosuppressed patients *Ificipro 250/500 should be only used: When Pseudomonas is considered AND the patient is allergic to antipseudomonal penicillins/cephalosporins; For resistant organisms with no other alternative antibiotics available.

		Rheumatoid Arthritis Humira is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Humira is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with disease modifying anti-rheumatic drugs. **Axial Spondyloarthritis** **Ankylosing Spondylitis** Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Non-radiographic Axial spondyloarthritis (Axial Spondyloarthritis without radiographic evidence of AS)** Humira is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. **Plaque Psoriasis** Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate.

BRU18112460P; BRU18112460PS2	Humira 40mg/0.4ml Solution For Injection	**Crohn's Disease** Humira is indicated for the treatment of moderately to severely active Crohn's Disease in adult patients who have inadequate response to conventional therapy. Humira is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab. **Ulcerative colitis** Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Hidradenitis Suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate. **<u>Paediatrics</u>** **Juvenile idiopathic arthritis** **Polyarticular Juvenile Idiopathic Arthritis** Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

		Enthesitis-Related Arthritis Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. **Paediatric Crohn's Disease** Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindication for such therapies. **Paediatric Plaque Psoriasis** Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Paediatric Uveitis** Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. **Adolescent hidradenitis suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Ulcerative Colitis** Humira is indicated for inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18112461P	Imach Injection 1ml	Allergy in acute urticaria, insect bites and stings, drug and serum reactions, desensitisation reactions, hay fever, vasometer rhinitis, pruritis.
BRU18112462NP	Silverderm Cream	For prevention and treatment of infection in burn wounds. It has also been used as an aid to the short-term treatment in other skin conditions, such as leg ulcers where infections may prevent healing and as an aid to prophylaxis of infection in skin grafting.
BRU18112463P	Granisetron-AFT Solution For Injection 1mg/ml	GRANISETRON-AFT is indicated for the prevention or treatment of nausea and vomiting induced by cytostatic therapy.
BRU18112464P	Lenvima 4mg Hard Capsule	LENVIMA is indicated for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hurthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). LENVIMA is indicated in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy. LENVIMA is indicated as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18112465P	Lenvima 10mg Hard Capsule	LENVIMA is indicated for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hurthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI). LENVIMA is indicated in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy. LENVIMA is indicated as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy.
BRU18112466P	Kisqali 200mg Film-Coated Tablet	KISQALI is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine-based therapy in pre/perimenopausal or postmenopausal women or in men; or • fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18112467P	Zylovaa Tablet 50mg	• Hypertension Zylovaa is indicated for the treatment of hypertension. • Hypertensive patients with left ventricular hypertrophy Zylovaa is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. • Nephropathy in Type 2 Diabetic Patients Indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio 300mg/g or more) in patients with type 2 diabetes and a history of hypertension. In this population, Zylovaa reduces the rate of progression of nephropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation) or death.
BRU18122468P	Cloxabiotic Injection 500mg	Cloxacillin is indicated for the treatment of:- -Skin and soft tissue infections caused by pneumococci -Upper and lower respiratory tract infection

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18122469P	Losartan Potassium Tablet 50mg	Hypertension: Losartan is indicated for the treatment of hypertension. Reduction in the Risk of Cardiovascular Morbidity and Mortality in Hypertensive Patients with Left Ventricular Hypertrophy: Losartan is indicated to reduce the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke, and myocardial infarction in hypertensive patients with left ventricular hypertrophy. Heart Failure: Losartan is indicated for the treatment of heart failure in patients who cannot tolerate an ACE inhibitor. Switching patients with heart failure who are stable on an ACE Inhibitor to Losartan is not recommended. Renal Protection in Type 2 Diabetic Patients with Proteinuria: Losartan is indicated to delay the progression of renal disease as measured by a reduction in the combined incidence of doubling of serum creatinine, end stage renal disease (need for dialysis or renal transplantation) or death; and to reduce proteinuria.
BRU18122470P	Losartan Potassium Tablet 100mg	Hypertension: Losartan is indicated for the treatment of hypertension. Reduction in the Risk of Cardiovascular Morbidity and Mortality in Hypertensive Patients with Left Ventricular Hypertrophy: Losartan is indicated to reduce the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke, and myocardial infarction in hypertensive patients with left ventricular hypertrophy. Heart Failure: Losartan is indicated for the treatment of heart failure in patients who cannot tolerate an ACE inhibitor. Switching patients with heart failure who are stable on an ACE Inhibitor to Losartan is not recommended. Renal Protection in Type 2 Diabetic Patients with Proteinuria: Losartan is indicated to delay the progression of renal disease as measured by a reduction in the combined incidence of doubling of serum creatinine, end stage renal disease (need for dialysis or renal transplantation) or death; and to reduce proteinuria.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18122471P	Injecsol LIG2 (Lignocaine Hydrochloride Injection 2% w/v)	Lignocaine is a local anaesthetic of the amide group. Lignocaine Hydrochloride Injection is for use in infiltration anaesthetic, intravenous regional anaesthesia and nerve blocks. Treatment or prophylaxis of life-threatening ventricular arrhythmias, including those associated with myocardial infarction, general anaesthesia in patients predisposed to ventricular arrhythmias, digitalis intoxication, or following resuscitation from cardiac arrest.
BRU18122472NP	Injecsol S20 (Sodium Chloride 20% w/v Injection BP)	Electrolyte rebalance when small supplementation of water is desired, in slow intravenous infusion. Sodium supplementation with reduced volume in solutions for parenteral nutrition.
BRU18122473NP	Dyna Ferrous Fumarate Tablet	For the treatment or prophylaxis of iron deficiency anaemia.
BRU18122474P	Oxynorm 5mg Capsules	The management of opioid responsive, moderate to severe pain.
BRU18122475P	Oxynorm 10mg Capsules	The management of opioid responsive, moderate to severe pain.
BRU18122480PS1; BRU18122480PS2	Mucodin Tablet 375mg	Mucolytic agents for adjunctive therapy of respiratory disorders.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU18122482NP	Belcid Suspension	BELCID is used as an antacid, antiflatulent and demulcent in gastric hyperacidity, heartburn and used in the symptomatic relief of peptic and duodenal ulcer pains.
BRU18122484NP	Mifulin Lotion	For treatment of corns, warts and ringworm.
BRU18122485P	Ketazon Shampoo	Reduction of scaling due to dandruff, seborrheic dermatitis and pityriasis versicolor.
BRU18122486P	Duratocin® RTS 100 mcg/ml	Prevention of postpartum haemorrhage due to uterine atony.
BRU18122487NP	Alucid Suspension	• **Alucid Suspension** can be used for relief of gastric pain, hyperacidity, flatulence and heartburn. • **Alucid Suspension** will relieve and control pain in the symptomatic management of gastric and duodenal ulcers and reflux oesophagitis by neutralising hydrochloric acid in gastric secretion. • **Alucid Suspension** is also suitable as a domestic remedy in conditions affecting the stomach which may not necessarily be related to hyperacidity.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19012488P	Benzapen 2.4MIU Injection	Intramuscular Benzathine Benzylpenicillin is indicated in the treatment of infections due to penicillin-sensitive micro-organisms that are susceptible to the low and very prolonged serum levels common to this particular dosage form. The following infections will usually respond to adequate dosage of intramuscular Benzathine Benzylpenicllin: • Mild-to-moderate infections of the upper-respiratory tract due to susceptible streptococci • Venereal infections – Syphilis, yaws, bejel and pinta Medical conditions in which Penicillin G Benzathine Therapy is indicated as Prophylaxis: • Rheumatic fever and/or chorea – Prophylaxis with penicillin G benzathine has proven effective in preventing recurrence of these conditions • It has also been used as follow-up prophylactic therapy for rheumatic heart disease and acute glomerulonephritis.
BRU19012489NP	Vitbion Forte Tablet	It is used as a supplement in the treatment of polyneuritis, neuralgias, diabetic neuropathy, drug induced neuropathy.
BRU19012491P	Fentanyl-Hameln 50 mcg/ml Injection	Fentanyl is indicated: • for use as an opioid analgesic supplement in general or regional anaesthesia. • for administration with a neuroleptic as an anaesthetic premedication, for the induction of anaesthesia, and as an adjunct in the maintenance of general and regional anaesthesia. • for use as an anaesthetic agent with oxygen in selected high-risk patients undergoing major surgery.
BRU19012492P	Axinol Tablet 20mg	Axinol is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19012493P	HCQS (Hydroxychloroquine Tablets BP 200mg)	Hydroxychloroquine is indicated for o Acute or chronic rheumatoid arthritis o Systemic and discoid lupus erythematosus

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19012494P	Vaxcel Cefepime 1g Injection	Adults: Vaxcel Cefepime 1g Injection is indicated in adults for the treatment of the following infections when caused by susceptible strains of bacteria: Lower respiratory tract infections (including pneumonia and bronchitis). Urinary tract infections (both complicated, including pyelonephritis and uncomplicated infections). Skin and skin structure infections. Intra-abdominal infections (including peritonitis and biliary tract infections). Gynecologic infections. Septicemia. Empiric treatment in febrile neutropenic patients. Peadiatrics: Vaxcel Cefepime 1g Injection is indicated in pediatric patients for treatment of infections when caused by susceptible bacteria: Pneumonia Urinary tract infections (both complicated and uncomplicated, including pyelonephritis) Skin and skin structure infections Septicemia Empiric treatment in febrile neutropenia Culture and susceptibility studies should be performed when appropriate to determine susceptibility of the causative organism(s) to cefepime. Empiric therapy with Vaxcel Cefepime may be instituted before results of susceptibility studies are known; however, once these results become available, the antibiotic treatment should be adjusted accordingly. Because of its broad spectrum of bactericidal activity against gram-positive and gram-negative bacteria, Vaxcel Cefepime can be used as monotherapy prior to identification of the causative organisms(s). In patients who are at risk of mixed aerobic-anaerobic infection, particularly if bacteria not susceptible to cefepime may be present, concurrent initial therapy with anti-anaerobic agent is recommended before the causative agents may or may not be necessary, depending on the susceptibility profile.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19012495NP	Three Legs Povidone Iodine	For the treatment of wounds, cuts, abrasions and minor skin infections.
BRU19012496P	Altra™ Tablet 10mg	• Chronic and prophylaxis treatment of asthma in adults • Symptomatic relief of seasonal allergic rhinitis in adults
BRU19012497P	Axcel Flemin Junior Expectorant	Relief of cough and alleviation of nasal and bronchial congestion.
BRU19012498NP	Visipaque 320mg I/ml, Solution For Injection	X-ray contrast medium for cardio angiography, cerebral angiography (conventional), peripheral arteriography (conventional), abdominal angiography (i.a.DSA), urography, venography, CT-enhancement. Lumbar, thoracic and cervical myelography.
BRU19012499PS1; BRU19012499PS2	Albunorm 20%, 200g/l, Solution For Infusion	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19012500PS1; BRU19012500PS2	Albunorm 5%, 50g/l, Solution For Infusion	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.
BRU19012501PS1; BRU19012501PS2	Albunorm 25%, 250g/l, Solution For Infusion	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.
BRU19012502P	Vaxigrip Tetra Suspension For Injection In Pre-Filled Syringe	VaxigripTetra is indicated for active immunisation of adults and children from 6 months of age and older for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19012503NP	Regiocit Solution For Haemofiltration	Regiocit solution is indicated as replacement fluid before dialyzer for continuous renal replacement therapy (CRRT) using regional citrate anticoagulation. Citrate is particularly relevant when systemic anticoagulation with heparin is contraindicated, for example in patients with increased bleeding risks. In paediatric patients, Regiocit solution is indicated in all age groups provided that the equipment used is adapted to the weight of the child.
BRU19012504P	Pyronium Injection 200mcg/ml	1) To protect against the peripheral muscarinic actions of anticholinesterases such as neostigmine and pyridostigmine used to reverse residual neuromuscular blockade produced by non-depolarising muscle relaxants; 2) As a preoperative antimuscarinic agent to reduce salivary, tracheobronchial and pharyngeal secretions, and to reduce the acidity of the gastric contents; 3) As a preoperative or intraoperative antimuscarinic to attenuate or prevent intraoperative bradycardia associated with the use of suxamethonium or due to cardiac vagal reflexes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19012505P	Herceptin Solution For Injection 600mg/5ml	*Metastatic Breast Cancer (MBC)* Herceptin is indicated for the treatment of patients with metastatic breast cancer who have tumors that overexpress HER2: a) as monotherapy for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease b) in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease c) in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer, not previously treated with trastuzumab. This indication is based on data from one Phase III trial which studied the use of Herceptin in combination with anastrozole. Experience with other aromatase inhibitors is limited. *Early Breast Cancer (EBC)* Herceptin is indicated for the treatment of patients with HER2 positive early breast cancer. - following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). - following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel. - in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin. - in combination with neoadjuvant chemotherapy followed by adjuvant Herceptin therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter. Herceptin should only be used in patients whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19022507P	Apo-Fluconazole 100mg Tablets	APO-FLUCONAZOLE (Fluconazole) is indicated for the treatment of: 1. Oropharyngeal and esophageal candidiasis. APO-FLUCONAZOLE is also effective for the treatment of serious systemic candidal infections, including urinary tract infection, peritonitis, pneumonia. 2. Cryptococcal meningitis 3. Prevention of the recurrence of cryptococcal meningitis in patients with acquired immunodeficiency syndrome (AIDS). APO-FLUCONAZOLE is also indicated to decrease the incidence of candidiasis in patients undergoing bone marrow transplantation who receive cytotoxic chemotherapy and/or radiation therapy.
BRU19022508NP	Nutrilite Iron Folic Tablet	As dietary supplement.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19022509P	Cefatum Injection 1g	Ceftazidime is indicated for the treatment of single and mixed infections caused by susceptible aerobic organisms with suspected resistance to other antimicrobials, but not to ceftazidime, as an alternative to aminoglycosides in pseudomonal infection in patients in whom aminoglycosides toxicity is a cause for concern and other pseudomonal antibiotics cannot be used. Indications include: Septicaemia including neonatal sepsis. Bacteraemia e.g. infected burns. Respiratory infections: pneumonia, broncho-pneumonia, infected pleurisy, infected bronchiectasis and bronchitis. Severe ear, nose and throat infections: otitis media, mastoiditis. Urinary tract infections: acute and chronic pyelonephritis, pyelitis, cystitis, urethritis (bacterial only) and infections associated with bladder and renal stones. Skin and soft tissue infections: erysipelas, abscesses, cellulitis, infected burns and wounds, mastitis. Gastro-intestinal and abdominal infections: intra-abdominal abscesses, enterocolitis. Bone and joint infections: osteitis, osteomyelitis, septic arthritis, infected bursitis.
BRU19022510NP	Hovid-Folic Acid Tablets 5mg	For the prevention and treatment of folate deficiency states, For the prevention of neural tube defect in the foetus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19022511P	Clopine 100mg Tablet	The use of clozapine is indicated in the treatment of resistant schizophrenic patients only, ie. Schizophrenic patients who are non-responsive to or intolerant of classical neuroleptics. Non-responsiveness is defined as lack of satisfactory clinical improvement despite the use of adequate doses of at least two marketed neuroleptics prescribed for adequate durations. Intolerance is defined as the impossibility of achieving adequate clinical benefit with classical neuroleptic drugs because of severe and untreatable neurological adverse reactions (extrapyramidal side effects or tardive dyskinesia). Clozapine is also indicated for reducing the risk of recurrent suicidal behavior in patients with schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behavior, based on history and recent clinical state.
BRU19022512P	Vaxcel Omeprazole 40mg Injection	Duodenal ulcer, gastric ulcer reflux oesophagitis and Zollinger-Ellison Syndrome.
BRU19022513NP	Medon 500 Capsule	For the relief of fever, headache and pain associated with common cold.
BRU19022515NP	Paracetamol-AFT Solution For Infusion 10mg/ml	Indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19022516P	Domi Injection 15mg (3ml Amp)	Intravenously as an agent for conscious sedation prior to short surgical, diagnostic, therapeutic or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography and cardiac characterisation, either alone or in conjunction with a narcotic. Intravenously for induction of anaesthesia, preliminary to administration of other anaesthetic agents. With the use of a narcotic premedicant, induction of anaesthesia can be attained with a narrower dose range and in shorter period of time. Sedation in intensive care units by intravenous intermittent administration or continuous infusion. Intramuscularly for preoperative sedation (induction of sleepiness or drowsiness and relief of apprehension) and to impair memory of perioperative events.
BRU19022519P	Chloroquine Tablets 250mg	Chloroquine is used for the suppression and treatment of malaria. It is especially active against the erythrocytic forms of malaria. It is not active against tissue forms of the malaria parasites.
BRU19022520P	Keno Oral Paste	Keno Oral Paste is indicated for the adjunctive treatment and for the temporary relief of symptoms associated with inflammatory or ulcerative lesions of oral mucosa resulting from trauma.
BRU19022521P	Atracurium-Hameln 10mg/ml Injection, 2.5ml	Intravenous use during surgical and other procedures and in intensive care. Atracurium besilate is used as an adjunct to general anaesthesia, to facilitate tracheal intubation and controlled ventilation.
BRU19022522NP	Kidz PCM 250 Suspension (Strawberry)	For the relief of fever and mild to moderate pain in children, including headache and toothache.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19022523NP	Povil Antacid Tablet	For the relief of gastrointestinal conditions including gastric hyperacidity, peptic ulcer, heartburn, dyspepsia and flatulence.
BRU19022524P	Inlyta® 1mg Film-Coated Tablet	Axitinib is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.
BRU19022525P	Inlyta® 5mg Film-Coated Tablet	Axitinib is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.
BRU19022527NP	Paracil Suspension 250mg/5ml	1. Relief of fever and discomfort associated with common cold and flu 2. Relief of teething pain, toothache and earache
BRU19022528P	DTI For Injection 200mg	Metastatic malignant melanoma, Hodgkin's disease, soft-tissue sarcoma including leiomyosarcoma.
BRU19022529P	Sildegra 100mg Tablets	Sildenafil is indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil to be effective, sexual stimulation is required.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19032530P	Imexa Powder For Oral Suspension 200mg/5ml	Imexa is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present). In sexually transmitted diseases in men and women, Imexa is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated in the treatment of uncomplicated genital infection due to non-multiresistant *Neisseria gonorrhoea* , concurrent infection with Treponema pallidum should be excluded. Imexa is indicated, either alone or in combination with rifabutin, for prophylaxis against *Mycobacterium avium – Intracellulare complex* (MAC) infection, an opportunistic infection prevalent in patients with advanced human immunodeficiency virus (HIV).
BRU19032531P	Dysolvon Syrup (Raspberry)	Administered in bronchitis and other respiratory conditions to aid expectoration. Reduction of sputum-viscosity.
BRU19032532NP	Paracil Tablet 500mg	1) Relief of fever and discomfort associated with the common cold and flu. 2) Relief of teething pain, toothache and earache.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19032533NP	Three Legs Ai Kan Shan Fever Powder Paracetamol 500mg/Sachet	For relief of fever, headache, toothache and mild to moderate pain.
BRU19032534NP	Dyna Calamine Lotion	Indicated in the relief of itchiness associated with prickly heat, acne, insect bites and sunburn.
BRU19032535P	Gazyva Concentrate For Solution For Infusion	**Chronic Lymphocytic Leukaemia** Gazyva in combination with chlorambucil is indicated for the treatment of patients with previously untreated chronic lymphocytic leukaemia (CLL). **Follicular Lymphoma** GAZYVA in combination in chemotherapy, followed by GAZYVA maintenance in patients achieving a response, is indicated for the treatment of patients with previously untreated advanced follicular lymphoma. Gazyva in combination with bendamustine, followed by Gazyva maintenance is indicated for the treatment of patients with follicular lymphoma (FL) who did not respond to, or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen.
BRU19032536P	Pyrimine Tablet 60mg	Pyrimine Tablet 60mg is indicated in the treatment of Myasthenia Gravis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19032538NP	U-Lite Effervescent Granules	U-Lite Effervescent Granules is indicated to relieve the burning discomfort caused by mild urinary tract infections. It also helps to reduce the formation of uric acid and cystine calculi in chronic gout. It may enhance the action of certain antibiotics such as Sulphonamide and relieves symptoms associated with gastric hyperacidity.
BRU19032539P	Coldmax Suspension	Coldmax Suspension relieves common cold and flu symptoms including fever and pain, headache, body aches, nasal congestion and runny nose. It also relieves allergies symptoms such as sneezing, itching and watery eyes.
BRU19032540NP	Kidz PCM 250 Suspension (Orange)	For the relief of fever and mild to moderate pain in children, including headache and toothache.
BRU19032541NP	Uni-Ma Enema Solution	Relief of occasional constipation. Part of bowel cleansing regimen in preparing the colon for surgery, x-ray, or endoscopic examination.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19032542P	Ciprocep Tablet 250mg	Ciprocep is indicated for infections caused by ciprofloxacin-sensitive pathogens: • The respiratory tract: In the treatment of outpatients with pneumonia due to Pneumococcus, Ciprocep should not be used as a first drug of choice. Ciprocep can be regarded as an advisable treatment for pneumonias caused by Klebsiella, Enterobacter, Proteus, Pseudomonas, Haemophilus, Branhamella, Legionella and Staphylococcus. • Middle ear (otitis media) and paranasal sinuses (sinusitis), especially if these are caused by gram-negative organisms including Pseudomonas, or by Staphylococcus. • The eyes: kidney and/or the efferent urinary tract; genital organs, including gonorrhoea and chronic bacterial prostatitis; abdominal cavity (eg. Bacterial infections of the gastrointestinal tract or of the biliary tract, peritonitis); the skin and soft tissue; bones and joints • Sepsis • Prophylaxis in those patients whose immune system has been weakened (eg. Patients on immunosuppressant or in a state of neutropenia) • Selective intestinal decontamination in immunosuppressed patients • Inhalation anthrax (post-exposure): To reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis The following pathogens can be regarded as sensitive: E.coli, Shigella, Salmonella, Citrobacter, Klebsiella, Enterobacter, Serratia, Hafnia, Edwardsiella, Proteus (indole-positive and indole-negative), Providencia, Morganella, Yersinia, Vibrio, Aeromonas, Plesiomonas, Pasteurella, Haemophilus, Campylobacter, Pseudomonas, Legionella, Neisseria, Moraxella, Acinetobacter, Brucella, Staphylococcus, Listeria, Corynebacterium, Chlamydia. The following pathogens show varying degrees of sensitivity: Gardnerella, Flavobacterium, Alcaligenes, Streptococcus pyogenes, Enterococcus faecalis, Streptococcus agalactiae, Streptococcus pneumoniae, Mycoplasma hominis, and Mycobacterium. The following pathogens are usually resistant: Ureaplasma urealyticum, Clostridium difficile, Nocardia asteroides. Insufficient data are available on the efficacy of Ciprocep against Treponema pallidum.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19032543P	Ferriprox 1000mg Film Coated Tablet	Ferriprox is indicated for the treatment of patients with transfusional iron overload due to thalassaemia syndromes when current chelation therapy is inadequate.
BRU19032544P	Octocaine 100	OCTOCAINE Solutions are indicated for the production of local anaesthesia for dental procedures by nerve block or infiltration techniques.
BRU19032545NP	Aniosgel 85 NPC	Thxotropic hydroalcoholic gel for hygienic treatment and surgical disinfection of hands by rubbing.
BRU19032546NP	Antiphlamine S Lotion	For the temporary relief of minor aches and pains of muscles, simple backaches, strains and sprains.
BRU19032547NP	Woods Peppermint Cough Syrup For Children	Woods' Peppermint Cough Syrup for Children provides relief of wet, productive cough. It helps loosen phlegm and thins bronchial secretions to rid bronchial passageways of bothersome mucus and make cough more productive.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19032548NP	Xubil Oral Solution	• For the relief of occasional constipation • For use as part of a bowel cleansing regiment in preparing the patient for surgery or for preparing the colon or endoscopic examination
BRU19042549P	Oxytocin-Richter Solution For Injection 10 IU/1ml	*Antepartum* • Induction of labour for medical reasons, e.g. in cases of post-term gestation, premature rupture of the membranes, pregnancy-induced hypertension (pre-eclampsia) • Stimulation of labour in hypotonic uterine inertia • Early stages of pregnancy as adjunctive therapy for the management of incomplete, inevitable, or missed abortion. *Postpartum* • During caesarean section, but following delivery of the child • Prevention and treatment of postpartum uterine atony and haemorrhage
BRU19042550P	Vivic Tablet 100mg	Vivic is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19042551P	Requip PD 24 Hour Prolonged Release Tablet 4mg	• REQUIP PD 24 HOUR is indicated for the treatment of idiopathic Parkinson's disease • REQUIP PD 24 HOUR may be used alone (without Levodopa [L-Dopa]) in the treatment of idiopathic Parkinson's disease. • Addition of REQUIP PD 24 HOUR to levodopa may be used to control 'on-off' fluctuations and permit a reduction in the total daily dose of L-Dopa.
BRU19042552NP	Axcel Folic Acid Tablet 5mg	Folic acid is a member of the vitamin-B group. It is necessary for the normal production and maturation of red blood cells. Folic acid produces a haemopoietic response in nutritional macrocytic anaemia, megaloblastic anaemia of infancy, and the anaemias of pregnancy, pellagra, and sprue, and that following gastrectomy, and in pernicious anaemia.
BRU19042553P	Maxigesic Tablet 500mg/150mg	Maxigesic tablets are indicated for temporary relief of pain associated with: headache, migraine, backache, period pain, dental pain, muscular pain, cold and flu symptoms, sore throat and fever.
BRU19042555P	Clavomax 625mg Tablet	Clavomax is indicated for the treatment of common bacterial infections where antibiotic therapy is indicated including: 1) Lower upper respiratory tract infections (including ENT) e.g. Sinusitis, tonsillitis, otitis media 2) Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis, lobar and bronchpneumonia 3) Skin and soft tissue infections e.g. boils/abcesses, cellulitis and would infections 4) Genito-urinary tract infections e.g. Cystitis, urethritis, pyelonephritis 5) Bone and joint infections e.g. osteomyelitis 6) Other infections: intra-abdominal sepsis

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19042556P	Chlorop Eye Ointment 1%	Indicated for the treatment of ocular infections involving the conjunctiva and/or cornea caused by chloramphenicol susceptible organisms. Chloramphenicol should be used only in serious infections for which less potent drugs are ineffective or contraindicated.
BRU19042557P	Akoset Injection 20mg/2ml	For the treatment of the oedema associated with congestive heart failure, cirrhosis of the liver and renal disease, including the nephrotic syndrome. Particularly useful when an agent with greater diuretic potential than that of the more commonly used agents is desired. Intravenous administration is indicated when a rapid onset of diuresis is desired, e.g. acute pulmonary oedema. Intramuscular or intravenous route is indicated if gastrointestinal absorption is impaired or oral medication is not practicable for any reason. Note: Parenteral administration should be reserved for patients with whom oral medication Is not practical.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19042558P	Lipiodol Ultra Fluid 480mg I/ml, Solution For Injection	<u>In diagnostic radiology</u> Lymphography. Diagnosis of liver lesions. Diagnosis of the spread of malignant lesions, whether hepatic or not, by selective hepatic arterial injection. <u>In interventional radiology</u> Visualisation, localisation and vectorisation during Trans-Arterial Chemo-Embolisation (TACE) of hepatocellular carcinoma at intermediate stage, in adults. Embolization with surgical glues. In association with surgical glues during vascular embolizations. <u>In endocrinology</u> The use of Lipiodol in prevention of iodine deficiency disorders should exclusively be reserved to countries in which other methods of supplementation, particularly iodization of salt and/or drinking water, cannot be undertaken.
BRU19042559NP	Povil Antacid Mixture (Peppermint)	For the relief of gastric pain and discomforts of peptic ulcer, heartburn, dyspepsia (indigestion) and acid reflux.
BRU19042560P	Betacort Cream 0.1% w/w	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses e.g. psoriasis, eczemas, pruritus, contact dermatitis, neurodermatitis, lichen planus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19042563P	Apo-Amilzide Tablet	Fixed-dose combination drugs are not indicated for initial therapy. Patients should be titrated on the individual drugs. If the fixed combination represents the dosage so determined, its use may be more convenient in patient management. If during maintenance therapy dosage adjustment is necessary, it is advisable to use the individual drugs. APO-Amilzide (hydrochlorothiazide and amiloride hydrochloride) is indicated in the maintenance therapy of patients with hepatic cirrhosis with ascites and oedema. Patients with oedema of cardiac origin or with arterial hypertension who are hypokalaemic or in whom maintenance of normal potassium levels is considered to be clinically important, i.e. digitalized patients, patients in whom adequate dietary intake of potassium is not feasible or patients with cardiac arrhythmias. Use in Hepatic Cirrhosis with Ascites and Oedema: Amiloride hydrochloride used alone may provide satisfactory diuresis with diminished potassium loss and with a reduced risk of metabolic alkalosis. In resistant cases, amiloride hydrochloride may be used with kaliuretic diuretic agents to help produce satisfactory diuretics, while maintaining a more balanced serum electrolyte pattern. As with all therapy for the ascites of hepatic cirrhosis, gradual weight loss and avoidance of electrolyte imbalance are the chief objectives.

BRU19042564P	Tenof-EM Tablet	**Treatment of HIV-1 infection:** Emtricitabine and Tenofovir disoproxil fumarate is indicated in combination with other antiretroviral agents (such as non-nucleoside reverse transcriptase inhibitors or protease inhibitors) for the treatment of HIV-1 infection in adults. The following points should be considered when initiating therapy with Emtricitabine and Tenofovir disoproxil fumarate for the treatment of HIV-1 infection: • It is not recommended that Emtricitabine and Tenofovir disoproxil fumarate be used as a component of a triple nucleoside regimen. • Emtricitabine and Tenofovir disoproxil fumarate should not be co-administered with lamivudine+tenofovir DF+Efavirenz, emtricitabine, tenofovir DF or lamivudine-containing products. In treatment experienced patients, the use of Emtricitabine and Tenofovir disoproxil fumarate should be guided by laboratory testing and treatment history. **Pre-exposure prophylaxis (PrEP):** Emtricitabine/Tenofovir Disoproxil is indicated in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. When prescribing TENOF-EM for PrEP, healthcare providers must: - prescribe TENOF-EM as part of a comprehensive prevention strategy because emtricitabine/tenofovir disoproxil is not always effective in preventing the acquisition of HIV-1 infection. - counsel all uninfected individuals to strictly adhere to the recommended TENOF-EM dosing schedule because the effectiveness of emtricitabine/tenofovir disoproxil in reducing the risk of acquiring HIV-1 was strongly correlated with adherence as demonstrated by measurable drug levels in clinical trials. - confirm a negative HIV-1 test immediately prior to initiating TENOF-EM for a PrEP indication. If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposures are suspected, delay starting PrEP for at least one month and reconfirm HIV-1 status, including acute or primary HIV-1 infection; and - screen for HIV-1 infection at least once every 3 months while taking emtricitabine/tenofovir disoproxil for PrEP.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19042565P	Freederm Lotion	Once daily antifungal treatment for tinea and other fungal skin infections – athlete's foot (tinea pedis), jock itch (tinea curis), ringworm (tinea corporis), Pityriasis versicolor and fungal nail infection (cutaneous candidiasis).
BRU19042566NP	Yellow Lotion 0.4%	Antiseptic for the treatment of infected wounds, cuts, burns or for skin disinfection.
BRU19042569P	Lamitor 50mg Tablet	LAMITOR is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalized seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome.
BRU19042570P	Onsia Tablet 8mg	• For the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy; • For the prevention of post-operative nausea and vomiting. For treatment of established post-operative nausea and vomiting, administration by injection is recommended.
BRU19042571P	Tivicay 50mg Film-Coated Tablets	Tivicay is indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19042574P: BRU19042574PS2	Spiriva Respimat 2.5mcg Solution For Inhalation	<u>COPD</u> Tiotropium is indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD). <u>Asthma</u> Spiriva Respimat is indicated as an add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year.
BRU19042575P	Lavudin Standard F.C. Tablet 100mg	Lamivudine is indicated for the treatment of patients ≥ 16 years of age with chronic hepatitis B and evidence of hepatitis B virus (HBV) replication with one or more of the following conditions: - Elevated serum alanine aminotransferase (ALT) ≥ 2 times normal - Liver cirrhosis - Decompensated liver disease - Biopsy-proven necro-inflammatory liver disease - Immunocompromised state - Liver transplant

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19042576P	Faslodex Solution For Injection 250mg/5ml	Faslodex is indicated: • as monotherapy for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women: - who are human epidermal growth factor receptor 2 (HER2)-negative and not previously treated with endocrine therapy. - with disease relapse on or after adjuvant endocrine therapy, or disease progression on endocrine therapy. • in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy. In pre- or perimenopausal women, the combination treatment with palbociclib should be combined with a luteinizing hormone releasing hormone (LHRH) agonist.
BRU19042577NP	Multibic Potassium-Free Solution For Haemodialysis/Haemofiltration (Solution, Sterile)	multiBic® potassium-free is a solution for haemofiltration (removal of waste products from the body in people with kidney disease). It is used in patients with acute kidney failure. The type of solution you are given depends on the amount of potassium (a salt) in your blood. Your doctor will check your potassium levels regularly.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19052578P	Pregeb Capsules 75mg	Neuropathic Pain: Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy: Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder: Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. Fibromyalgia: Pregabalin is indicated for the management of fibromyalgia.
BRU19052579NP	Omnipaque 300mg l/mL, Solution For Injection/Infusion	X-ray contrast medium for use in adults and children for cardioangiography, arteriography, urography, phlebography and CT-enhancement. Lumbar, thoracic, cervical myelography and computed tomography of the basal cisterns, following subarachnoid injection. Arthrography, endoscopic retrograde pancreatography, (ERP), endoscopic retrograde cholangiopancreatography (ERCP), herniography, hysterosalpingography, sialography and studies of the gastrointestinal tract. Contrast-enhanced mammography (CEM) in adult women to assess and detect known or suspect lesions in the breast, – as an addition to mammography (with or without ultrasound) or – as an alternative to magnetic resonance imaging (MRI) when MRI is contraindicated or not available.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19052580NP	Omnipaque 350mg l/mL, Solution For Injection/Infusion	X-ray contrast medium for use in adults and children for cardioangiography, arteriography, urography, phlebography and CT-enhancement. Lumbar, thoracic, cervical myelography and computed tomography of the basal cisterns, following subarachnoid injection. Arthrography, endoscopic retrograde pancreatography, (ERP), endoscopic retrograde cholangiopancreatography (ERCP), herniography, hysterosalpingography, sialography and studies of the gastrointestinal tract. Contrast-enhanced mammography (CEM) in adult women to assess and detect known or suspect lesions in the breast, – as an addition to mammography (with or without ultrasound) or – as an alternative to magnetic resonance imaging (MRI) when MRI is contraindicated or not available.
BRU19052581P	Streptin Injection 1g	Tuberculosis, Plaque and tularaemia, Bacterial endocarditis (only used in combination with penicillin G or ampicillin), Brucellosis (in conjunction with a tetracycline), Granuloma inguinale.
BRU19052582P	Aricept Evess 5mg Orodispersible Tablet	Aricept Evess tablets are indicated for the treatment of mild, moderate and severe dementia in Alzheimer's Disease.
BRU19052583P	Aricept Evess 10mg Orodispersible Tablet	Aricept Evess tablets are indicated for the treatment of mild, moderate and severe dementia in Alzheimer's Disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19052584P	Yucomy Shampoo 2% w/w	Treatment and prophylaxis of infections in which the yeast Pityrosporum is involved, e.g. pityriasis versicolor (localized), seborrhoeic dermatitis and pityriaysis capitis (dandruff).
BRU19052585P	Mapin 0.4mg/ml Injection	Naloxone is indicated for the complete or partial reversal of narcotic depression including respiratory depression induced by opioids including natural and synthetic narcotics, propoxyphene, methadone and the narcotic-antagonist analgesics nalbuphine, pentazocine and butorphanol. Naloxone is also indicated for the diagnosis of suspected acute opioid overdosage.
BRU19052587PS1; BRU19052587PS2	Medovir 400mg Tablet	MEDOVIR Tablets are indicated: For the treatment of herpes simplex virus infections of the skin and mucous membranes including initial and recurrent genital herpes. For the suppression (prevention of recurrences) of recurrent herpes simplex infections in immune-competent patients. For the prophylaxis of herpes simplex infections in immune-compromised patients. For the treatment of herpes zoster infections.
BRU19052588P	Bisloc 2.5	Indicated for the treatment of: • Hypertension • Stable chronic angina • Stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19052589P	Derzid Cream	Betamethasone valerate is a potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following: o Atopic dermatitis (including infantile atopic dermatitis) o Nummular dermatitis (discoid eczema) o Prurigo nodularis o Psoriasis (excluding widespread plaque psoriasis) o Lichen simplex chronicus (neurodermatitis) and lichen planus o Seborrhoeic dermatitis o Irritant or allergic contact dermatitis o Discoid lupus erythematosus o Adjunct to systemic steroid therapy in generalized erythroderma o Insect bite reactions
BRU19052590P	Pentasa® Prolonged Release Tablet 500mg	Treatment of mild to moderate ulcerative colitis and Crohn's disease.
BRU19052594P	SW Bromhexine Elixir	It is indicated in bronchitis and other respiratory conditions as an aid to expectoration.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19052595P	Allersin Syrup 4mg/5ml	It is indicated in allergic conditions responsive to antihistamines.
BRU19052596P	Quetiapine Sandoz 100mg Tablets	• Treatment of schizophrenia. • Treatment of acute manic episodes associated with bipolar I disorder. • Treatment of moderate to severe depressive episodes associated with bipolar disorder. • Preventing recurrence in maintenance treatment of bipolar I disorder (manic, mixed or depressive episode) as monotherapy or in combination with lithium or valproate.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19052597P	Cifloxin Infusion (2mg/ml)	Ciprofloxacin solution for infusion is indicated for the treatment of the following infections. Special attention should be paid to available information on resistance to ciprofloxacin before commencing therapy. Consideration should be given to official guidance on the appropriate use of antibacterial agents. Adults • Lower respiratory tract infections due to Gram-negative bacteria - exacerbations of chronic obstructive pulmonary disease - broncho-pulmonary infections in cystic fibrosis or in bronchiectasis - pneumonia • Chronic suppurative otitis media • Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria • Urinary tract infections • Genital tract infections - epididymo-orchitis including cases due to susceptible Neisseria gonorrhoeae - pelvic inflammatory disease including cases due to susceptible Neisseria gonorrhoeae • Infections of the gastrointestinal tract (e.g. travellers` diarrhoea) • Intra-abdominal infections • Infections of the skin and soft tissue caused by Gram-negative bacteria • Malignant external otitis • Infections of the bones and joints • Inhalation anthrax (post-exposure prophylaxis and curative treatment) Ciprofloxacin may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection. Children and adolescents • Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa • Complicated urinary tract infections and pyelonephritis • Inhalation anthrax (post-exposure prophylaxis and curative treatment)

		Ciprofloxacin may also be used to treat severe infections in children and adolescents when this is considered to be necessary. Treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.
BRU19052598NP	Tiger Balm Soft	For relief of minor headaches due to muscle tension, itchiness from insect bites, muscular aches and pains of joints, backaches, arthritis and rheumatism.
BRU19052599P	Vizomet Cream 0.1% w/w	Vizomet is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.
BRU19052600P	Vizomet Ointment 0.1% w/w	Vizomet is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19052601P	Eperon Film Coated Tablets 2mg	Eperon is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. Eperon alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. Eperon is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Risperidone is indicated for the short-term treatment of persistent aggression in patients with moderate to severe dementia of the Alzheimer's type unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. Eperon is indicated for the treatment of behavioural disorders associated with autism (eg irritability, social withdrawal, stereotypic behaviour, hyperactivity and inappropriate speech) in children and adolescents. Eperon is also indicated for bipolar mania. Adjunctive therapy: Eperon is indicated as adjunctive therapy to mood stabilizers in the treatment of manic episodes associated with bipolar disorders. These episodes are characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviors. Monotherapy: Eperon is indicated in the treatment of acute manic episodes associated with bipolar 1 disorder. The effectiveness of Eperon for more than 12 weeks of treatment of an acute episode, and for the prevention of new manic episodes has not been established. Eperon is indicated in the treatment of conduct and other disruptive behavior disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviors (e.g. aggression, impulsivity and self-injurious behaviors) are prominent.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19052602P	Quetiapine Sandoz 25mg Tablets	• Treatment of schizophrenia. • Treatment of acute manic episodes associated with bipolar I disorder. • Treatment of moderate to severe depressive episodes associated with bipolar disorder. • Preventing recurrence in maintenance treatment of bipolar I disorder (manic, mixed or depressive episode) as monotherapy or in combination with lithium or valproate.
BRU19072603P	Vectibix Concentrate For Solution For Infusion 100mg/Vial	Vectibix is indicated for the treatment of adult patients with wild-type RAS metastatic colorectal cancer (mCRC): ♦In first-line in combination with FOLFOX or FOLFIRI. ♦In second-line in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan) ♦As monotherapy after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072604P	Simponi I.V. Concentrate For Solution For Infusion 12.5mg/1ml	*Rheumatoid arthritis (RA):* SIMPONI, by IV administration, in combination with MTX, is indicated for: • the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease modifying anti rheumatic drug (DMARD) therapy including MTX has been inadequate. SIMPONI, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X ray and to improve physical function. *Ankylosing spondylitis (AS):* SIMPONI® by IV administration is indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to conventional therapies. *Psoriatic arthritis (PsA):* SIMPONI, by IV administration, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate.
BRU19072607NP	Thelban Suspension	Antihelmintic, which exhibit vermicidal, ovicidal and larvacidal activity in the treatment of Roundworm (Ascaris lumbriocides), Whipworm (Trichuris trichura), Pinworm or Threadworm (Enterobius vermicualris), Hookworm (Ancylostoma duodenale and Nectar americanus). Strongyloides stercoralis, Taenia sodium, Taenia saginata and Opisthorchis viverrini.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072608NP	Xenetix 300 Solution For Injection	This medicinal product is for diagnostic use only. Contrast agent for use in: • Intravenous urography • Computed tomography • Intravenous digital subtraction angiography • Arteriography • Angiocardiography • Arthrography • Hysterosalpingography
BRU19072609NP	Xenetix 350 Solution For Injection	This medicinal product is for diagnostic use only. Contrast agent for use in: • Intravenous urography • Computed tomography • Intravenous digital subtraction angiography • Arteriography • Angiocardiography
BRU19072610P	Fycompa 2mg Film-Coated Tablets	Fycompa (perampanel) is indicated for the adjunctive treatment of - partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older. - primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072611P	Fycompa 4mg Film-Coated Tablets	Fycompa (perampanel) is indicated for the adjunctive treatment of - partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older. - primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE).
BRU19072612P	Fycompa 8mg Film-Coated Tablets	Fycompa (perampanel) is indicated for the adjunctive treatment of - partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older. - primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE).
BRU19072614P	Tacarline Injection 1mg/ml	It is used in the emergency treatment of anaphylactic shock due to reaction from insect bites and drugs and for symptomatic relief of serum sickness, urticarial, pruritus, angioneurotic, oedema, respiratory distress due to bronchospasm, and relief of hypersensitivity reactions to drugs and other allergens.
BRU19072615P	Ranexa Prolonged-Release Tablet 375mg	Ranexa is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta- blockers and/or calcium antagonists).

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BRU19072616P	Ranexa Prolonged-Release Tablet 500mg	Ranexa is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta- blockers and/or calcium antagonists).
BRU19072617P	Ranexa Prolonged-Release Tablet 750mg	Ranexa is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies (such as beta- blockers and/or calcium antagonists).
BRU19072618P	SotaHexal 80mg Tablet	Oral administration of sotalol is indicated for: • Ventricular arrhythmias: Prevention of recurrence of life-threatening ventricular tachyarrhythmias; treatment of symptomatic non-sustained ventricular tachyarrhythmias. • Supraventricular arrhythmias: Prophylaxis of paroxysmal atrial tachycardia, paroxysmal atrial fibrillation, paroxysmal A-V nodal re-entrant tachycardia, paroxysmal A-V re-entrant tachycardia using accessory pathways, and paroxysmal supraventricular tachycardia after surgery; maintenance of normal sinus rhythm following conversion of atrial fibrillation or atrial flutter.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072619P	Zafibral 200mg Tablets Film Coated	BEZAFIBRATE is indicated for use in hyperlipidaemias of type IIa, IIb, III, IV and V. (Fredrickson Classification) which are illustrated below: Type Major Lipid Elevation IIa Cholesterol IIb Cholesterol and Triglycerides III Cholesterol and Triglycerides IV Triglycerides V Triglycerides (possibly cholesterol) BEZAFIBRATE is therefore indicated for use only in patients with a fully defined and diagnosed abnormality where diet alone is insufficient to correct the condition and in whom the long-term risks associated with the condition warrant treatment. The rationale for the use of BEZAFIBRATE to control abnormal elevations of serum lipids and lipoproteins is to reduce or prevent the long-term adverse effects which have been shown by many major epidemiological studies to be positively and strongly correlated with such dyslipidaemias. The possible beneficial and adverse long-term consequences of some drugs used in the hyperlipidaemias are still the subject of scientific discussion, however, and there is currently no clinical evidence to demonstrate that BEZAFIBRATE is effective in the prevention of heart disease.

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BRU19072620P	Apo-Azathioprine 50mg Tablets	Used as an immunosuppressant antimetabolite either alone or, more commonly, in combination with other agents (usually corticosteroids) and procedures which influence the immune response. Therapeutic effect may be evident only after weeks or months and can include a steroidsparing effect, thereby reducing the toxicity associated with high dosage and prolonged usage of corticosteroids. Apo-Azathioprine, in combination with corticosteroids and/or other immunosuppressive agents and procedures, is indicated to enhance the survival of organ transplants, such as renal transplants, cardiac transplants, and hepatic transplants; and to reduce the corticosteroid requirements of renal transplant recipients. Apo-Azathioprine, either alone or more usually in combination with corticosteroids and/or other drugs and procedures, has been used with clinical benefit (which may include reduction of dosage or discontinuation of corticosteroids) in a proportion of patients suffering from the following: severe rheumatoid arthritis; systemic lupus erythematosus; dermatomyositis and polymyositis; auto-immune chronic active hepatitis; pemphigus vulgaris; polyarteritis nodosa; auto-immune haemolytic anaemia; chronic refractory idiopathic thrombocytopenic purpura
BRU19072621P	Pergoveris Powder And Solvent For Solution For Injection	Pergoveris is indicated for the stimulation of follicular development in adult women with severe LH and FSH deficiency. In clinical trials, these patients were defined by an endogenous serum LH level < 1.2IU/L.

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BRU19072622P	Trustiva Tablet	TRUSTIVA is indicated for the treatment of HIV-1 infection in adults.
BRU19072624P	Pemirex Injection 100mg	1) Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma. 2) Pemetrexed in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. 3) Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. 4) Pemetrexed is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.
BRU19072625P	Pemirex Injection 500mg	1) Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma. 2) Pemetrexed in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. 3) Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. 4) Pemetrexed is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

BRU19072627P; BRU19072627PS2	Cyramza 100mg/10ml Concentrate For Solution For Infusion	<u>Gastric cancer</u> Cyramza in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. Cyramza monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate. <u>Colorectal cancer</u> Cyramza, in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine. <u>Non-small cell lung cancer</u> Cyramza in combination with erlotinib is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations. Cyramza in combination with docetaxel is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum-based chemotherapy. <u>Hepatocellular carcinoma</u> Cyramza monotherapy is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have a serum alpha fetoprotein (AFP) of ≥ 400ng/ml and who have been previously treated with sorafenib.

BRU19072628P; BRU19072628PS2	Cyramza 500mg/50ml Concentrate For Solution For Infusion	<u>Gastric cancer</u> Cyramza in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. Cyramza monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate. <u>Colorectal cancer</u> Cyramza, in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine. <u>Non-small cell lung cancer</u> Cyramza in combination with erlotinib is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer with activating epidermal growth factor receptor (EGFR) mutations. Cyramza in combination with docetaxel is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with disease progression after platinum-based chemotherapy. <u>Hepatocellular carcinoma</u> Cyramza monotherapy is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have a serum alpha fetoprotein (AFP) of ≥ 400ng/ml and who have been previously treated with sorafenib.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072629P	Hydrocortisone Cream 1% w/w	Hydrocortisone is a mild corticosteroid indicated for irritant contact dermatitis, allergic contact dermatitis and insect bites. Irritant dermatitis, may be caused by common household products such as detergents, bleaches, washing powders and various chemicals found in the workplace. Allergic contact dermatitis is caused by sensitisation to allergens in materials such as cosmetics, resins, rubber, adhesive plaster and plants. It may also be helpful in treating napkin rash if used under medical supervision.
BRU19072630NP	Microshield 4 Chlorhexidine Surgical Handwash	●Antimicrobial handwashing ●Surgical handwashing ●Body washing
BRU19072632NP	Betadine Sore Throat Spray 0.45% w/v	Betadine® Sore Throat Spray is used for relief of throat chapping, throat pain, throat swelling, throat discomfort and hoarseness caused by inflammation of the throat. Kelegaan untuk tekak kering dan gatal, sakit tekak, bengkak tekak, ketidakselesaan tekak dan serak disebabkan oleh radang tekak.
BRU19072633P	Fludarabine Sandoz 50mg/2ml Concentrate For Solution For Injection Or Infusion	Treatment of B-cell chronic lymphocytic leukemia (CLL) in patients with sufficient bone marrow reserves. First line treatment in patients with advanced disease, Rai stages III/IV (Binet stages C), or Rai stages I/II (Binet stages A/B) where the patient has disease-related symptoms or evidence of progressive disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072634P	Platol (Cisplatin Concentrate For Solution For Infusion 50mg/50ml)	Cisplatin may be used single or in combination with other chemotherapeutic agents in the treatment of: Metastatic non-seminomatous germ cell carcinoma Advanced stage, refractory ovarian carcinoma Advanced stage, refractory bladder carcinoma Refractory squamous cell carcinoma of the head and neck
BRU19072635P	Doxorubicin 2mg/ml Concentrate For Solution For Infusion	Breast cancer, sarcoma, small-cell carcinoma of the lung, Hodgkin disease or non-Hodgkin lymphoma, acute leukaemia, cancer of the thyroid, bladder, ovaries, Paediatric tumours, such as neuroblastoma. Doxorubicin is frequently used in combination chemotherapy regimens with other cytotoxic drugs.
BRU19072636P	Montelukast Sandoz 10mg Film-Coated Tablet	For the prophylaxis and chronic treatment of asthma in adults and pediatric patients 12 months of age and older. Montelukast is indicated in adults and pediatric patients 2 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis.
BRU19072637P	Lakan Injection 1% (10ml Vial)	For local anaesthesia, peripheral nerve block, infiltration anaesthesia and diagnostic or therapeutic block.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072638P	Lakan Injection 2% (10ml Vial)	For local anaesthesia, peripheral nerve block, infiltration anaesthesia and diagnostic or therapeutic block.
BRU19072639P	Zosaar 50mg Tablets	1. Hypertension Zosaar is indicated for the treatment of hypertension. 2. Reduction in the risk of cardiovascular morbidity and mortality in hypertensive patients with left ventricular hypertrophy Indicated to reduce the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke and myocardial infarction in hypertension patients with left ventricular hypertrophy. 3. Renal protection in Type 2 Diabetic patients with proteinuria Indicated to delay the progression of renal disease as measured by a reduction in the combined incidence of doubling of serum creatinine, end stage renal disease (need for dialysis or renal transplantation) or death and to reduce proteinuria.
BRU19072640P; BRU19072640PS2; BRU19072640PS3	Converium 150mg Tablet	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072642P	Clozole Cream 1%	Candidiasis, cutaneous (treatment) – Cutaneous candidiasis caused by Canadida albicans. Tinea corporis, Tinea cruris, Tinea pedis, Tinea versicolor.
BRU19072643NP	Thelban Tablet	Antihelmintic which exhibits vermicidal, ovicidal and larvicidal activityin the treatment of Roundworm (Ascaris lumbricoides), Whipworm (Trichuris trichura), Pinworm or Threadworm (Enterobius vermicularis), Hookworm (Ancylostoma duodenale and Nector americanus), Strongyloides stercoralis, Taenia solium, Taenia saginata and Opisthorchis viverrini.
BRU19072644P	Ribomustin 25mg/Vial Powder For Concentrate For Solution For Infusion	Ribomustin is indicated for monotherapy in patients with chronic lymphocytic leukaemia. Efficacy relative to first line therapies other than chlorambucil has not been established. Ribomustin is indicated for monotherapy in patients with indolent B-cell non-Hodgkin's lymphomas that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
BRU19072645P	Ribomustin 100mg/Vial Powder For Concentrate For Solution For Infusion	Ribomustin is indicated for monotherapy in patients with chronic lymphocytic leukaemia. Efficacy relative to first line therapies other than chlorambucil has not been established. Ribomustin is indicated for monotherapy in patients with indolent B-cell non-Hodgkin's lymphomas that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072646P	Rydapt® 25mg Soft Capsules	Rydapt is indicated: ♦in combination with standard daunorubicin and cytarabine induction and high-dose cytarabine consolidation chemotherapy, and for patients in complete response followed by Rydapt single agent maintenance therapy, for adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FLT3 mutation-positive (see 4.2); as monotherapy for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated haematological neoplasm (SM-AHN), or mast cell leukaemia (MCL).

BRU19072647P	Tecentriq Concentrate For Solution For Infusion 1200mg/20ml	**Early-stage non-small cell lung cancer** Tecentriq as monotherapy is indicated as adjuvant treatment following complete resection for adult patients with Stage II to IIIA (7th edition of the UICC/AJCC-staging system) non-small cell lung cancer (NSCLC) whose tumours have PD-L1 expression on ≥ 50% of tumour cells (TC) and whose disease has not progressed following platinum-based adjuvant chemotherapy (see Section 3.1.2 Clinical / Efficacy Studies). **Metastatic non-small cell lung cancer** Tecentriq, in combination with Avastin, paclitaxel and carboplatin, is indicated for the treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) who had not received prior chemotherapy. Tecentriq as monotherapy is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have disease progression on approved therapy for these aberrations prior to receiving Tecentriq. Tecentriq, in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumor aberrations. Tecentriq as monotherapy is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have a PD-L1 expression ≥ 50% tumor cells (TC) or ≥ 10% tumor-infiltrating immune cells (IC) and who do not have EGFR or ALK genomic tumor aberrations. **Small cell lung cancer** Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ESSCLC).

		Triple-negative breast cancer Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression of ≥1% on IC, and who have not received prior chemotherapy for metastatic disease. **Hepatocellular carcinoma** Tecentriq, in combination with Avastin, is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.
BRU19072648NP	Tiger Balm Plaster - RD	Muscular pain, stiff neck and shoulders, contusion, sprain, backache and arthritic pain.
BRU19072649P	Carvedilol Sandoz 6.25mg	- Essential hypertension - Chronic stable angina pectoris - Adjunctive treatment of symptomatic chronic heart failure
BRU19072650P	Carvedilol Sandoz 25mg	- Essential hypertension - Chronic stable angina pectoris - Adjunctive treatment of symptomatic chronic heart failure

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072651P	Betacylic Ointment	Relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses e.g., psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.
BRU19072652NP	Woods Peppermint Cough Syrup	Woods' Peppermint Cough Syrup provides relief of wet, productive cough. It helps loosen phlegm and thins bronchial secretions to rid bronchial passageways of bothersome mucus and make cough more productive.
BRU19072653P	Gabapentin Sandoz Capsules 300mg	<u>Epilepsy</u> Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 3 years and older. Safety and effectiveness for adjunctive therapy in pediatric patients younger than 3 years have not been established. <u>Treatment of peripheral neuropathic pain</u> Gabapentin is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy, post-herpetic neuralgia and trigeminal neuralgia. Safety and effectiveness in patients below the age of 18 years have not been established.
BRU19072654P	Aremed 1mg Tablet	Aremed is indicated for the treatment of hormone receptor-positive advanced breast cancer in postmenopausal women

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19072655P	Uniflex Cream 0.1% w/w	For the relief of the inflammatory manifestations of corticosteroid - responsive dermatoses such as in eczema, infantile eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, seborrhoeic dermatitis, neurodermatitis, some form of psoriasis and intertrigo.
BRU19072656P	Finil 8 Tablet	Indicated in the: Candesartan Cilexetil is indicated for the: -Treatment of essential hypertension in adults. -Treatment of hypertension in children and adolescents aged 6 to < 18 years. Treatment of adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction ≤ 40%) when Angiotensin Converting Enzyme (ACE)-inhibitors are not tolerated or as add-on therapy to ACE-inhibitors in patients with symptomatic heart failure, despite optimal therapy, when mineralocorticoid receptor antagonists are not tolerated.
BRU19072657NP	Shine Cutie Chewable Tablet	As a dietary and nutritional supplement for children.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19082658P	Motidone Tablet 10mg	Domperidone is indicated for the relief of the symptoms of nausea and vomiting. This includes: ♦Nausea and vomiting of functional, organic, infectious or dietary origin. ♦Nausea and vomiting induced by: -Radiotherapy or drug therapy. -Dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson's disease.
BRU19082659P	Hovid Alendronate 70mg Tablet	Hovid Alendronate Tablet 70 mg is indicated in adults for the treatment of postmenopausal osteoporosis. It reduces the risk of vertebral and hip fractures.
BRU19082660P	Zobid Injection 3ml	Initial treatment of the following: Acute, severe pain caused by inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, spondylarthiritis Painful syndromes of the vertebral column. non-articular rheumatism, acute attacks of gout, renal colic and biliary colic. painful post- traumatic and post-operative inflammation and swelling.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19082662NP	Biphozyl Solution For Haemodialysis/Haemo filtration	Biphozyl solution is used as replacement solution and as dialysate for treatment of acute kidney injury during continuous renal replacement therapy (CRRT). Biphozyl solution is used in a post-acute phase after initiation of renal replacement therapy when pH, potassium and phosphate concentration have returned to normal. Biphozyl solution is also used when other buffer sources are available as well as during regional citrate anticoagulation. Moreover, Biphozyl solution is used in patients with hypercalcaemia. Biphozyl solution may also be used in cases of drug poisoning or intoxications when the substances are dialysable or filterable.
BRU19082663P	Exjade 90mg Film-Coated Tablet	Exjade film-coated tablet is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and pediatric patients (aged 2 years and over). Exjade film-coated tablets is also indicated for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10 years and over.
BRU19082665P	Exjade 360mg Film-Coated Tablet	Exjade film-coated tablet is indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and pediatric patients (aged 2 years and over). Exjade film-coated tablets is also indicated for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10 years and over.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19082669P	Minirin Tablet 0.1mg	Central diabetes insipidus. The use of MINIRIN® in patients with an established diagnosis will result in a reduction in urinary output with concomitant increase in urine osmolality and decrease in plasma osmolality. This will result in decreased urinary frequency and decreased nocturia. Primary nocturnal enuresis in children aged 5 years or more. Symptomatic treatment of nocturia in adults, associated with nocturnal polyuria, i.e. nocturnal urine production exceeding bladder capacity.
BRU19082670P	Minirin Tablet 0.2mg	Central diabetes insipidus. The use of MINIRIN® in patients with an established diagnosis will result in a reduction in urinary output with concomitant increase in urine osmolality and decrease in plasma osmolality. This will result in decreased urinary frequency and decreased nocturia. Primary nocturnal enuresis in children aged 5 years or more. Symptomatic treatment of nocturia in adults, associated with nocturnal polyuria, i.e. nocturnal urine production exceeding bladder capacity.
BRU19082671NP	Dermoplex Antiseptic Cream	A topical antibacterial cream which helps prevent infections and assists in the healing of minor cuts and burns, nappy rashes, blisters, sunburn, insect bites and stings.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19082673P	Atoris Film-Coated Tablet 40mg	<u>Hypercholesterolemia</u> Atoris is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atoris is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. <u>Prevention of cardiovascular disease</u> Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU19082674P	Avorax Cream 5% w/w	Avorax Cream is indicated in the treatment of herpes simplex infections of the skin, including initial and recurrent labial and genital herpes simplex infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19082675P	Letram OS (Levetiracetam Oral Solution 100mg/ml)	LEVETIRACETAM is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy. LEVETIRACETAM is indicated as adjunctive therapy: ♦In the treatment of partial onset seizures with or without secondary generalization in adults and children from4 years of age with epilepsy. ♦In the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. ♦In the treatment of primary generalized tonic-clonic seizures in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.
BRU19082676NP	Unilac Lactulose 3.35g/5ml Oral Solution USP	For constipation and the treatment of hepatic encephalopathy.
BRU19082677NP	Senna 7.5mg Tablet	Senna is indicated for the treatment of occasional constipation.

BRU19092678P	Flurocort Injection 40mg/ml	Where oral therapy is not feasible or is temporarily undesirable in the judgment of the physician, flurocort is indicated **for Intramuscular use as follows:** Endocrine disorder: Nonsuppurative thyroiditis Rheumatic disorder: As adjunctive therapy for short term administration (to tide the patient over an acute episode of exacerbation) in post-traumatic osteoarthritis; synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; epicondylitis; acute non-specific tenosynovitis; acute gouty arthritis, psoriatic arthritis; ankylosing spondylitis; juvenile rheumatoid arthritis. Collagen Diseases: During an exacerbation as maintenance therapy in selected cases of systemic lupus erythematosus: acute rheumatic carditis. Dermatologic Disease: Pemphigus, severe erythema multiforme (Steven-Johnson Syndrome), exfoliative dermatitis, bullous dermatitis herpetiformis, severe seborrheic dermatitis; severe psoriasis. Allergic states: Control of severe or incapacitating allergic condition intractable to adequate trials of conventional treatment in bronchial asthma; contact dermatitis; atopic dermatitis, seasonal or perennial allergic rhinitis. Ophthalmic Diseases: Severe chronic allergic and inflammatory process involving the eye, e.g herpes zoster ophthalmicus, iritis, indocyclitis, chorioretinitis; diffuse posterior uvertis and choroditis; optic neuritis; sympathetic ophthalmia; anterior segment inflammation. Gastrointestinal diseases: to tide to patient over a critical period of disease in ulcerative colitis (systemic therapy), regional anteritis (systemic therapy). Respiratory Diseases: Symptomatic sarcoidosis; berylliosis; aspiration pneumonitis. Hemolytic Disorders: Acquired (autoimmune) haemolytic anaemia. Neoplastic Diseases: For palliative management of leukaemia and lymphomas in adults and acute leukaemia of childhood. Edematous State: To include diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus. **Intra-Articular:** Flurocort IM is indicated for intra-articular administration and for injections into tendon sheaths, as adjunctive therapy for short-term administration (to tide the patient over an acute episodes or exacerbation) in synovitis of osteoarthritis, rheumatoid arthritis, acute and sub acute bursitis; acute gouty arthritis; epicondylitis, acute non specific tenosynovitis, post-traumatic osteoarthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19092679PS1; BRU19092679PS2	Imbruvica 140mg Capsule	IMBRUVICA is indicated for the treatment of adult patients with mantle cell lymphoma (MCL). IMBRUVICA as a single agent or in combination with rituximab or obinutuzumab or venetoclax is indicated for the treatment of adult patients with previously untreated chronic lympocytic leukaemia (CLL). IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. IMBRUVICA as a single agent is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with WM. IMBRUVICA is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.
BRU19092680NP	Vitabiotics Pregnacare Plus Omega-3 Tablet/Capsule	For the prevention and correction of vitamin and mineral deficiency states.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19092681P	Flexin 20mg Capsule	Depression: Treatment of symptoms of depressive illness, with or without associated anxiety symptoms. Obsessive-compulsive disorder. Treatment of premenstrual dysphoric disorder (PMDD).
BRU19092685P	Curam 1000mg + 200mg Powder For Intravenous Solution	Curam 1000mg + 200mg of Powder for intravenous solution may be administered for the short-term treatment of primarily serious infections due to micro-organisms that are resistant to amoxicillin and other B-lactam antibiotics as a result of the formation of a clavulanic acid-susceptible β-lactamase, such as: • Upper respiratory tract infections (including ENT) e.g. recurrent tonsillitis, sinusitis, otitis media. • Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis, lobar and bronchopneumonia. • Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis. • Skin and soft tissue infections e.g. boils, abscesses, cellulites, wound infections. • Bone and joint infections e.g. osteomyelitis. • Other infections e.g. intra-abdominal sepsis. Curam 1000mg + 200mg Powder for intravenous solution can be used for prophylaxis against infections in major surgery such as gastrointestinal, pelvic, head and neck, cardiac, renal, joint replacement and biliary tract.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19092687PS1; BRU19092687PS2; BRU19092687PS3	Insulatard Penfill 100IU/ml Suspension For Injection In Cartridge	To treat diabetes mellitus.
BRU19092688P	Maviret Film-Coated Tablets	Maviret is indicated for the treatment of adults and adolescents 12 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19092689P	Gemcitabine Sandoz Concentrate For Solution For Infusion 40mg/ml	Non-small Cell Lung Cancer (NSCLC) Gemcitabine, in combination with cisplatin, is indicated as first line treatment of patients with locally advanced (inoperable stage IIIA or IIIB) or metastatic (stage IV) non-small cell lung cancer (NSCLC). Gemcitabine is indicated for the palliative treatment of adult patients with locally advanced or metastatic NSCLC. Pancreatic Cancer Gemcitabine is indicated for the treatment of adult patients with locally advanced or metastatic adenocarcinoma of the pancreas. Gemcitabine is indicated for patients with 5-FU refractory pancreatic cancer. Bladder Cancer Gemcitabine is indicated for the treatment of advanced bladder cancer (muscle invasive Stage IV tumours with or without metastases) in combination with cisplatin therapy. Breast Cancer Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.
BRU19092690NP	Flexijoint 3-In-1 Joint Care Powder	As adjuvant therapy for osteoarthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19092691P	Rexom Bromhexine Elixir 4mg/5ml	Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport.
BRU19092692P	Akynzeo (Netupitant/Palonosetron) 300mg/0.5mg Hard Capsules	Akynzeo (netupitant/ palonosetron) in combination with dexamethasone, is indicated for once-per-cycletreatment in adult patients for: - Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cancer chemotherapy. - Prevention of acute nausea and vomiting associated with moderately emetogenic cancer therapy that is uncontrolled by a 5-HT_3 receptor antagonist alone.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19092693P	Aslene Capsule 120mg	Aslene is indicated in conjunction with a mildly hypocaloric diet for the treatment of obese patients with a body mass index (BMI) greater or equal to 30 kg/m^2, or overweight patients (BMI ≥ 28 kg/m^2) with risk factors associated with obesity. Aslene is effective in weight loss, weight maintenance and prevention of weight regains. Treatment with Aslene results in an improvement of risk factors and comorbidities associated with obesity, including hypercholesterolemia, noninsulin dependent diabetes mellitus (NIDDM), impaired glucose tolerance, hyperinsulinemia, hypertension and in a reduction of visceral fat. The use of Aslene in type 2 diabetic patients who are overweight (BMI ≥ 28 kg/m^2) or obese (BMI ≥ 30 kg/m^2), in conjunction with a mildly hypocaloric diet, provides additional glycemic control when used in combination with antidiabetic agents such as metformin, sulfonylurea and/or insulin. Treatment with Aslene should only be started if diet alone has previously produced a weight loss of at least 2.5kg over a period of 4 consecutive weeks. Treatment with Aslene should be discontinued after 12 weeks if patients have been unable to lose at least 5% of the body weight as measured at the start of therapy.
BRU19092694P	Lentronat (Letrozole Tablets USP, 2.5mg)	Letrozole is not indicated in hormone receptor negative disease. Letrozole is indicated in: • Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer. • Extended adjuvant treatment of invasive early breast cancer in post menopausal women who have received prior standard adjuvant tamoxifen therapy for five years. • First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer. • Treatment of advanced breast cancer after relapse or disease progression, in women with natural or artificially induced postmenopausal endocrine status, who have previously been treated with anti-oestrogens.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19092696P	Vencid Enteric-Coated Tablet 40mg	• Moderate and severe cases of inflammation of the oesophagus (gastro-oesophageal reflux disease). • Duodenal and gastric ulcer. • Eradication of *Helicobacter pylori (H.pylori)* in combination with two appropriate antibiotics in patients with peptic ulcers with the objective of reducing the recurrence of duodenal and gastric ulcers caused by this microorganism. • Zollinger-Ellison Syndrome and other pathological hypersecretory conditions.
BRU19092697P	Breathnine Syrup 2mg/5ml	- Relief of bronchial asthma - Chronic bronchitis - Emphysema - Acute dyspnea
BRU19112699P	Beathorphan Tablets 15mg	Used for the relief of unproductive cough.
BRU19112702P	Lartil Injection 12.5mg/ml (1ml Amp)	Nausea and vomiting due to various causes including migraine; vertigo due to Meniere's syndrome, labyrinthitis and other causes; minor mental and emotional disturbances.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112703NP	Phebra Calcium Chloride Dihydrate 10% 1g/10mL	Parenteral administration of calcium is indicated in the treatment of hypocalcaemia where a rapid increase in plasma calcium is required, such as in hypocalcaemic tetany and tetany due to parathyroid deficiency. Intravenous calcium is also indicated to antagonize the cardiotoxicity of hyperkalaemia.
BRU19112704PS1; BRU19112704PS2; BRU19112704PS3	Actrapid Penfill 100IU/ml, 3ml Cartridge Solution For Injection	Treatment of diabetes mellitus.
BRU19112705P	Uptravi 200mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112706P	Uptravi 400mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112707P	Uptravi 600mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112708P	Uptravi 800mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112709P	Uptravi 1000mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112710P	Uptravi 1200mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112711P	Uptravi 1400mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112712P	Uptravi 1600mcg Film Coated Tablets	Uptravi is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO functional class (FC) II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.
BRU19112713NP; BRU19112713NPS2	Tiger Balm Plus Ointment	For relief of minor aches and pains of muscle and joints associated with simple backaches, arthritis pains, rheumatic pains sciatica and sprains.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112714NP	Tiger Balm Plaster	Muscular pain, stiff neck and shoulders, contusion, sprain, backache and arthritic pain.
BRU19112715NP	Microshield® Handrub	For rapid hand antisepsis. For skin antisepsis.
BRU19112716P; BRU19112716PS2	Glyxambi Film-Coated Tablet 10mg/5mg	GLYXAMBI is indicated to improve glycaemic control in adults with type 2 diabetes mellitus: ♦Instead of empagliflozin, when diet, exercise and treatment with empagliflozin ± metformin do not provide adequate glycaemic control ♦Instead of linagliptin, when diet, exercise and treatment with linagliptin ± metformin do not provide adequate glycaemic control GLYXAMBI can be used to replace the free combination of empagliflozin and linagliptin in adult patients with type 2 diabetes mellitus who are already being treated with this combination.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112717P; BRU19112717PS2	Glyxambi Film-Coated Tablet 25mg/5mg	GLYXAMBI is indicated to improve glycaemic control in adults with type 2 diabetes mellitus: ♦Instead of empagliflozin, when diet, exercise and treatment with empagliflozin ± metformin do not provide adequate glycaemic control ♦Instead of linagliptin, when diet, exercise and treatment with linagliptin ± metformin do not provide adequate glycaemic control GLYXAMBI can be used to replace the free combination of empagliflozin and linagliptin in adult patients with type 2 diabetes mellitus who are already being treated with this combination.
BRU19112718NP	Shine Multivitamin and Mineral Capsule	Used as a health supplement.
BRU19112719P	Melicron Tablet 80mg	Melicron is indicated for the treatment of non-insulin-dependent Diabetes Mellitus. It is used to supplement treatment by dietary modification when such modification has proved insufficient.
BRU19112721NP	Tiger Balm Active Muscle Rub	Tiger Balm Active Muscle Rub is a specially formulated non-greasy cream. It provides temporary relief of aches and pains from sore muscles, sprains and strains for active people.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112722NP	Tiger Balm Active Muscle Gel	Tiger Balm Active Muscle Gel provides temporary pain relief from minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, and sprains.
BRU19112723P	Loraten Tablet 10mg	Indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. It is also indicated for relief of symptoms and signs of chronic urticarial and other allergic dermatologic disorders.
BRU19112724P	Irinotecan Hydrochloride 20mg/ml Concentrate For Solution For Infusion	Irinotecan is indicated for the treatment of patients with advanced colorectal cancer: • in combination with 5-fluorouracil and folinic acid in patients without prior chemotherapy for advanced disease, • as a single agent in patients who have failed an established 5-fluorouracil containing treatment regimen. Irinotecan in combination with cetuximab it is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer, who had not received prior treatment for metastatic disease or after failure of irinotecan-including cytotoxic therapy. Irinotecan in combination with 5-fluorouracil, folinic acid and bevacizumab is indicated for first-line treatment of patients with metastatic carcinoma of the colon or rectum. Irinotecan in combination with capecitabine with or without bevacizumab it is indicated for first-line treatment of patients with metastatic colorectal carcinoma.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112725P	Torleva 500mg Tablet	TORLEVA is indicated as monotherapy in the treatment of partial seizure with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy. TORLEVA is indicated as adjunctive therapy: ♦In the treatment of partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy ♦In the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME) ♦In the treatment of primary generalized tonic-clonic seizures (PGTCS) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.
BRU19112726P	Torleva 250mg Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in patients from 16 years newly diagnosed with epilepsy. Levetiracetam is indicated as adjunctive therapy ♦In the treatment of partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy ♦In the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy ♦In the treatment of primary generalized tonic-clonic seizures in adults and children from 12 years of age with Idiopathic Generalised Epilepsy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112727P	Torleva 1000mg Tablet	TORLEVA is indicated as monotherapy in the treatment of partial seizure with or without secondary generalization in patients from 16 years of age with newly diagnosed epilepsy. TORLEVA is indicated as adjunctive therapy: ♦In the treatment of partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy ♦In the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy (JME) ♦In the treatment of primary generalized tonic-clonic seizures (PGTCS) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112728P	Piperacillin/Tazobactam Sandoz Powder For Solution For Injection/Infusion 4.5g Vials	Piperacillin/Tazobactam is indicated for the treatment of the following systemic and/or local infections in which susceptible pathogens have been detected or are suspected: *Adults* In threatening situations therapy with Piperacillin/Tazobactam can be initiated, even before an antibiogram is available. In the case of treatment of neutropenic patients, Piperacillin/Tazobactam in the usual dose should be combined with an aminoglycoside. Lower respiratory tract infections; urinary tract infections (complicated and uncomplicated); intra-abdominal infections; skin and skin structure infections; bacterial septicaemia. *Children under 12 years of age* Piperacillin/Tazobactam is indicated for hospitalised children for the treatment of intra-abdominal infections and biliary infections. The efficacy and safety for children under 2 years old with these indications has not been investigated. Official recommendations on the appropriate use of antibiotics must be observed, in particular administration recommendations on the prevention of the increase in resistance to antibiotics.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112729P	Nexpro Tablet 40mg	Esomeprazole is indicated for the treatment of: Gastro-Oesophageal Reflux Disease (GERD) ♦Treatment of erosive reflux oesophagitis ♦Long-term management of patients with healed oesophagitis to prevent relapse ♦Symptomatic treatment of gastro-oesophageal reflux disease (GERD) In combination with an appropriate antibacterial therapeutic regimen for the eradication of Helicobacter pylori and ♦Healing of Helicobacter pylori associated with duodenal ulcer ♦Prevention of relapse of peptic ulcers in patients with Helicobacter pylori associated ulcers Patients requiring continued NSAID therapy ♦Healing of gastric ulcers associated with NSAID therapy ♦Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk Prolonged treatment after IV induced prevention of rebleeding of peptic ulcers Treatment of Zollinger Ellison Syndrome

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112731P	Xigduo XR (Dapagliflozin/Metformin HCl Extended-Release) Tablets 10mg/500mg	Glycaemic control Xigduo XR is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise, to improve glycaemic control when treatment with both dapagliflozin and metformin is appropriate. Reduction in risk of hospitalization for heart failure Dapagliflozin is indicated to reduce the risk of hospitalization for heart failure in adults with typ 2 diabetes mellitus and establishsed cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
BRU19112732P	Xigduo XR (Dapagliflozin/Metformin HCl Extended-Release) Tablets 10mg/1000mg	Glycaemic control Xigduo XR is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise, to improve glycaemic control when treatment with both dapagliflozin and metformin is appropriate. Reduction in risk of hospitalization for heart failure Dapagliflozin is indicated to reduce the risk of hospitalization for heart failure in adults with typ 2 diabetes mellitus and establishsed cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112733P	Onsia Injection	Adults: ♦Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy ♦Prevention and treatment of post-operative nausea and vomiting (PONV). Paediatric Population: Injection & Oral formulations: Management of chemotherapy-induced nausea and vomiting (CINV). No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of PONV; IV injection is recommended for this purpose.
BRU19112734P	Retorin Powder For Suspension 200mg/5ml	Genitourinary tract infections, Pneumonia, Diphteria, Erythrasma, Gonorrhoea, Legionnaires disease, Listeria infections, Pertussis, Pharyngitis, Respiratory tract infections – upper and lower, Rheumatic fever (prophylaxis) skin and soft tissue infections, and Syphilis.
BRU19112735P	Anastrozole Sandoz Film Coated Tablet 1mg	ANASTROZOLE SANDOZ is indicated for adjuvant treatment of postmenopausal women with hormone receptor positive early invasive breast cancer. Treatment of advanced breast cancer in postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. Efficacy has not been demonstrated in oestrogen receptor negative patients unless they had a previous positive clinical response to tamoxifen.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112736NP	Betadine Vaginal Gel 10% w/w With Applicator	a) Disinfection of the vagina before and after operations. b) In acute and chronic vaginal infections (vaginitis, vulvo-vaginitis): - Mixed infections and unspecific infections (bacterial vaginosis; *Gardnerella vag.*). - Fungal infections (*Candida albicans*). - Trichomonal infections. c) After antibiotic or steroid therapy in case of complications.
BRU19112737P	Elonza-50 Tablet	Indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.
BRU19112738P	Zenpro Capsule 20mg	Zenpro Capsule is indicated for: • Treatment of duodenal and benign gastric ulcers • Eradication of Helicobacter pylori in peptic ulcer disease • Treatment of reflux oesophagitis and symptomatic treatment of heartburn and regurgitation in gastro-oesophageal reflux disease (GORD) • Treatment of Pathological Hypersecretory Conditions (Zollinger-Ellison syndrome) • Prophylactic treatment in patients with an increased risk of NSAIDs associated peptic ulcer, gastro-duodenal erosion or dyspeptic symptoms • Treatment of NSAIDs induced peptic and gastro-duodenal erosion

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19112739P	Creobic Gold Cream 1% w/w	Treatment of topical fungal infections caused by dermatophytes such as *Epidermophyton floccosum, Microsporum canis, and Trichophyton* (e.g. T.rubrum, T.mentagrophytes, T.verrucosum, T.violaceum); yeast infections of the skin; pityriasis versicolor due to *Malassezia furfur* or *Pityrosporum orbiculare;* and cutaneous candidiasis.
BRU19122740PS2	Olvion 50mg Film-Coated Tablet	Treatment of men with erectile dysfunction, which is the inability to achieve or maintain penile erection sufficient for satisfactory sexual performance. In order for Olvion to be effective, sexual stimulation is required.
BRU19122741P	SKYCellflu Quadrivalent Pre-Filled Syringe	Active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine, for adults and children 3 years of age and older.
BRU19122742NP	Biotase Chewable Tablet	As an adjuvant in the treatment of indigestion as well as digestive disorder manifested by bloating, belching, flatulence, abdominal discomfort or feeling of fullness.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19122745NP	Phoxilium 1.2 mmol/l Phosphate Solution For Haemodialysis/Haemofiltration	Phoxilium solution is used for CRRT (Continuous Renal Replacement Therapy) in critically ill patients with ARF (Acute Renal Failure) when pH and kalaemia have been restored to normal and when the patients need phosphate supplementation for loss of phosphate in the ultrafiltrate or to the dialysate during CRRT. Phoxilium may also be used in cases of drug poisoning or intoxications when the poisons ate dialyzable or pass through the membrane. Phoxilium solution is indicated for use in patients with normal kalaemia and normal or hypophosphataemia.
BRU19122746PS1; BRU19122746PS2	Bisohexal Tablet 5mg	Treatment of hypertension as well as treatment of coronary heart disease (angina pectoris). Treatment of stable chronic, moderate to severe heart failure with reduced systolic ventricular function (ejection fraction ≤ 35%, based on echocardiography) in addition to ACE inhibitors and diuretics, and optionally cardiac glycosides.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19122747P	Azamun 50mg Tablet	**AZAMUN** is used as an immunosuppressant anti-metabolite either alone, or more commonly in combination with other agents (usually corticosteroids) and procedures that influence the immune response. The therapeutic effect of **AZAMUN** may be evident only after weeks or months and can include a steroid-sparing effect, thereby reducing the toxicity associated with high dosage and the prolonged use of corticosteroids. **AZAMUN**, in combination with corticosteroids and/or other immune-suppressive agents and procedures is indicated to enhance the survival or organ transplants, such as renal, cardiac and hepatic transplants; and to reduce the corticosteroid requirements of renal transplant recipients. **AZAMUN**, either alone or in combination with corticosteroids and/or other medicines and procedures has been used with clinical benefit (which may result in a dose reduction to/or the discontinuation of corticosteroid therapy) in a proportion of patients suffering from: severe rheumatoid arthritis; systemic lupus erythematosus; dermatomyositis and polymyositis; auto-immune chronic active hepatitis; pemphigus vulgaris; polyarteritis nodosa; auto-immune haemolytic anaemia and chronic refractory idiopathic thrombocytopenic purpura.
BRU19122748P	Candesartan Sandoz Tablet 16mg	Treatment of hypertension. Treatment of patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction ≤ 40%) as add-on therapy to ACE inhibitors or when ACE inhibitors are not tolerated.
BRU19122749P	Concor AM 5mg / 10mg Tablet	Concor AM is indicated for the treatment of hypertension as substitution therapy in patients adequately controlled with the individual products given concurrently at the same doses level as in the combination, but as separate tablets.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU19122750P	Pregabalin Sandoz 75mg Capsules	• Neuropathic Pain: Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. • Epilepsy: As adjunctive therapy in adults with partial seizures with or without secondary generalization. • Generalised Anxiety Disorder: Treatment of Generalised Anxiety (GAD) in adults. • Fibromyalgia: Management of fibromyalgia.
BRU19122751P	Gentamicin-POS Eye Drops	Gentamicin-POS is indicated in infections of the anterior eye including conjunctivitis, keratitis, blepharitis, and hordeolum, caused by gentamicin-sensitive pathogens.
BRU19122753NP	Actimol Menstrual Tablet	For symptomatic relief of bloating, water-weight gain, backache, muscular aches, discomfort prior to pre-menstrual and during menstrual and also can be used for relief fever and headache.
BRU20012756P	Fusix Tablet 40mg	Frusemide is indicated in the treatment of edema associated with congestive heart failure, hepatic cirrhosis and renal disease (including nephrotic syndrome). It is also indicated in the treatment of mild to moderate hypertension, usually in combination with other antihypertensive agents.
BRU20012757P	Non-Preg Injection	It is a long-term contraceptive agent and treatment of endometriosis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20012758P	Bisloc 5 Tablet	Indicated for the treatment of: - Hypertension - Stable chronic angina - Stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics and optionally cardiac glycosides
BRU20012759P	Comazole N Tablet	For the treatment of urinary tract infections (upper and lower), respiratory infections, genital tract infections, gastrointestinal tract infections, skin and wound infections, other bacterial infections caused by sensitive organisms, fungal skin infection; south America blastomycosis.
BRU20012760P	QUANTIA 25 Film Coated Tablet	Indicated for the treatment of: • Treatment of schizophrenia • Treatment of bipolar disorder: - For the treatment of moderate to severe manic episodes in bipolar disorder - For the treatment of major depressive episodes in bipolar disorder - For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to Quetiapine treatment.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20012761P	QUANTIA 100 Film Coated Tablet	Indicated for the treatment of: • Treatment of schizophrenia • Treatment of bipolar disorder: - For the treatment of moderate to severe manic episodes in bipolar disorder - For the treatment of major depressive episodes in bipolar disorder - For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to Quetiapine treatment.
BRU20012762P	QUANTIA 200 Film Coated Tablet	Indicated for the treatment of: • Treatment of schizophrenia • Treatment of bipolar disorder: - For the treatment of moderate to severe manic episodes in bipolar disorder - For the treatment of major depressive episodes in bipolar disorder - For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to Quetiapine treatment.
BRU20012763NP	IFIMOL IV (Paracetamol Solution For Intravenous Infusion 10mg/ml)	Paracetamol is indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20012764P	Sofilex Capsule 250mg	Cephalexin is administered by mouth for the treatment of susceptible infections including those of the respiratory, urinary tracts and of the skin. It is also indicated in upper respiratory infections including pharyngitis and tonsillitis (caused by *Streptococcus pyogenes*) and otitis media (caused by *Strep. Pneumoniae, H. Influenza, Staphlococci and S. pyogenes*).
BRU20012765P	Cavumox 1.2g Injection	**CAVUMOX® (1.2 G INJECTION)** is indicated for the treatment of the following infections in adults and children: • Severe infections of the ear, nose and throat (such as mastoiditis, peritonsillar infections, epiglottitis, and sinusitis when accompanied by severe systemic signs and symptoms) • Acute exacerbations of chronic bronchitis (adequately diagnosed) • Community acquired pneumonia • Cystitis • Pyelonephritis • Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis • Bone and joint infections, in particular osteomyelitis • Intra-abdominal infections • Female genital infections

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20012766P	Combiwave SF 125 (Salmeterol 25mcg/Actuation And Fluticasone Propionate 125mcg/Actuation Pressurised Inhalation)	Reversible Obstructive Airways Disease (ROAD): Salmeterol and Fluticasone Propionate Pressurized Inhalation is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: • Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. Chronic Obstructive Pulmonary Disease (COPD): Salmeterol and Fluticasone Propionate Pressurized Inhalation is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU20012767P	Combiwave SF 250 (Salmeterol 25mcg/Actuation And Fluticasone Propionate 250mcg/Actuation Pressurised Inhalation)	Reversible Obstructive Airways Disease (ROAD): Salmeterol and Fluticasone Propionate Pressurized Inhalation is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: • Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. Chronic Obstructive Pulmonary Disease (COPD): Salmeterol and Fluticasone Propionate Pressurized Inhalation is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20012769P	Covastin Tablet 20mg	Therapy with lipid-altering agents should be considered in those individuals at increased risk for atherosclerosis-related clinical events as a function of cholesterol level, the presence of congestive heart failure, or other risk factors. Covastin is used when the response to a saturated fat and cholesterol-restricted diet and other non-pharmacological measures alone has been inadequate. Coronary Heart Disease In patients with coronary heart disease and hypercholesterolemia, Covastin is indicated to: • Reduce the risk of total mortality by reducing coronary death. • Reduce the risk of non-fatal myocardial infarction. • Reduce the risk for undergoing myocardial revascularization procedures (coronary artery bypass grafting and percutaneous transluminal coronary angioplasty). •Slow the progression of coronary atherosclerosis, including reducing the development of new lesions and new total occlusions. Hyperlipidemia Covastin is indicated as an adjunct to diet for reduction of elevated total-cholesterol, LDL-C, apolipoprotein B (Apo B), and TG in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate. Covastin also raises HDL-C and therefore lowers the LDL/HDL and total cholesterol/HDL ratios.
BRU20012770NP	FlameX Suspension	FlameX Suspension is indicated in the relief of symptoms of gastroesophageal reflux such as acid regurgitation, heartburn and indigestion.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20012771P	Letrozole Mevon Tablet 2.5mg	• Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer. • Extended adjuvant treatment of early breast cancer in postmenopausal women who have received prior standard adjuvant tamoxifen therapy. • First-line treatment in postmenopausal women with advanced hormone-dependent breast cancer. • Treatment of advance breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antioestrogens.

BRU20012772P	Flucozole (Intravenous Infusion) 2mg/ml	**FLUCOZOLE (INTRAVENOUS INFUSION)** is indicated in adults for the treatment of: • Cryptococcal meningitis. • Coccidioidomycosis. • Invasive candidiasis. • Mucosal candidiasis including oropharyngeal, oesophageal candidiasis, candiduria and chronic mucocutaneous candidiasis. • Chronic oral atrophic candidiasis (denture sore mouth) if dental hygiene or topical treatment are insufficient. **FLUCOZOLE (INTRAVENOUS INFUSION)** is indicated in adults for the prophylaxis of: • Relapse of cryptococcal meningitis in patients with high risk of recurrence. • Relapse of oropharyngeal or oesophageal candidiasis in patients infected with HIV who are at high risk of experiencing relapse. • Prophylaxis of candidal infections in patients with prolonged neutropenia (such as patients with haematological malignancies receiving chemotherapy or patients receiving Hematopoietic Stem Cell Transplantation. **FLUCOZOLE (INTRAVENOUS INFUSION)** is indicated in term newborn infants, infants, toddlers, children and adolescents aged from 0 to 17 years old: **FLUCOZOLE (INTRAVENOUS INFUSION)** is used for the treatment of mucosal candidiasis (oropharyngeal, oesophageal), invasive candidiasis, cryptococcal meningitis and the prophylaxis of candidal infections in immunocompromised patients. **FLUCOZOLE (INTRAVENOUS INFUSION)** can be used as maintenance therapy to prevent relapse of cryptococcal meningitis in children with high risk of reoccurrence. Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. Consideration should be given to official guidance on the appropriate use of antifungals.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20022773NP	Patent Blue V Sodium Guerbet 2.5%	This medicinal product is for diagnostic use only. Identification of lymph vessels and arterial territories. Identification of sentinel lymph nodes before biopsy in patients with operable breast cancer.
BRU20022774P	Micosten Cream 2%	For topical application in the treatment of tinea pedis (athlete's foot), tinea cruris, and tinea corporis caused by *Trichophyton rubrum, Trichophyton mentagrophytes,* and *Epidermophyton floccosum.* Also indicated in the treatment of cutaneous candidiasis (moniliasis) caused by *Candida albicans* . Topical miconazole nitrate is also indicated in the treatment of tinea versicolor caused by *Malassezia furfur.*
BRU20022775P	Mobitil Injection 20ml Vial	Dobutamine Hydrochloride is indicated in adults who require short-term treatment of cardiac failure secondary to acute myocardial infarction or cardiac surgery.
BRU20022776P	Fytosid Injection 20mg/ml	• Small cell carcinoma of the lung • Acute monocytic and myelomonocytic leukaemia • Hodgkin's disease • Non-Hodgkin's lymphoma

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20022777P	Fleming Oral Suspension (457mg/5ml)	Fleming is indicated for short-term treatment of bacterial infections at the following sites: Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media. Lower respiratory tract infections e.g. acute and acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis. Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections. Bone and joint infections e.g. osteomyelitis. Dental infections e.g. dentoalveolar abscess Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis.
BRU20022778P	Repatha Solution For Injection In Prefilled Syringe 140mg/ml	<u>Prevention of Cardiovascular Events</u> In adults with established cardiovascular disease, Repatha in combination with an optimally dosed statin and/or other lipid-lowering therapies is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularisation. <u>Primary Hypercholesterolaemia and Mixed Dyslipidaemia</u> Repatha is indicated as an adjunct to diet, for the treatment of adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and paediatric patients aged 10 years and over with heterozygous familial hypercholesterolaemia to reduce low density lipoprotein cholesterol (LDL-C): • In combination with a statin or statin with other lipid-lowering therapies in patients who are unable to reach LDL-C goals with a statin or; • Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. <u>Homozygous Familial Hypercholesterolaemia</u> Repatha is indicated in adults and paediatric patients aged 10 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20022779P	Repatha Solution For Injection In Prefilled Autoinjector 140mg/ml	<u>Prevention of Cardiovascular Events</u> In adults with established cardiovascular disease, Repatha in combination with an optimally dosed statin and/or other lipid-lowering therapies is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularisation. <u>Primary Hypercholesterolaemia and Mixed Dyslipidaemia</u> Repatha is indicated as an adjunct to diet, for the treatment of adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and paediatric patients aged 10 years and over with heterozygous familial hypercholesterolaemia to reduce low density lipoprotein cholesterol (LDL-C): • In combination with a statin or statin with other lipid-lowering therapies in patients who are unable to reach LDL-C goals with a statin or; • Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. <u>Homozygous Familial Hypercholesterolaemia</u> Repatha is indicated in adults and paediatric patients aged 10 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20022780P	Pemetrexed Seacross 500mg Powder For Concentrate For Solution For Infusion	<u>Malignant pleural mesothelioma</u> Pemetrexed Seacross in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. <u>Non-small cell lung cancer</u> Pemetrexed Seacross in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. Pemetrexed Seacross is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemetrexed Seacross is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20022781P	Pemetrexed Seacross 100mg Powder For Concentrate For Solution For Infusion	<u>Malignant pleural mesothelioma</u> Pemetrexed Seacross in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. <u>Non-small cell lung cancer</u> Pemetrexed Seacross in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. Pemetrexed Seacross is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemetrexed Seacross is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.
BRU20022783P	Momate Nasal Spray 50mcg	Mometasone Furoate Nasal Spray is indicated for use in adults, adolescents and children between the ages of 3 and 11 years to treat the symptoms of seasonal allergic or perennial rhinitis. In patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis, prophylactic treatment with Mometasone Furoate Nasal Spray is recommended two to four weeks prior to the anticipated start of the pollen season. Mometasone Furoate Nasal Spray is indicated for the treatment of nasal polyps in adults 18 years of age and older. Mometasone Furoate Nasal Spray is indicated for the treatment of symptoms associated with acute rhinosinusitis in patients 12 years of age and older without signs or symptoms of severe bacterial infection.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20022784P	Somidem Tablet 10mg	Zolpidem is indicated for short-term treatment of insomnia. Hypnotics should generally be limited to 7 to 10 days of use, and re-evaluation of the patient is recommended if insomnia fails to remit after this period.
BRU20022785P	Ibicar 100 (Beclometasone Pressurised Inhalation BP 100µg/Actuation)	**Ibicar** is indicated in the prophylactic management of asthma.
BRU20022786NP	Tonbien Solution Jen Sheng 150mg/ml	Tonbien Solution Jen Sheng is used for relieving constipation through external application via the anus. The medicine works quickly by stimulating the bowels as well as softening the excreata upon application for immediate relief. This contrasts sharply with oral medicines which have to be taken hours before any effect can be realized.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20022788P	Azimax 250mg Tablet	Azithromycin is indicated for the treatment of the following infections when known or likely to be due to one or more susceptible microorganisms: • Bronchitis • Community-Acquired Pneumonia • Sinusitis • Pharyngitis/Tonsillitis • Otitis Media • Skin and soft tissue infections • Uncomplicated genital infections due to *Chlamydia trachomatis*
BRU20032789P	Kisan Injection 10mg/ml	Haemorrhage or threatened haemorrhage as a result of severe 'hypoprothrombinemia (ie. deficiency of coagulation factors II, VII, IX and X) due, for instance, to overdosage of anticoagulants of the dicoumaral type or their combination with phenylbutazone, or to other forms of hypovitaminosis K (eg. Obstructive jaundice, liver and intestinal disorders, or prolonged administration of antibiotics, sulfonamides or salicylates)
BRU20032790P	Basalog One Insulin Glargine Injection (rDNA origin) 100 IU/mL Prefilled Pen	For the treatment of adults, adolescents and children of 2 years or above with diabetes mellitus, where treatment with insulin is required.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20032791P	Tasigna 50mg Capsule	Tasigna is indicated for: •the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP).Clinical effectiveness of TASIGNA in adults with newly diagnosed Ph+ CML-CP is based on major molecular response rate at 12 months and complete cytogenetic response rate by 12 months. the treatment of paediatric patients 2 years of age and older with newly diagnosed Ph+ CML-CP.Clinical effectiveness of TASIGNA in paediatric patients with newly diagnosed Ph+CML-CP is based on major molecular response by 12 cycles and complete cytogenetic response at 12 cycles. •the treatment of chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib.Clinical effectiveness of TASIGNA in adults with imatinib-resistant or -intolerant Ph+CML-CP was based on the unconfirmed major cytogenetic and complete hematologic response rates. Clinical effectiveness of TASIGNA in imatinib-resistant or -intolerant Ph+ CML-AP for adult patients was based on the confirmed hematologic response rates and the unconfirmed major cytogenetic response rates. •the treatment of paediatric patients 2 years of age and older with Ph+ CML-CP with resistance or intolerance to prior therapy including imatinib. Clinical effectiveness of TASIGNA in paediatric patients with imatinib-resistant or intolerant Ph+ CML-CP was based on the MMR rate at 6 cycles. No overall survival benefit has been demonstrated.
BRU20032793P	Xgeva Solution For Injection 120mg/Vial	Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with multiple myeloma and in patients with bone metastases from solid tumours. Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20032794P	Rekaxime Injection 1000mg	Infections of the respiratory tract, including throat and nose; of the ear; of the kidneys and urinary tract; of the skin and soft tissues; of the bones and joints; of the genital organs, including gonorrhoea; of the abdominal region. Septicaemia, bacterial endocarditis, meningitis; for perioperative prophylaxis in patients who are at increased risk from infection, and for the prophylaxis of infections in patients with reduced resistance.
BRU20032795P	Setisin Injection 2.5mg/ml (1ml Amp)	Reversal of the effects on nondepolarising neuromuscular blocking agents (e.g. tubocurarine, pancuronium, etc.). Prophylaxis and treatment of post-operative intestinal atony and urinary retention. Also treatment of myasthenia gravis.
BRU20032796P	Avarin Softgel Capsule	This medication is an antispasmodic that reduces intestinal gas. This medication is recommended for relieving painful digestion with stomach distension. It is indicated for use in the relief of smooth muscle spasm, in condition such as irritable bowel syndrome.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20032797P	MENOPUR® Multidose 600IU Powder And Solvent For Solution For Injection	MENOPUR® is indicated for the treatment of infertility in the following clinical situations: Anovulation, including polycystic ovarian disease (PCOD), in women who have been unresponsive to treatment with clomiphene citrate. Controlled ovarian hyperstimulation to induce the development of multiple follicles for assisted reproductive technologies (ART) (e.g. in vitro fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI).
BRU20032798P	Fleming Oral Suspension (228.5mg/5ml)	Fleming is indicated for short-term treatment of bacterial infections at the following sites: Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media. Lower respiratory tract infections e.g. acute and acute exacerbations of chronic bronchitis, lobar and bronchopneumonia. Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis. Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections. Bone and joint infections e.g. osteomyelitis. Dental infections e.g. dentoalveolar abscess Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20032800P	Vivocin (Vancomycin Hydrochloride For Injection USP 500mg/Vial)	Vancomycin is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant (beta-lactam-resistant) staphylococci. It is indicated for penicillin-allergic patients, for patients who cannot receive or who have failed to respond to other drugs, including the penicillins or cephalosporins, and for infections caused by vancomycin-susceptible organisms that are resistant to other antimicrobial drugs. Vancomycin is indicated for initial therapy when methicillin-resistant staphylococci are suspected, but after susceptibility data are available, therapy should be adjusted accordingly. Vancomycin's effectiveness has been documented in other infections due to staphylococci, including septicemia, bone infections, lower respiratory tract infections, skin, and skin structure infections. When staphylococcal infections are localized and purulent, antibiotics are used as adjuncts to appropriate surgical measures. Specimens for bacteriologic cultures should be obtained in order to isolate and identify causative organisms and to determine their susceptibilities to vancomycin. To reduce the development of drug-resistant bacteria and maintain the effectiveness of vancomycin and other antibacterial drugs, vancomycin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

		Rheumatoid Arthritis Humira is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Humira is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with disease modifying anti-rheumatic drugs. **Axial Spondyloarthritis** **Ankylosing Spondylitis** Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Non-radiographic Axial spondyloarthritis (Axial Spondyloarthritis without radiographic evidence of AS)** Humira is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.

BRU20032801P; BRU20032801PS2	Humira Solution For Injection In Pre-Filled Syringe 80mg/0.8ml	**Plaque Psoriasis** Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Crohn's Disease** Humira is indicated for the treatment of moderately to severely active Crohn's Disease in adult patients who have inadequate response to conventional therapy. Humira is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab. **Ulcerative colitis** Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Hidradenitis Suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate.

Paediatrics

Juvenile idiopathic arthritis

Polyarticular Juvenile Idiopathic Arthritis

Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

Enthesitis-Related Arthritis

Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Paediatric Crohn's Disease

Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindication for such therapies.

Paediatric Plaque Psoriasis

Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy.

Paediatric Uveitis

Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

		Adolescent hidradenitis suppurativa Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Ulcerative Colitis** Humira is indicated for inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

		Rheumatoid Arthritis Humira is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Humira is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with disease modifying anti-rheumatic drugs. **Axial Spondyloarthritis** **Ankylosing Spondylitis** Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Non-radiographic Axial spondyloarthritis (Axial Spondyloarthritis without radiographic evidence of AS)** Humira is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.

BRU20032802P; BRU20032802PS2	Humira Solution For Injection In Pre-Filled Pen 80mg/0.8ml	**Plaque Psoriasis** Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Crohn's Disease** Humira is indicated for the treatment of moderately to severely active Crohn's Disease in adult patients who have inadequate response to conventional therapy. Humira is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab. **Ulcerative colitis** Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Hidradenitis Suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate.

Paediatrics

Juvenile idiopathic arthritis

Polyarticular Juvenile Idiopathic Arthritis

Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

Enthesitis-Related Arthritis

Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Paediatric Crohn's Disease

Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindication for such therapies.

Paediatric Plaque Psoriasis

Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy.

Paediatric Uveitis

Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

		Adolescent hidradenitis suppurativa Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Ulcerative Colitis** Humira is indicated for inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.
BRU20032803NP	Betadine Antiseptic Cream 5% w/w	Betadine Antiseptic Cream is indicated for: ♦Bacterial and mycotic (fungal) skin infections ♦Bed sore and leg ulcer ♦Minor burns, cuts and abrasions ♦ Herpes genitalis
BRU20032804P	Kytron Solution For Injection/Infusion 3mg/3ml	Kytron Solution for Injection/Infusion 3mg/3ml is indicated for the prevention and treatment (control) of a) acute and delayed nausea and vomiting associated with chemotherapy and radiotherapy b) post-operative nausea and vomiting

BRU20032809P	Ebetaxel Injection 6mg/ml	***Ovarian Carcinoma*** • First-line therapy in combination with platinum compound for the treatment of advanced metastatic carcinoma of the ovary. • Second-line therapy for the treatment of advanced metastatic carcinoma of the ovary. ***Breast Carcinoma*** • Adjuvant treatment of node-positive breast cancer administered sequentially to standard combination therapy. • First-line therapy of advanced or metastatic breast cancer after relapse within 6 months of adjuvant therapy. Prior therapy should have included an anthracycline unless clinically contraindicated. • First-line therapy of metastatic breast cancer in combination with trastuzumab in patients who overexpress HER-2 as determined by immunohistochemistry. • First-line therapy of metastatic breast cancer in combination with anthracycline in patients for whom anthracycline therapy is not suitable. • Second-line therapy of advanced or metastatic breast cancer after failure of combination chemotherapy for metastatic disease. Prior therapy should have included an anthracycline unless clinically contraindicated. ***Non-Small Cell Lung Carcinoma*** • First-line therapy in combination with a platinum compound or as a single agent for the treatment of non small cell carcinoma of the lung in patients who are not candidates for potentially curative surgery and/or radiation therapy. ***Kaposi's Sarcoma*** • Second-line treatment of AIDS-related Kaposi's Sarcoma

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20032810P	Imarem 400mg Tablet	Imarem is indicated for the treatment of • adult and pediatric patients with newly diagnosed chronic myeloid leukemia (CML) as well as for the treatment of adult and pediatric patients with CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. • adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy. • adult patients with relapsed or refractory Ph+ ALL as monotherapy. • adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. • adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα re-arrangement. • adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP). • adult patients with aggressive systemic mastocytosis (ASM) without the D816V cKit mutation or with c-Kit mutational status unknown. The effectiveness of Imarem is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and ASM and on objective response rates in adult patients with unresectable and/or metastatic DFSP. The experience with imatinib in patients with MDS/MPD associated with PDGFR gene rearrangements is very limited. Except in newly diagnosed chronic phase CML, there are no controlled trials demonstrating a clinical benefit or increased survival for these diseases.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20032811P	Imarem 100mg Tablet	Imarem is indicated for the treatment of • adult and pediatric patients with newly diagnosed chronic myeloid leukemia (CML) as well as for the treatment of adult and pediatric patients with CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy. • adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy. • adult patients with relapsed or refractory Ph+ ALL as monotherapy. • adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. • adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα re-arrangement. • adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP). • adult patients with aggressive systemic mastocytosis (ASM) without the D816V cKit mutation or with c-Kit mutational status unknown. The effectiveness of Imarem is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and ASM and on objective response rates in adult patients with unresectable and/or metastatic DFSP. The experience with imatinib in patients with MDS/MPD associated with PDGFR gene rearrangements is very limited. Except in newly diagnosed chronic phase CML, there are no controlled trials demonstrating a clinical benefit or increased survival for these diseases.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20032812P	Pharmidea Carbetocin 100mcg/ml	Pharmidea Carbetocin is indicated for the prevention of uterine atony and postpartum haemorrhage following elective caesarean section under epidural or spinal anaesthesia. Pharmidea Carbetocin has not been studied in cases involving emergency caesarean section, classical caesarean section, anaesthesia other than epidural or spinal, or in patients presenting significant heart disease, history of hypertension, known coagulopathy or evidence of liver, renal or endocrine disease (excluding gestational diabetes). Appropriate studies have not been undertaken and doses have not been established in women following labour or vaginal delivery.
BRU20032813P	Aurasert Tablet 50mg	Aurasert is indicated for the treatment of symptoms of depressive illness including accompanying symptoms of anxiety. It is also indicated in preventing relapse of the initial episode of depression or recurrence of further depressive episodes including accompanying symptoms of anxiety. Aurasert is indicated in the treatment of obsessions and compulsions in patients with obsessive compulsive disorder. Aurasert is indicated for the treatment of panic disorder with or without agoraphobia.
BRU20032814P	Aurasert Tablet 100mg	Aurasert is indicated for the treatment of symptoms of depressive illness including accompanying symptoms of anxiety. It is also indicated in preventing relapse of the initial episode of depression or recurrence of further depressive episodes including accompanying symptoms of anxiety. Aurasert is indicated in the treatment of obsessions and compulsions in patients with obsessive compulsive disorder. Aurasert is indicated for the treatment of panic disorder with or without agoraphobia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20032815NP	Septidin 10% Solution	Antiseptic Against Bacteria, Fungi, Viruses, Protozoa, Cysts & Spores For Minor Burns, Wounds & On Pre-Operative Preparation Of The Skin.
BRU20032819P	MYODEEN Adenosine Injection USP 3mg/ml	Rapid conversion to a normal sinus rhythm of paroxysmal supraventricular tachycardia, including those associated with accessory by-pass tracts (Wolff-Parkinson-White Syndrome). Diagnostic Indications Aid to diagnosis of broad or narrow complex supraventricular tachycardia. Although Adenosine will not convert atrial flutter, atrial fibrillation or ventricular tachycardia to sinus rhythm, the slowing of AV conduction helps diagnosis of atrial activity. Sensitization of intra-cavitary electrophysiological investigations.
BRU20032821P	Supirocin Ointment 2% w/w	Supirocin Ointment is indicated for the bacterial skin infections e.g.: impetigo, folliculitis and furunculitis.
BRU20032822NP	Minyak Urut GPU (Gosok-Pijat-Urut) - Minyak Jahe	Helps to relieve of muscular pains, joint pains, backache, sprains, bruises and helps blood circulation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20042823PS1; BRU20042823PS2	Darzalex 100mg/5ml (20mg/ml) Concentrate For Solution For Infusion	DARZALEX is indicated for the treatment of adult patients with multiple myeloma: • in combination with lenalidomide and dexamethasone - in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. - in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. • in combination with bortezomib, melphalan, prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. • in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant. • in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. • in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. • as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20042824PS1; BRU20042824PS2	Darzalex 400mg/20ml (20mg/ml) Concentrate For Solution For Infusion	DARZALEX is indicated for the treatment of adult patients with multiple myeloma: • in combination with lenalidomide and dexamethasone - in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. - in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. • in combination with bortezomib, melphalan, prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. • in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant. • in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. • in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. • as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20042825P	Malon Injection 2ml Amp	Adult population: Malon Injection is indicated for use in adults in: • prevention of post-operative nausea and vomiting, • symptomatic treatment of nausea and vomiting, including nausea and vomiting induced by migraine attacks, • prevention of radiotherapy-induced nausea and vomiting Pediatric population: Malon Injection is indicated in children aged 1 to 18 years for: • prevention of delayed chemotherapy-induced nausea and vomiting as a second line option, • prevention of post-operative nausea and vomiting as second-line option
BRU20042826P	GC FLU Pre-Filled Syringe Injection	Prophylaxis against influenza.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20042827P	Thyrosit 100mcg Tablet	*Thyrosit 100mcg is used in the:* - Treatment of hypothyroidism - Replacement or substitution of diminished or absent thyroid function resulting from primary causes including functional deficiency, primary atrophy and partial or complete absence of the gland or from the effects or surgery, radiation of thyroid glands. - Replacement or supplemental therapy in patients with secondary or tertiary hypothyroidism. - Treatment of congenital hypothyroidism (cretinism). - Replacement therapy in the management of simple goitre and chronic lymphocytic thyroiditis.
BRU20042828P	Lecetam 250 Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of: • partial onset seizures with or without secondary generalization in adults, adolescents, and children from 1 month of age with epilepsy. • myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • primary generalized tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalized Epilepsy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20042829P	Pulmicort Respules 0.5mg/ml	PULMICORT RESPULES contain the potent non-halogenated corticosteroid budesonide for use in bronchial asthma in patients where use of a pressurized inhaler or dry powder formulation is unsatisfactory or inappropriate. PULMICORT RESPULES can be used for the treatment of acute laryngotracheobronchitis (croup) in infants and children. PULMICORT RESPULES can be used in patients with exacerbations of chronic obstructive pulmonary disease in persons without signs of acute respiratory insufficiency.
BRU20042830NP	Geliga Muscular Balm	Geliga Muscular Balm helps to relieve muscular and joint problems such as bruises, sprain and backaches. Geliga Muscular Balm is also good to be used as warming up balm for athletes.
BRU20042831NP	Minyak Urut GPU (Gosok-Pijat-Urut) - Minyak Sereh	Helps to relieve of muscular pains, joint pains, backache, sprains, bruises and promoting blood circulation.
BRU20042832P	Ceritec Syrup 1mg/ml	Adults and children ≥1 year: Cetirizine Hydrochloride is indicated for symptomatic treatment of seasonal rhinitis, perennial allergic rhinitis and urticaria of allergic origin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20042833P	Nexpro Tablets 20mg	Esomeprazole is indicated for the treatment of: **Gastro-Oesophageal Reflux Disease (GERD)** • Treatment of erosive reflux oesophagitis • Long-term management of patients with healed oesophagitis to prevent relapse • Symptomatic treatment of gastro-oesophageal reflux disease (GERD) **In combination with an appropriate antibacterial therapeutic regimen for the eradication of *Helicobacter pylori* and** • Healing of *Helicobacter pylori* associated with duodenal ulcer • Prevention of relapse of peptic ulcers in patients with *Helicobacter pylori* associated ulcers **Patients requiring continued NSAID therapy** • Healing of gastric ulcers associated with NSAID therapy • Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk **Prolonged treatment after IV induced prevention of rebleeding of peptic ulcers** **Treatment of Zollinger Ellison Syndrome**
BRU20042834NP	Rexom Potassium Citrate Mixture	For the relief of the symptoms of cystitis and other mild urinary tract infections.

BRU20042835P	SVOZ (0.5% Ophthalmic Solution)	Moxifloxacin is indicated: • For the treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of organisms listed below • Preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required) Table 1 Gram-Positive Bacteria : • *Corynebacterium* species* • *Microbacterium* species • *Micrococcus luteus* * [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains] • *Staphylococcus aureus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline, and/or trimethoprim resistant strains] • *Staphylococcus epidermidis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline, and/or trimethoprim resistant strains] • *Staphylococcus haemolyticus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline, and/or trimethoprim resistant strains] • *Staphylococcus hominis* * [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline, and/or trimethoprim resistant strains] • *Staphylococcus warneri* * [including erythromycin resistant strains] • *Streptococcus mitis* * [including penicillin, erythromycin, tetracycline, and/or trimethoprim resistant strains] • *Streptococcus pneumonia* [including penicillin, erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains] • *Streptococcus viridans* [including penicillin, erythromycin, tetracycline, and/or trimethoprim resistant strains]

		Gram-Negative Bacteria : • *Acinetobacter species* • *Haemophilus "alconae"* [including ampicillin resistant strains] • *Haemophilus influenza* [including ampicillin resistant strains] • *Klebsiella pneumoniae* * • *Moraxella catarrhalis* * • *Pseudomonas aeruginosa* * Other Microorganisms : • *Chlamydia trachomatis* *Note: * indicates efficacy for this organism was studied in fewer than 10 infections*
BRU20042836P	Disuf Ointment 2% w/w	DISUF OINTMENT is indicated for the treatment of skin infections caused by *staphylococci* , *streptococci* , *corynebacterium minutissimum* and other organisms sensitive to fusidic acid. The most important indications being: Impetigo, Boils, Carbuncles, Paronychia, Infected wounds, Sycosis barbae, Hidradenitis, Erythrasma, Folliculitis.

BRUNEI DARUSSALAM MEDICINES CONTROL AUTHORITY
MINISTRY OF HEALTH, BRUNEI DARUSSALAM

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20042837P	Hovid Allopurinol Tablet 100mg	For treatment or prevention of: • Chronic primary or secondary gout. • Uric acid nephropathy. • Uric acid stone formation. • Problems associated with hyperuricemia (i.e. tissue urate deposition, renal calculi, or acute urate nephropathy) secondary to cancer chemotherapy or radiation therapy.
BRU20042838P	Virest 5% Cream	It is used for the treatment of herpes simplex viral infections of the skin including initial and recurrent genital herpes and herpes labialis.
BRU20052839P	Conpanzole Enteric Coated Tablet 20mg	1) In combination with two appropriate antibiotics for the eradication of Helicobacter pylori in patients with peptic ulcers with the objective of reducing the recurrence of duodenal and gastric ulcers caused by this microorganism 2) Duodenal ulcer 3) Gastric ulcer 4) Moderate and severe cases of inflammation of the esophagus (reflux esophagitis) 5) Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20052840P	Conpanzole Enteric Coated Tablet 40mg	1) In combination with two appropriate antibiotics for the eradication of Helicobacter pylori in patients with peptic ulcers with the objective of reducing the recurrence of duodenal and gastric ulcers caused by this microorganism 2) Duodenal ulcer 3) Gastric ulcer 4) Moderate and severe cases of inflammation of the esophagus (reflux esophagitis) 5) Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions
BRU20052841P	Tensiber Film Coated Tablet 150mg	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen.
BRU20052842P	Unitrexate Tablet 2.5mg	1) Acute lymphoblastic leukemia 2) Methotrexate is indicated for the treatment of trophoblastic neoplasms (choriocarcinoma, chorioadenoma destruens, and hydatiform mole). 3) Rheumatoid arthritis. 4) It is also used in the treatment of severe, uncontrolled psoriasis which is not responsive to other therapy.
BRU20052843NP	Hovid-Paracetamol Suspension 250mg/5ml (Sugar Free)	Indicated for the relief of fever, headache and symptoms of cold and flu, toothache, discomfort of teething and fever after vaccination.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20052844P	A-Losartan 50mg Tablet	Treatment of hypertension.
BRU20052845P	A-Losartan 100mg Tablet	Treatment of hypertension.
BRU20052846P	Fustadin Cream 2% w/w	This cream is indicated for treatment of skin infections caused by staphylococci, streptococci, *Propionibacterium acnes, Corynebacterium minutissimum* and other organisms sensitive to fusidic acid. The most important indications being: • Impetigo • Infected wounds • Folliculitis • Boils • Sycosis barbae • Carbuncles • Hidradenitis • Paronychia • Erythrasma
BRU20052847P	Peace DM Syrup	Relief of dry irritating cough associated with common cold, upper respiratory tract infections and allergic rhinitis. Helps dry up running nose and opens congested bronchi to aid clear breathing.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20052848NP	Wintinea Cream	Wintinea Cream is indicated for the treatment of superficial fungal infection of the skin including athlete's foot (tinea pedis), jock itch (tinea cruris), body ringworm (tinea corporis) and pityriasis versicolor.
BRU20052849P	Losartan + HCT Mevon Tablet 100/25mg	<u>Hypertension</u> Losartan + HCT Mevon film-coated tablets are indicated for the treatment of hypertension, for patients in whom combination therapy is appropriate. <u>Hypertensive patients with left ventricular hypertrophy</u> Losartan + HCT Mevon film-coated tablets is a combination of losartan and hydrochlorothiazide. In patients with hypertension and left ventricular hypertrophy, losartan, often in combination with hydrochlorothiazide, reduced the risk of stroke in hypertensive patients with left ventricular hypertrophy.
BRU20052850P	Bencodyl Linctus	For productive cough and complication associated with allergic disorders and allergic manifestation of respiratory illness e.g. common cold, flu and bronchitis.
BRU20052851P	Defuzin-B Cream	Defuzin-B Cream is indicated for the inflammatory dermatoses where bacterial infection is present or likely to occur. Inflammatory dermatoses include atopic eczema, discoid eczema, stasis eczema, seborrheic dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis, discoid lupus erythematosus.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20052852P	Pharmaniaga Simvastatin Tablet 20mg	*Reductions in risk of coronary heart disease (CHD) mortality and cardiovascular events* In patients at high risk of coronary events because of existing coronary heart disease, diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease, simvastatin is indicated to: • Reduce the risk of total mortality by reducing CHD deaths. • Reduce the risk of non-fatal myocardial infarction and stroke. • Reduce the need for coronary and non-coronary revascularization procedures. *Hyperlipidaemia* Simvastatin is indicated as an adjunct to diet to reduce elevated total plasma cholesterol (total-C), lowdensity lipoprotein (LDL-C), apolipoprotein B (Apo B), and triglycerides (TG) and to increase highdensity lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate. Simvastatin therefore, lowers the LDL-C/HDL-C and the total-C/HDL-C ratios. *Pediatric patients with heterozygous familial hypercholesterolemia* Simvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, TG, and Apo B levels in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with heterozygous familial hypercholesterolemia (HeFH).
BRU20062854P	Basalog Insulin Glargine Injection (rDNA origin) 100IU/mL	For the treatment of adults, adolescents and children of 2 years or above with diabetes mellitus, where treatment with insulin is required.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20062856P	Zoledronic Acid 5mg/100ml Solution For Infusion	Treatment of osteoporosis • in post-menopausal women • in adult men at increased risk of fracture, including those with a recent low-trauma hip fracture. Treatment of osteoporosis associated with long-term systemic glucocorticoid therapy • in post-menopausal women • in adult men at increased risk of fracture. Treatment of Paget's disease of the bone in adults.
BRU20062857NP	Wellmex Atomic Enema	It is used for relieving constipation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20062858P	Vacodil 25mg Tablets	**Hypertension** Vacodil is indicated primarily for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents (e.g. calcium channel blockers, diuretics). **Treatment of angina pectoris** **Treatment of symptomatic chronic heart failure** Vacodil is indicated for the treatment of symptomatic chronic heart failure (CHF) to reduce mortality and cardiovascular hospitalizations, improve patient well-being and slow the progression of the disease. Vacodil may be used as adjunct to standard therapy, but may also be used in those patients unable to tolerate an ACE inhibitor, or those who are not receiving digitalis, hydralazine or nitrate therapy.
BRU20062859P	Mementor Tablets 10mg	Treatment of patients with moderate to severe Alzheimer's disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20062860P	Covastin Tablet 40mg	Therapy with lipid-altering agents should be considered in those individuals at increased risk for atherosclerosis-related clinical events as a function of cholesterol level, the presence of congestive heart failure, or other risk factors. Covastin is used when the response to a saturated fat and cholesterol-restricted diet and other non-pharmacological measures alone has been inadequate. ***Coronary Heart Disease*** In patients with coronary heart disease and hypercholesterolemia, Covastin is indicated to: • Reduce the risk of total mortality by reducing coronary death. • Reduce the risk of non-fatal myocardial infarction. • Reduce the risk for undergoing myocardial revascularization procedures (coronary artery bypass grafting and percutaneous transluminal coronary angioplasty). •Slow the progression of coronary atherosclerosis, including reducing the development of new lesions and new total occlusions. ***Hyperlipidemia*** Covastin is indicated as an adjunct to diet for reduction of elevated total-cholesterol, LDL-C, apolipoprotein B (Apo B), and TG in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate. Covastin also raises HDL-C and therefore lowers the LDL/HDL and total cholesterol/HDL ratios.
BRU20062861P	Myborte 3.5mg (Bortezomib Powder For Solution For Injection 3.5mg/Vial)	Bortezomib is indicated for the treatment of patients with multiple myeloma. Bortezomib is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20062863P	YSP Salbutamol Injection 0.5mg/ml	1) Relief of severe bronchospasm associated with asthma or bronchitis and for the treatment of status asthmaticus. 2) Management of uncomplicated premature labour in the last trimester of pregnancy.
BRU20062864P	YSP Bufencon Injection	This product is indicated for the treatment of acute and chronic corticosteroid-responsive disorders. Corticosteroid hormone therapy is an adjunct to, and not a replacement for, conventional therapy. **Musculoskeletal and Soft Tissue Conditions**: Rheumatoid arthritis; osteoarthritis; bursitis; ankylosing spondylitis; epicondylitis; radiculitis; coccydynia; sciatica; lumbago; torticollis; ganglion cyst; exostosis; fasciitis. **Allergic Conditions**: Chronic bronchial asthma (including adjunctive therapy for status asthmaticus); hay fever; angioneurotic edema; allergic bronchitis; seasonal or perennial allergic rhinitis; drug reactions; serum sickness; insect bites. **Dermatologic Conditions**: Atopic dermatitis (nummular eczema); neurodermatitis (circumscribed lichen simplex); contact dermatitis; severe solar dermatitis; urticaria; hypertrophic lichen planus; necrobiosis lipoidica diabeticorum; alopecia areata; discoid lupus erythematosus; psoriasis; keloids; pemphigus; dermatitis herpetiformis; cystic acne. **Collagen Diseases**: Disseminated lupus erythematosus; scleroderma; dermatomyositis; periarteritis nodosa. **Neoplastic Diseases**: For palliative management of leukaemias and lymphomas in adults; acute leukemia of childhood. **Other Conditions**: Adrenogenital syndrome; ulcerative colitis; regional ileitis; sprue; podiatric conditions (bursitis under heloma durum, hallux rigidus, digiti quinti varus); affections requiring subconjunctival injection; corticosteroid-responsive blood dyscrasias; nephritis, and nephritic syndrome. Primary and secondary adrenocortical insufficiency may be treated with this product but should be supplemented with mineralocorticoids, if applicable.

		This product is recommended for (1) Intramuscular injection in conditions responsive to systemic corticosteroids; (2) Injection directly into the affected soft tissues where indicated; (3) Intraarticular and periarticular injection in arthritides; (4) Intralesional injection in various dermatologic conditions; and (5) Local injection in certain inflammatory and cystic disorders of the foot.
BRU20062865P	Finil 16 Tablet	Indicated in the: • Treatment of essential hypertension in adults • Treatment of hypertension in children and adolescents aged 6 to < 18 years • Treatment of adult patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction ≤ 40%) when Angiotensin Converting Enzyme (ACE)-inhibitors are not tolerated or as add-on therapy to ACE-inhibitors in patients with symptomatic heart failure, despite optimal therapy, when mineralocorticoid receptor antagonists are not tolerated
BRU20062866NP	ActiMol Tablet 650mg	Relief of headache, backache, period pain, and aches due to cold and flu, pain related to mild arthritis and fever.
BRU20062867NP	BAGES Cream	Indicated for temporary relief of minor aches and pains of muscle and joints associated with simple backache, arthritis, strains, etc.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20062868P	Lorsedin Oral Solution 1mg/ml	Loratadine is indicated for the relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge (rhinorrhea) and itching, as well as ocular itching and burning. Nasal and ocular signs and symptoms are relieved rapidly after oral administration. Loratadine is also indicated for relief of symptoms and signs of chronic urticaria and other allergic dermatologic disorders.
BRU20062869P	Albumin (Human) U.S.P. Albutein 5%	Albutein 5% is indicated: a. For treatment of hypovolemic shock b. In conditions in which there is severe hypoalbuminemia. However, unless the pathologic condition responsible for the hypoalbuminemia can be corrected, administration of albumin can afford only symptomatic or supportive relief c. As an adjunct in hemodialysis and in cardiopulmonary bypass procedures In those conditions in which the colloid requirement is high and there is less need for fluid, albumin should be administered as a 25% solution. Pediatric Use: The pediatric use of Albutein 5% has not been clinically evaluated. Therefore, physicians should weigh the risks and benefits of the use of Albutein 5% in the pediatric population.
BRU20062870P	Mico Cream	Mico Cream is indicated for the topical treatment of the skin infections due to susceptible fungi (dermatophytes and yeasts) such as tinea pedis (athletes foot), tinea cruris, tinea corporis (ringworm), tinea versicolor (white spots) and candidiasis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20062871P	Sunvasc 5 Tablet	First-line treatment of hypertension and as the sole agent to control blood pressure in the majority of patients. Amlodipine has also been used successfully in combination with a thiazide diuretic, β-adrenoceptor-blocking agent or an angiotensin-converting enzyme inhibitor. Amlodipine is indicated for the 1st-line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used alone, as monotherapy or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of β-blockers.
BRU20062872P	Sensitamine Tablet	i) Symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis and allergic conjunctivitis due to inhalant allergens and foods. ii) Symptomatic treatment of pruritus associated with allergic reactions and of mild, uncomplicated allergic skin manifestation of urticaria and angioedema and in dermatographism. iii) May be used in combination with a decongestant (Pseudoephedrine) for the temporary relief of nasal and sinus congestion associated with the common cold and allergic rhinitis.
BRU20062873P	Uniflex-N Cream	Uniflex-N Cream is indicated for the relief of corticosteroid-responsive inflammatory dermatoses, especially when secondary bacterial infection is present or likely to be present. It is indicated for the treatment of eczema, psoriasis, lichen planus, sebborrhoeic dermatitis, intertrigo, contact sensitivity reactions, discoid lupus, erythematosus, generalised erythroderma. Uniflex-N Cream can be used for the relief of insect bites and stings.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20062874P	Orata 0.5 Film Coated Tablet	Entecavir is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with: • Compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis. • Decompensated liver disease For both compensated and decompensated liver disease, this indication is based on clinical trial data in nucleoside naive patients with HBeAg positive and HBeAg negative HBV infection.With respect to patients with Lamivudine-refractory hepatitis B. Entecavir is also indicated for the treatment of chronic HBV infection in nucleoside naive pediatric patients from 2 to < 18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis. With respect to the decision to initiate treatment in pediatric patients.
BRU20062875NP	INFUSOL D5 Intravenous Infusion	- Energy supply - Hypertonic dehydration - Vehicle solution for supplementary medication - Hypoglycaemia

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20062876P	Podoxred (Pemetrexed) Powder For Concentrate For Solution For Infusion 100mg	Malignant pleural mesothelioma: Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. Non-small cell lung cancer: Pemetrexed in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemetrexed is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20062877P	Podoxred (Pemetrexed) Powder For Concentrate For Solution For Infusion 500mg	Malignant pleural mesothelioma: Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. Non-small cell lung cancer: Pemetrexed in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemetrexed is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.
BRU20072878NP	Kwan Loong Minyak Angin	For effective relief of dizziness, headaches, travel sickness, stuffy nose, stomachache, insect bites, aches and pains of muscles and joints, backaches, bruises, sprains and strains, pains associated with arthritis.

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BRU20072879P	Nifecard XL Tablet 30mg	Treatment of: • Hypertension: - Treatment of 6321 hypertensive patients with at least one additional risk factor followed over 3 to 4.8 years in a multi-national, randomized, double-blind, prospective study. Nifedipine was shown to reduce cardiovascular and cerebrovascular events to a comparable degree as a standard diuretic combination. • Coronary heart disease: - Chronic stable angina pectoris (angina of effort)
BRU20072881P	Alecensa 150mg Hard Capsule	Alecensa is indicated for the first-line treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC). Alecensa is indicated for the treatment of patients with ALK-positive, locally advanced or metastatic NSCLC who have progressed on or are intolerant to crizotinib.
BRU20072882NP	Dermoplex Burn-Aid Cream	Antiseptic creams for burns. Also for minor cuts, wounds, insect bites, sores, rashes and abrasions.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20072883P	Avoxred (Azacitidine) Powder For Suspension For injection 100mg/Vial	Azacitidine is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with: • intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS), • chronic myelomonocytic leukaemia (CMML) with 10-29 % marrow blasts without myeloproliferative disorder, • acute myeloid leukaemia (AML) with 20-30 % blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification.
BRU20072884P	Redtibin (Decitabine) Powder For Injection 50mg/Vial	Decitabine is indicated for treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British (FAB) subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and Intermediate-1, Intermediate-2, and High-Risk International Prognostic Scoring System (IPSS) groups. For the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20072885P	Stelara 130mg/26ml Concentrate For Solution For Infusion	**Crohn's Disease** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies (see *Pharmacodynamic Properties*). **Ulcerative Colitis** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies (see *Pharmacodynamic Properties*).
BRU20072886P	Besomid 100mcg/Actuation HFA-Metered Dose Inhaler	It is indicated for the prophylactic management of asthma.
BRU20072887P	Timo-COMOD 0.5% Eye Drops	Timo-COMOD® 0.5% is indicated in elevated intraocular pressure, chronic open-angle glaucoma, aphakic glaucoma, congenital glaucoma, if other therapeutic regimens are not sufficient.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20072888P	Granisetron Kabi 1mg/ml Concentrate Solution For Injection/Infusion	Indicated for the prevention and treatment (control) of a) Acute and delayed nausea and vomiting associated with chemotherapy and radiotherapy. b) Post-operative nausea and vomiting.
BRU20072889NP	Unidine Povidone Iodine Solution 10% w/v	Disinfectant and antiseptic for the treatment of contaminated wounds, cuts and burns and also for the pre-operative preparation of the skin and mucous membrane.
BRU20072891P	Dezor Plus Shampoo	Dezor Plus Shampoo is indicated for use in the treatment of Dandruff and Seborrhoeic Dermatitis of scalp.
BRU20072893P	Vitraq Film-Coated Tablet 75mg	For the prevention of atherothrombotic events in: • Peripheral arterial disease, myocardial infarction, ischemic stroke • Acute coronary syndrome - Non-ST segment elevation (unstable angina or non-Q-wave myocardial infarction) that including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA). - ST-segment elevation acute myocardial infarction in combination with ASA in medically treated patients eligible for thrombolytic therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20072894P	Abiratred Abiraterone Acetate Tablets 250mg	Abiraterone is indicated with prednisone or prednisolone for: • The treatment of metastatic castration resistant prostate cancer in adult men whose disease has progressed after a docetaxel-based chemotherapy regimen. • The treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.
BRU20072895P	A-Lices Lotion 1% w/w	For the topical treatment of head lice.
BRU20072896P	Fusidasol Cream	Inflammatory dermatoses, psoriasis where bacterial infection caused by staphylococcus and streptococcus are present or likely to occur.
BRU20072897NP; BRU20072897PS2	Actimol Tablet 500mg	For the relief from fever. For the relief from mild to moderate pain including: headache, migraine, backache, musculoskeletal pain, myalgia and neuralgia, dysmenorrhea, pain of osteoarthritis, toothache, pain after dental procedures/tooth extraction, pain after vaccination and the discomfort from colds, influenza and sore throats.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20072898P	Proglutrol G2 Sustained Release Tablet 2/500mg	Proglutrol G2 is indicated as an adjunct to diet and exercise in non-insulin dependent diabetes mellitus (NIDDM) (Type 2) patients who are unable to achieve sufficient glycaemic control with monotherapy of metformin or glimepiride alone or who are already treated with combination of metformin and glimepiride as separate tablets.
BRU20082899P	Vacodil Tablets 6.25mg	*Hypertension* Vacodil is indicated primarily for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents (e.g. calcium channel blockers, diuretics). *Treatment of angina pectoris* *Treatment of symptomatic chronic heart failure* Vacodil is indicated for the treatment of symptomatic chronic heart failure (CHF) to reduce mortality and cardiovascular hospitalizations, improve patient well-being and slow the progression of the disease. Vacodil may be used as adjunct to standard therapy, but may also be used in those patients unable to tolerate an ACE inhibitor, or those who are not receiving digitalis, hydralazine or nitrate therapy.
BRU20082900P	Viranz 600 (Efavirenz Tablets USP 600mg)	VIRANZ 600 (efavirenz) in combination with other antiretroviral agents is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and in pediatric patients at least 3 months old and weighing at least 3.5 kg.
BRU20082901NP	Ubat Minyak Geliga	Known in its properties as counter-irritant and for temporary relief of minor aches, pains of muscles and joints.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20082906P	Erysol For Oral Suspension 200mg/5ml	**Erysol** is indicated for the treatment of infections due to susceptible organisms such as in upper and lower respiratory infections, soft tissue infections, skin infections, clostridial infections urethritis. It is also indicated as an alternative to penicillin in patients who are hypersensitive to penicillin.
BRU20082907P	Raloxon 60mg Film-Coated Tablets	Raloxifene is indicated for the treatment and prevention of osteoporosis in postmenopausal women. A significant reduction in the incidence of vertebral, but not hip fractures has been demonstrated. For those postmenopausal women taking raloxifene for osteoporosis treatment, raloxifene has been shown to reduce the risk of invasive breast cancer. When determining the choice of raloxifene or other therapies, including oestrogens, for an individual postmenopausal woman, consideration should be given to menopausal symptoms, effects on uterine and breast tissues, and cardiovascular risks and benefits.
BRU20082908NP	Throatsil (Menthol Flavour)	For relief of mouth and throat infections.
BRU20082909NP	Throatsil (Prune Flavour)	For relief of mouth and throat infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20082910NP	Throatsil (Orange Flavour)	For relief of mouth and throat infections.
BRU20082911NP	Throatsil (Wild Berries Flavour)	For relief of mouth and throat infections.
BRU20082912P	Univate Cream	Univate is indicated for the treatment of severe inflammatory skin disorders such as eczema, discoid lupus erythematosus, psoriasis, lichen planus and other conditions or in patients which do not respond to less potent corticosteroids.
BRU20082913P	Univate Ointment	Univate is indicated for the treatment of severe inflammatory skin disorders such as eczema, discoid lupus erythematosus, psoriasis, lichen planus and other conditions or in patients which do not respond to less potent corticosteroids.
BRU20082914P	Leflunomide Mevon Film-Coated Tablets 20mg	Leflunomide is indicated for the treatment of adult patients with: • active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD), • active psoriatic arthritis. Recent or concurrent treatment with hepatotoxic or haematotoxic DMARDs (e.g. methotrexate) may result in an increased risk of serious adverse reactions; therefore, the initiation of leflunomide treatment has to be carefully considered regarding these benefit/risk aspects. Moreover, switching from leflunomide to another DMARD without following the washout procedure may also increase the risk of serious adverse reactions even for a long time after the switching.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20082915P	Celxib 200 Capsule	Celecoxib is indicated in adults for the symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The decision to prescribe a selective cyclooxygenase-2 (COX-2) inhibitor should be based on an assessment of the individual patient's overall risks.
BRU20082916P	Rexom Salbutamol Elixir 2mg/5ml	Salbutamol is used as a bronchodilator in the management of reversible airways obstruction, as in asthma and in some patients with chronic obstructive pulmonary disease.
BRU20082917P	Remafen Enteric-Coated Tablet 50mg	Treatment of: -Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism. -Acute attacks of gout -Painful post-traumatic and post-operative inflammation and swelling -Primary dysmenorrhoea
BRU20082918P	Peace Syrup	Symptomatic relief of sneezing, stuffy nose, and rhinorrhea caused by seasonal, allergic and vasomotor rhinitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20082919NP	Addaven Concentrate For Solution For Infusion	To meet basal to moderately increased requirements of trace elements in intravenous nutrition.
BRU20082920P	Matenol MR Tablet	Indicated in adults as an add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20082921P	Lamoga-50 Tablet	Epilepsy ***Adults and adolescents aged 13 years and above*** -Adjunctive or monotherapy treatment of partial seizures and generalised seizures, including tonic-clonic seizures -Seizures associated with Lennox-Gastaut syndrome. Lamotrigine tablet is given as adjunctive therapy but may be the initial antiepileptic drug (AED) to start with in Lennox-Gastaut syndrome ***Children and adolescents aged 2 to 12 years*** -Adjunctive treatment of partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome -Monotherapy of typical absence seizures Bipolar disorder ***Adults aged 18 years and above*** -Prevention of depressive episodes in patients with bipolar I disorder who experience predominantly depressive episodes Lamotrigine tablet is not indicated for the acute treatment of manic or depressive episodes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20082922P	Lamoga-100 Tablet	Epilepsy ***Adults and adolescents aged 13 years and above*** -Adjunctive or monotherapy treatment of partial seizures and generalised seizures, including tonic-clonic seizures -Seizures associated with Lennox-Gastaut syndrome. Lamotrigine tablet is given as adjunctive therapy but may be the initial antiepileptic drug (AED) to start with in Lennox-Gastaut syndrome ***Children and adolescents aged 2 to 12 years*** -Adjunctive treatment of partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut syndrome -Monotherapy of typical absence seizures Bipolar disorder ***Adults aged 18 years and above*** -Prevention of depressive episodes in patients with bipolar I disorder who experience predominantly depressive episodes Lamotrigine tablet is not indicated for the acute treatment of manic or depressive episodes.
BRU20082923P	Ultracet Tablet	ULTRACET is indicated for the management of moderate to severe pain.
BRU20092924NP	Dermoplex Calamine Lotion	Soothes and relieves minor skin irritations, insect bites, sunburn, prickly heat and nappy rashes.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20092925P	Tremfya 100mg/ml Solution For Injection	**Plaque psoriasis** TREMFYA is indicated for the treatment of adults ~~patients~~ with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis** TREMFYA, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. **Palmoplantar pustulosis** TREMFYA is indicated for the treatment of moderate to severe palmoplantar pustulosis (PPP) in adult patients who do not adequately respond to conventional therapy.
BRU20092926NP	Breacol Expectorant For Adults	Breacol Expectorant for Adults is used as an expectorant for symptomatic relief of coughs due to colds and upper respiratory tract infections.
BRU20092928NP	Hydrosil Tablet	Hydrosil is used for the relief of pain in gastric ulcer, gastric pain or discomfort due to excessive acid secretion in the stomach (dyspepsia) and in reflux oesophagitis (heartburn).
BRU20092929P	Tolmide 500mg Tablet	Tolbutamide reduces blood sugar in non-insulin dependent cases of diabetes mellitus in adjunct to diet. It may use in cases which do not respond to other sulphonylurea agents.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20092931P	Edyfil Film Coated Tablet 100mg	Sildenafil is indicated for treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil to be effective, sexual stimulation is required.
BRU20092932P	Rhinitin Tablet	Indicated for relief of symptoms associated with allergic rhinitis as well as ocular itching and burning, chronic urticaria and other allergic dermatologic disorders.
BRU20092933P	Bisocor Tablet 2.5mg	Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.
BRU20092934P	Bisocor Tablet 5mg	1. Treatment of high blood pressure (hypertension). 2. Treatment of coronary heart disease (angina pectoris). 3. Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20092935P	Letara 2.5mg Tablet	• Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. • Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown oestrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy). • First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer. • Treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antioestrogens.

		Rheumatoid Arthritis Humira is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Humira is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with disease modifying anti-rheumatic drugs. **Axial Spondyloarthritis** **Ankylosing Spondylitis** Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Non-radiographic Axial spondyloarthritis (Axial Spondyloarthritis without radiographic evidence of AS)** Humira is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.

BRU20102936P	HUMIRA Solution For Injection In Pre-Filled Syringe 20mg/0.2ml	**Plaque Psoriasis** Humira is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Crohn's Disease** Humira is indicated for the treatment of moderately to severely active Crohn's Disease in adult patients who have inadequate response to conventional therapy. Humira is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab. **Ulcerative colitis** Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Hidradenitis Suppurativa** Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate.

Paediatrics

Juvenile idiopathic arthritis

Polyarticular Juvenile Idiopathic Arthritis

Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

Enthesitis-Related Arthritis

Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Paediatric Crohn's Disease

Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindication for such therapies.

Paediatric Plaque Psoriasis

Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy.

Paediatric Uveitis

Humira is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

		Adolescent hidradenitis suppurativa Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Ulcerative Colitis** Humira is indicated for inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.
BRU20102937P	Venclexta Film-Coated Tablets 10mg	VENCLEXTA in combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. VENCLEXTA in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated CLL. VENCLEXTA (venetoclax) monotherapy is indicated for the treatment of patients with chronic lymphocytic leukaemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options. VENCLEXTA is indicated, in combination with azacitidine, or decitabine, or low- dose cytarabine for the treatment of newly diagnosed acute myeloid leukaemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

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BRU20102938P	Venclexta Film-Coated Tablets 50mg	VENCLEXTA in combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. VENCLEXTA in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated CLL. VENCLEXTA (venetoclax) monotherapy is indicated for the treatment of patients with chronic lymphocytic leukaemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options. VENCLEXTA is indicated, in combination with azacitidine, or decitabine, or low- dose cytarabine for the treatment of newly diagnosed acute myeloid leukaemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
BRU20102939P	Venclexta Film-Coated Tablets 100mg	VENCLEXTA in combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. VENCLEXTA in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated CLL. VENCLEXTA (venetoclax) monotherapy is indicated for the treatment of patients with chronic lymphocytic leukaemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options. VENCLEXTA is indicated, in combination with azacitidine, or decitabine, or low- dose cytarabine for the treatment of newly diagnosed acute myeloid leukaemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20102940P	Mementor Tablets 20mg	Treatment of patients with moderate to severe Alzheimer's disease.
BRU20102941P	Menelat 30mg Tablets	Episode of major depression.
BRU20102942NP	Uphalyte Salts	For replacement of water and electrolyte loss associated with diarrhoea and vomiting.
BRU20102943NP	Uphalyte Oral Rehydration Salts (Orange)	For replacement of water and electrolyte loss associated with diarrhoea and vomiting.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20102944P	Zytiga 500mg Film-Coated Tablets	ZYTIGA is indicated with prednisone or prednisolone for • the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. • the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. ZYTIGA is also indicated in combination with prednisone or prednisolone and androgen deprivation therapy (ADT) for the treatment of patients with newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) who may have received up to 3 months of prior ADT.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20102945PS1; BRU20102945PS2	Imfinzi (Durvalumab) Concentrate For Solution For Intravenous Infusion 50mg/ml	**Non-Small Cell Lung Cancer (NSCLC)** IMFINZI is indicated for the treatment of patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. **Small Cell Lung Cancer (SCLC)** IMFINZI in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). **Biliary Tract Cancers (BTC)** IMFINZI in combination with gemcitabine-based chemotherapy is indicated for the treatment of patients with locally advanced or metastatic biliary tract cancer (BTC). **Endometrial Cancer** IMFINZI in combination with carboplatin and paclitaxel is indicated for the first-line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with: IMFINZI as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR) IMFINZI in combination with olaparib in endometrial cancer that is mismatch repair proficient (pMMR).
BRU20102946NP	CNI Fire-Sens Mentholated Rub	Provides symptomatic relief of muscle and joint pain, rheumatism, backache and sprains.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20102947NP	UTIpure Effervescent Granules	• For relieving discomfort in mild urinary tract infections (UTI). • For symptomatic relief of dysuria (painful or difficult urination). • To enhance the action of certain antibiotics, especially sulphonamides. • For prevention of urates crystallization in gout therapy.
BRU20102948P	Defuzin Ointment 2% w/w	Defuzin is indicated for treatment of skin infections caused by staphylococci, streptococci, *Propionibacterium acnes* , *Corynebacterium minutissimum* and other organisms sensitive to Fusidic acid/Sodium Fusidate. The most important indications are impetigo, infected wounds, folliculitis, boils, sycosis barbae, carbuncles, hidradenitis, paronychia and erythrasma.
BRU20102949P	Cotren Vaginal Tablets 100mg	Vaginal infections caused by fungi-mainly candida and/or trichomonas.

BRU20102950P	Paclitaxel 6mg/ml Concentrate For Solution For Infusion	Paclitaxel 6 mg/ml concentrate for solution for infusion is indicated in adults. **Ovarian carcinoma**: in the first-line chemotherapy of ovarian cancer, paclitaxel is indicated for the treatment of patients with advanced carcinoma of the ovary or with residual disease (> 1 cm) after initial laparotomy, in combination with cisplatin. In the second-line chemotherapy of ovarian cancer, Paclitaxel is indicated for the treatment of metastatic carcinoma of the ovary after failure of standard, platinum containing therapy. **Breast carcinoma**: In the adjuvant setting, Paclitaxel is indicated for the treatment of patients with node-positive breast carcinoma following anthracycline and cyclophosphamide (AC) therapy. Adjuvant treatment with Paclitaxel should be regarded as an alternative to extended AC therapy. Paclitaxel is indicated for the initial treatment of locally advanced or metastatic breast cancer either in combination with an anthracycline in patients for whom anthracycline therapy is suitable, or in combination with trastuzumab, in patients who over-express HER-2 at a 3+level as determined by immunohistochemistry and for whom an anthracycline is not suitable (see section 4.4 and 5.1). As a single agent, Paclitaxel is indicated for the treatment of metastatic carcinoma of the breast in patients who have failed, or are not candidates for standard, anthracycline containing therapy. **Advanced non-small cell lung carcinoma**: Paclitaxel, in combination with cisplatin, is indicated for the treatment of non-small cell lung carcinoma (NSCLC) in patients who are not candidates for potentially curative surgery and/or radiation therapy. **AIDS-related Kaposi's sarcoma**: Paclitaxel is indicated for the treatment of patients with advanced AIDS-related Kaposi's sarcoma (KS) who have failed prior liposomal anthracycline therapy. Limited efficacy data supports this indication; a summary of the relevant studies is shown in section 5.1.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20102951P	Bezartan Tablet 150mg	Treatment of essential hypertension. Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Bezartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).
BRU20102952P	Bezartan Tablet 300mg	Treatment of essential hypertension. Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (>300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Bezartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).
BRU20102953NP	Rexom Wina Calamine Lotion	For the relief of minor skin rashes and irritation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20102954P	Eberil 60 Film-Coated Tablet	Etoricoxib is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis. Etoricoxib is indicated in adults and adolescents 16 years of age and older for the short-term treatment of moderate pain associated with dental surgery. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.
BRU20102955P	Eberil 90 Film-Coated Tablet	Etoricoxib is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis. Etoricoxib is indicated in adults and adolescents 16 years of age and older for the short-term treatment of moderate pain associated with dental surgery. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.
BRU20102956P	Eberil 120 Film-Coated Tablet	Etoricoxib is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis. Etoricoxib is indicated in adults and adolescents 16 years of age and older for the short-term treatment of moderate pain associated with dental surgery. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122957P	Salbutamol 100mcg/Actuation HFA Metered Dose Inhaler	Salbutamol inhaler is indicated in the treatment and prophylaxis of bronchospasm in bronchial asthma, chronic bronchitis and emphysema.
BRU20122959P	Dimax MR 30mg Tablet	Gliclazide is indicated for the treatment of non-insulin dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122960P	Imipenem/Cilastin Kabi 500mg/500mg Powder For Solution For Infusion	The activity of Imipenem/Cilastatin Kabi against an unusual broad spectrum of pathogens makes it particularly useful in the treatment of polymicrobic and mixed aerobic/anaroebic infections, as well as initial therapy prior to the identification of the causative organisms. Imipenem/Cilastatin Kabi is indicated for the treatment of the following infections due to susceptible organisms: • intra-abdominal infections • lower respiratory tract infections • gynaecological infections • septicaemia • genitourinary tract infections • bone and join infections • skin and soft tissue infections • endocarditis Imipenem/Cilastatin Kabi is indicated for the treatment of mixed infections caused by susceptible strains of aerobic and anaerobic bacteria. The majority of these mixed infections are associated with contamination by faecal flora and fauna originating from the vagina, skin and mouth. In these mixed infections, Bacteroides fragilis is the most commonly encountered anaerobic pathogen and is usually resistant to aminoglycosides, cephalosporins and penicillins. However, Bacteroides fragilis is usually susceptible to Imipenem/Cilastatin Kabi. Imipenem/Cilastatin Kabi has demonstrated efficacy against many infections caused by aerobic and anaroebic gram-positive and gram-negative bacteria resistant to the cephalosporins, including cefazolin, cefoperazone, cephalothin, cefoxitin, cefotaxime, moxalactam, cefamandole, ceftazidime and cefrioxone. Similarly, many infactions caused by organisms resistant to aminoglycosides (gentamicin, amikacin, tobramycin) and/or penicillin (ampicillin, carbenicillin, penicillin-G, ticarcillin, piperacillin, azlocillin, mezlocillin) responded to treatment with Imipenem/Cilastatin Kabi.

		Imipenem/Cilastatin Kabi is not indicated for the treatment of meningitis. Prophylaxis: Imipenem/Cilastatin Kabi is also indicated for the prevention of certain post-operative infections in patients undergoing contaminated or potentially contaminated surgical procedures or where the occurrence of post-operative infection could be especially serious.
BRU20122961NP	Actal Tablet	ACTAL Tablet is used for the relief of stomach discomfort such as indigestion, heartburn due to gastric hyperacidity (excessive acid) and peptic ulcer (an ulcer of the stomach, duodenum or lower end of esophagus).

BRU20122962P	Risperidone Mevon 1mg Tablets	RISPERIDONE is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERIDONE alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERIDONE is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERIDONE is indicated for the short-term treatment of persistent aggression in patients with moderate to severe dementia of the Alzheimer's type unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. RISPERIDONE is indicated for the treatment of behavioural disorders associated with autism (eg irritability, social withdrawal, stereotypic behaviour, hyperactivity and inappropriate speech) in children and adolescents. RISPERIDONE is also indicated for bipolar mania. Adjunctive therapy: RISPERIDONE is indicated as adjunctive therapy to mood stabilizers in the treatment of manic episodes associated with bipolar disorders. These episodes are characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviors. Monotherapy: RISPERIDONE is indicated in the treatment of acute manic episodes associated with bipolar 1 disorder. The effectiveness of RISPERIDONE for more than 12 weeks of treatment of an acute episode, and for the prevention of new manic episodes has not been established. RISPERIDONE is indicated in the treatment of conduct and other disruptive behavior disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviors (e.g. aggression, impulsivity and self-injurious behaviors) are prominent. As with all symptomatic treatments, the continued use of RISPERIDONE must be evaluated and justified on an ongoing basis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122963P	Risperidone Mevon 2mg Tablets	RISPERIDONE is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERIDONE alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISPERIDONE is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISPERIDONE is indicated for the short-term treatment of persistent aggression in patients with moderate to severe dementia of the Alzheimer's type unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. RISPERIDONE is indicated for the treatment of behavioural disorders associated with autism (eg irritability, social withdrawal, stereotypic behaviour, hyperactivity and inappropriate speech) in children and adolescents. RISPERIDONE is also indicated for bipolar mania. Adjunctive therapy: RISPERIDONE is indicated as adjunctive therapy to mood stabilizers in the treatment of manic episodes associated with bipolar disorders. These episodes are characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviors. Monotherapy: RISPERIDONE is indicated in the treatment of acute manic episodes associated with bipolar 1 disorder. The effectiveness of RISPERIDONE for more than 12 weeks of treatment of an acute episode, and for the prevention of new manic episodes has not been established. RISPERIDONE is indicated in the treatment of conduct and other disruptive behavior disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviors (e.g. aggression, impulsivity and self-injurious behaviors) are prominent. As with all symptomatic treatments, the continued use of RISPERIDONE must be evaluated and justified on an ongoing basis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122964P	Ator 20mg Film Coated Tablets	**Hypercholesterolaemia:** **Ator** is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. **Ator** is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. **Prevention of cardiovascular disease:** Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU20122965P	Onsia 4mg Tablet	• For the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. • For the prevention of post-operative nausea and vomiting; for treatment of established post-operative nausea and vomiting, administration by injection is recommended.
BRU20122967P	Trezilent 250mg (200mg + 50mg) Film Coated Tablets	TREZILENT is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122968P	Trezilent 300mg (150mg + 150mg) Film Coated Tablets	TREZILENT is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.
BRU20122969P	Siagran 50mg Tablet	Sumatriptan are indicated for the acute relief of migraine attacks with or without aura, including the acute treatment of migraine attacks associated with the menstrual period in women.
BRU20122970P	Vifas 60mg Tablet	**VIFAS (60 MG TABLET)** is indicated for relief of symptoms associated with allergic rhinitis in adult and children 6 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes. **VIFAS (60 MG TABLET)** is indicated for relief of symptoms associated with chronic idiopathic urticaria in adults and children 6 years of age and older.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122971P; BRU20122971PS2	Intacape Film Coated Tablet 500mg	*Breast Cancer:* INTACAPE in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. INTACAPE is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of a taxane and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. *Colorectal Cancer:* INTACAPE is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. INTACAPE is indicated for the treatment of metastatic colorectal carcinoma. *Gastric Cancer:* INTACAPE is indicated for first-line treatment of advanced gastric cancer in combination with a platinum-based regimen.
BRU20122972P; BRU20122972PS2	Intacape Film Coated Tablet 150mg	*Breast Cancer:* INTACAPE in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. INTACAPE is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of a taxane and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. *Colorectal Cancer:* INTACAPE is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer. INTACAPE is indicated for the treatment of metastatic colorectal carcinoma. *Gastric Cancer:* INTACAPE is indicated for first-line treatment of advanced gastric cancer in combination with a platinum-based regimen.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122973P	Calcelar 25 Film Coated Tablet	Indicated for secondary hyperparathyroidism patients undergoing maintenance dialysis.
BRU20122974NP	Vemizol Suspension 200mg/5ml	Single or mixed infestations of intestinal parasites. Albendazole is effective in the treatment of Ascaris lumbricoides (roundworm), Trichuris trichiura (whipworm), Enterobius vermicularis (pinworm/threadworm), Ancylostoma duodenale and Necator americanus (hookworm), H. nana and Taenia sp (tapeworm), Strongyloides stercoralis and Opisthorchis viverrini and Opisthorchis sinensis.
BRU20122975NP	Actal Plus Tablet	ACTAL PLUS Tablet is used for the relief of pain and flatulence (wind) associated with gastric hyperacidity (excessive acid), heartburn, peptic ulcer (an ulcer of the stomach, duodenum or lower end of esophagus) and indigestion.
BRU20122976NP	Betadine PVP-I Antiseptic Liquid 10% w/v	• Cuts and bruises. • Wounds and burns. • Bacterial and Mycotic (fungal) skin infections e.g. at groins, feet. Cold sores. • Herpes simplex, Herpes genitalis. • Disinfection of perineal wounds and skin. • Pre and post-operative disinfection and preparing of the skin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122977P	Pregabalin Sandoz 150mg Capsules	• Neuropathic Pain: Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. • Epilepsy: As adjunctive therapy in adults with partial seizures with or without secondary generalisation. • Generalised Anxiety Disorder: Treatment of Generalised Anxiety Disorder (GAD) in adults. • Fibromyalgia: Management of fibromyalgia.
BRU20122978P	Levet 250mg Film-Coated Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of: • partial onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy. • myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy.
BRU20122979P	Levet 500mg Film-Coated Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of: • partial onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy. • myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122980P	Siamik Injection 500mg	Amikacin is indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including *Pseudomonas* species. Although amikacin is not the drug of choice for infections due to *staphylococci* , at times it may be indicated for the treatment of known or suspected staphylococcal disease. These situations include: the initiation of therapy for severe infections when the organisms suspected are either Gram-negative or *staphylococci* , patients allergic to other antibiotics, and mixed staphylococcal/Gram-negative infections. Therapy with amikacin may be administered prior to obtaining the results of sensitivity testing. Surgical procedures should be performed where indicated. Consideration should be given to official guidance on the appropriate use of antibacterial agents.
BRU20122981P	Bonair HFA Inhaler 100mcg/Actuation	Bonair HFA inhaler provides short-acting (4 to 6 hour) bronchodilation with fast onset (within 5 minutes) in reversible airways obstruction. It is particularly suitable for the relief & prevention of asthma symptoms. It should be used to relieve symptoms when they occur, & to prevent them in circumstances recognized by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure). Bonair HFA inhaler is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction & use of regular inhaled corticosteroid therapy.
BRU20122982NP	Betadine® Gargle & Mouth Wash	For minor irritation of the mouth and throat. Relief and prevention of painful infection as in pharyngitis, oral moniliasis, tonsillitis, aphthous ulcers, stomatitis, gingivitis, inflammatory conditions of the mouth & pharynx. Routine use to promote oral hygiene.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122983P	Invega Trinza 175mg/0.875ml Prolonged-Release Suspension For Intramuscular Injection	INVEGA TRINZA, a 3-month injection, is indicated for the maintenance treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product for at least four months.
BRU20122984P	Invega Trinza 263mg/1.315ml Prolonged-Release Suspension For Intramuscular Injection	INVEGA TRINZA, a 3-month injection, is indicated for the maintenance treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product for at least four months.
BRU20122985P	Invega Trinza 350mg/1.750ml Prolonged-Release Suspension For Intramuscular Injection	INVEGA TRINZA, a 3-month injection, is indicated for the maintenance treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product for at least four months.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122986P	Invega Trinza 525mg/2.625ml Prolonged-Release Suspension For Intramuscular Injection	INVEGA TRINZA, a 3-month injection, is indicated for the maintenance treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product for at least four months.
BRU20122987NP	DifflamAB™ Sore Throat Lozenges (Lemon)	For the symptomatic relief of mouth and throat infections.
BRU20122988NP	DifflamAB™ Sore Throat Lozenges (Blackcurrant)	For the symptomatic relief of mouth and throat infections.
BRU20122989NP	DifflamAB™ Sore Throat Lozenges (Orange)	For the symptomatic relief of mouth and throat infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU20122990P	Oxitan Injection 5mg/ml	Oxaliplatin in combination with 5-fluorouracil (5-FU) and folinic acid (FA) is indicated for: • Adjuvant treatment of stage III (Dude's C) colon cancer after complete resection of primary tumor. • Treatment of metastatic colorectal cancer.
BRU20122991P	Bactricin Ointment 2% w/w	Treatment of bacterial skin infections, e.g. impetigo, folliculitis and furunculosis.
BRU21012992NP	Dermoplex Antifungal Cream	Treatment of fungal infections such as athlete's foot, ringworm, tinea versicolor (white spot) and jock (groin) itch. (Infections due to Trichophyton rubrum may relapse and a second course of treatment may be required).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21012993P	Lipez Tablets 10mg	Primary Hypercholesterolemia LIPEZ, administered with an HMG-CoA reductase inhibitor (statin) or alone, is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C) and apolipoprotein B (Apo B) in patients with primary (heterozygous familial and non-familial) hypercholesterolemia. Homozygous Familial Hypercholesterolemia (HoFH) LIPEZ, administered with atorvastatin or simvastatin, is indicated for the reduction of elevated total-C and LDL-C levels in patients with HoFH, as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. Homozygous Sitosterolemia (Phytosterolemia) LIPEZ, is indicated as adjunctive therapy to diet for the reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolemia.
BRU21012994NP	Avofer Injection 100mg/5ml	Avofer is indicated in the treatment of iron deficiency in the following indications: • Where there is a clinical need for a rapid iron supply • In patients who cannot tolerate oral iron therapy or who are non-compliant • Where oral iron preparations are ineffective (e.g., in active inflammatory bowel disease). Avofer should only be administered where the indication is confirmed by appropriate investigations.
BRU21012995P	Oxyla 10IU/ml Injection	Induction of labour for medical reasons (e.g. postmaturity, pre-mature rupture of the membranes, preeclampsia). Caesarean section following delivery of the infant. Prevention and treatment of postpartum haemorrhage associated with uterine atony.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21012996P	Beclate-100 Inhaler (CFC Free)	Beclate CFC free inhaler is indicated in the maintenance treatment of asthma as prophylactic therapy. It is also indicated for asthma patients who require systemic corticosteroid administration, where adding Beclate CFC free inhaler may reduce or eliminate the need for the systemic corticosteroids. Beclate is NOT indicated for the relief of acute bronchospasm.
BRU21012997P	Azadine Azacitidine For Injection 100mg/Vial	Azadine is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation with: • intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS), • chronic myelomonocytic leukaemia (CMML) with 10-29 % marrow blasts without myeloproliferative disorder, • acute myeloid leukaemia (AML) with 20-30 % blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification. Azadine is indicated for the treatment of adult patients aged 65 years or older who are not eligible for HSCT with AML with >30% marrow blasts according to the WHO classification.
BRU21012998P	Growell Scalp Lotion 5% w/v	Growell is used to treat male pattern hair loss in man and woman by rejuvenating hair follicles and stimulating hair growth. The preparation is intended for use in patients suffering from hair loss of hereditary type only. Consult your doctor or pharmacist to ensure that this treatment is appropriate for your type of hair loss.
BRU21012999NP	Eucalyptus Oil Kangaroo Brand	Common Colds For Wind and Flatulence For Muscle Stiffness, Minor Bruises and Minor Sprains

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21013000NP	Lion Ball Corn Remover Solution 20% w/v	For the treatment of corns, warts and callouses.
BRU21033001P	Euthyrox 75mcg Tablet	• Treatment of benign euthyroid goitre • Prophylaxis of relapse after surgery for euthyroid goitre • Substitution therapy in hypothyroidism • Concomitant therapy during anti-thyroid medicinal treatment of hyperthyroidism • Suppression therapy in thyroid cancer *Applies only to tablets of 100 microgram* : • Diagnostic use for thyroid suppression testing.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033002P	ONTREX 500mg Powder For Concentrate For Solution For Infusion	Malignant Pleural Mesothelioma: ONTREX in combination with cisplatin is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma. Non-small Cell Lung Cancer: ONTREX in combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. ONTREX is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. ONTREX is indicated as monotherapy for the second-line treatment of patients with locally advanced or metastatic non- small cell lung cancer other than predominantly squamous cell histology.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033003P	Rinvoq 15mg Extended Release Tablets	**For RINVOQ® 15 mg only:** Rheumatoid arthritis RINVOQ® is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). RINVOQ® may be used as monotherapy or in combination with methotrexate. Psoriatic arthritis RINVOQ® is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. RINVOQ® may be used as monotherapy or in combination with methotrexate. Non-radiographic axial spondyloarthritis (nr-axSpA) RINVOQ is indicated for the treatment of active non-radiographic axial spondyloarthritis in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal antiinflammatory drugs (NSAIDs). Ankylosing Spondylitis (AS, radiographic axial spondyloarthritis) RINVOQ is indicated for the treatment of active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy.

		For RINVOQ® 15 mg and 30 mg: Atopic dermatitis RINVOQ is indicated for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. Ulcerative Colitis RINVOQ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent. Crohn's disease RINVOQ is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.
BRU21033004P	Metrolex (Solution For Injection) 500mg/100ml	• Prevention of postoperative infections due to sensitive anaerobic bacteria particularly species of *bacteroides* and anaerobic *streptococcus* . • For the treatment of severe infection which sensitive anaerobic bacteria particularly *bacteriodes* and anaerobic *streptococci* are suspected to be the cause.
BRU21033005P	Atracurium Kalceks 10mg/ml Solution For Injection/Infusion	Atracurium is a highly selective, competitive or non-depolarising neuromuscular blocking agent which is used as an adjunct to general anaesthesia to enable tracheal intubation to be performed and to relax skeletal muscles during surgery or controlled ventilation, and to facilitate mechanical ventilation in Intensive Care Unit (ICU) patients.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033006P	Pemcord 500 Powder For Solution For Infusion 500mg/Vial	<u>Malignant pleural mesothelioma</u> Pemcord in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. <u>Non-small cell lung cancer</u> Pemcord in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer. Pemcord is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-squamous non-small cell lung cancer in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemcord is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-squamous non-small cell lung cancer.
BRU21033007P	Zoledronic Acid Kabi 4mg/5ml Concentrate For Solution For Infusion	• Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in patients with advanced malignancies involving bone. • Treatment of hypercalcaemia of malignancy (HCM).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033008P	Seroflo-125 Inhaler	Reversible Obstructive Airways Disease (ROAD) Seroflo Inhaler (CFC Free) is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination bronchodilator and inhaled corticosteroid is appropriate. This may include: • Patients on effective maintenance doses of long -acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. Chronic Obstructive Pulmonary Disease (COPD) Seroflo Inhaler (CFC Free) is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033009P	Seroflo-250 Inhaler	Reversible Obstructive Airways Disease (ROAD) Seroflo Inhaler (CFC Free) is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination bronchodilator and inhaled corticosteroid is appropriate. This may include: • Patients on effective maintenance doses of long -acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. Chronic Obstructive Pulmonary Disease (COPD) Seroflo Inhaler (CFC Free) is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU21033010P	Plazilin Injection BP 5mg/mL, 2mL Ampoule	Adult population PLAZILIN is indicated for use in adults for: • Prevention of post-operative nausea and vomiting. • Symptomatic treatment of nausea and vomiting, including nausea and vomiting induced by migraine attacks. • Prevention of radiotherapy induced nausea and vomiting. Pediatric population PLAZILIN is indicated in children aged 1 to 18 years for: • Prevention of delayed Chemotherapy induced nausea and vomiting as a second-line option. • Prevention of postoperative nausea and vomiting as a second-line option.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033011P	Rocuronium Kabi 10mg/ml Solution For Injection/Infusion	Rocuronium Kabi is indicated as an adjunct to general anaesthesia to facilitate endotracheal intubation, to provide skeletal muscle relaxation and to facilitate mechanical ventilation in adults, children and infants from one month of age. Rocuronium Kabi is also indicated as an adjunct in the intensive care unit (ICU) to facilitate mechanical ventilation as part of Rapid Sequence Induction, however, this has not been studied in infants and children.
BRU21033012P	Chloramphenicol Ear Drops 5% w/v	Infections of the ear caused by organisms susceptible to Chloramphenicol.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033013P	Ciflox Film-Coated Tablet 500mg	<u>Uncomplicated and complicated infections caused by ciprofloxacin sensitive pathogens:</u> • Infections of the respiratory tract In the treatment of outpatients with pneumonia due to Pneumococcus, ciprofloxacin should not be used as a first choice of drug. Ciprofloxacin can be regarded as an advisable treatment for pneumonias* caused by Klebsiella, Enterobacter, Proteus, E. coli, Pseudomonas, Haemophilus, Branhamella, Legionella, and Staphylococcus. • Infections of the middle ear (otitis media*), of the paranasal sinuses (sinusitis*), especially if these are caused by gram negative organisms including Pseudomonas or by Staphylococcus. • Infections of the eyes • Infections of the kidneys and/or the efferent urinary tract* • Infections of the genital organs, including adnexitis, gonnorhoea, prostatitis • Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or of the biliary tract, peritonitis) • Infections of the skin and soft tissue • Infections of the bones and joints • Sepsis* • Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or have neutropenia) *'Ciflox' Film-Coated Tablet should only be used: • When Pseudomonas is considered AND the patient is allergic to antipseudomonal penicillin/cephalosporins; • For resistant organisms with no other alternative antibiotics available <u>Inhalational anthrax (post-exposure) in adults and in children:</u> To reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis.
BRU21033014P	Bicalox 50mg Film Coated Tablet	Treatment of advanced prostate cancer in combination with luteinising hormone-releasing hormone (LHRH) analogue therapy or surgical castration.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033015PS1; BRU21033015PS2	Zepilen 1G Powder For Solution For Injection/Infusion	'Zepilen' is indicated for the treatment of the following infections caused by susceptible bacteria: • Biliary tract infections • Bone and joint infections • Endocarditis • Genito-urinary tract infections • Respiratory tract infections • Skin and soft tissue infections • Septicaemia It may also be used as a prophylactic, for perioperative administration to patients undergoing contaminated or potentially contaminated surgical procedures (hysterectomy, cholecystectomy, open heart surgery, bone and joint surgery), or in whom postoperative infection would be serious. In such cases it may reduce the incidence of postoperative infection. Cefazolin, in vitro, is active against: Gram positive organisms: Staphylococcus aureus (both penicillin sensitive and resistant), Staphylococcus epidermidis, group A β-haemolytic streptococci, and other strains of streptococci (many enterococci strains are resistant), Streptococci pneumoniae. Gram negative organisms: Enterobacter aerogenes, Escherichia coli, Haemophilus influenzae, Klebsiella sp., Proteus mirabilis.
BRU21033016P	Bonky Soft Capsule	• Osteoporosis • Rickets, osteomalacia (vitamin D dependent rickets, hypophosphatemic vitamin D resistant rickets) • Hypoparathyroidism (postoperative, idiopathic hypoparathyroidism, pseudohypoparathyroidism) • Patients with chronic renal failure. particularly renal osteodystrophy in patients undergoing hemodialysis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033017P	Zithrolide Tablet 250mg	Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infection including bronchitis and pneumonia – skin and soft tissue infections – acute otitis media – upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present). In sexually transmitted disease in men and women, azithromycin is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated in the treatment of Chancroid due to H.ducreyi and uncomplicated genital infection due to non-multiresistant *Neisseria gonorrhoea* , concurrent infection with *Treponema pallidum* should be excluded. Azithromycin is indicated, either alone or in combination with rifabutin, for prophylaxis against *Mycobacterium avium-intracellulare complex* (MAC) infection, an opportunistic infection prevalent in patients with advanced human immunodeficiency virus (HIV). Azithromycin is indicated in combination with ethambutol for the treatment of disseminated MAC (DMAC) infection in patients with advanced HIV infection.

BRU21033018P	Lynparza Film-Coated Tablets 100mg	<u>Ovarian cancer</u> Lynparza is indicated as monotherapy for the: • maintenance treatment of adult patients with advanced (FIGO stages III and IV) *BRCA1/2* -mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. • maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Lynparza is indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: • a deleterious or suspected deleterious BRCA mutation, and/or • genomic instability <u>Breast cancer</u> Lynparza is indicated for the adjuvant treatment of adult patients with germline *BRCA* -mutated HER2 negative high risk early breast cancer who have previously been treated with neoadjuvant or adjuvant chemotherapy (see sections 4.2 and 5.1). Lynparza is indicated as monotherapy for the treatment of adult patients with germline *BRCA1/2* -mutations, who have HER2 negative metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the neoadjuvant, adjuvant or metastatic setting unless patients were not suitable for these treatments (see section 5.1). Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy.

		Pancreatic cancer Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreaticc adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Prostate cancer Lynparza is indicated: • as monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline and/or somatic *BRCA* or *ATM* mutated metastatic castration resistant prostate cancer (mCRPC) who have progressed following prior treatment with a new hormonal agent (e.g. abiraterone or enzalutamide). • in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious *BRCA* -mutated (*BRCA* m) metastatic castration-resistant prostate cancer (mCRPC).

BRU21033019P	Lynparza Film-Coated Tablets 150mg	<u>Ovarian cancer</u> Lynparza is indicated as monotherapy for the: • maintenance treatment of adult patients with advanced (FIGO stages III and IV) *BRCA1/2* -mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. • maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Lynparza is indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: • a deleterious or suspected deleterious BRCA mutation, and/or • genomic instability <u>Breast cancer</u> Lynparza is indicated for the adjuvant treatment of adult patients with germline *BRCA* -mutated HER2 negative high risk early breast cancer who have previously been treated with neoadjuvant or adjuvant chemotherapy (see sections 4.2 and 5.1). Lynparza is indicated as monotherapy for the treatment of adult patients with germline *BRCA1/2* -mutations, who have HER2 negative metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the neoadjuvant, adjuvant or metastatic setting unless patients were not suitable for these treatments (see section 5.1). Patients with hormone receptor (HR)-positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy.

		<u>Pancreatic cancer</u> Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreaticc adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. <u>Prostate cancer</u> Lynparza is indicated: • as monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline and/or somatic *BRCA* or *ATM* mutated metastatic castration resistant prostate cancer (mCRPC) who have progressed following prior treatment with a new hormonal agent (e.g. abiraterone or enzalutamide). • in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious *BRCA* -mutated (*BRCA* m) metastatic castration-resistant prostate cancer (mCRPC).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033020P	Meropenem Kabi 500mg Powder For Solution For Injection Or Infusion	Meropenem IV is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem. • Pneumonias and Nosocomial pneumonias • Urinary Tract Infections • Intra-abdominal Infections • Gynaecological Infections, such as endometritis and pelvic inflammatory disease • Bacterial Meningitis • Septicaemia • Empiric treatment, for presumed infections in patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents. Meropenem IV has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033021P	Yulareb 50mg Film-Coated Tablets	**1.1 Early Breast Cancer** YULAREB ® (abemaciclib) is indicated: • YULAREB in combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence [see *Dosage and Administration (2.1) and Clinical Studies (14.1)*]. • In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. **1.2 Advanced or Metastatic Breast Cancer** YULAREB ® (abemaciclib) is indicated: • in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. • in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advance or metastatic breast cancer with disease progression following endocrine therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033022P	Yulareb 100mg Film-Coated Tablets	**1.1 Early Breast Cancer** YULAREB ® (abemaciclib) is indicated: • YULAREB in combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence [see *Dosage and Administration (2.1) and Clinical Studies (14.1)*]. • In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. **1.2 Advanced or Metastatic Breast Cancer** YULAREB ® (abemaciclib) is indicated: • in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. • in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advance or metastatic breast cancer with disease progression following endocrine therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21033023P	Yulareb 150mg Film-Coated Tablets	**1.1 Early Breast Cancer** YULAREB ® (abemaciclib) is indicated: • YULAREB in combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence [see *Dosage and Administration (2.1) and Clinical Studies (14.1)*]. • In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. **1.2 Advanced or Metastatic Breast Cancer** YULAREB ® (abemaciclib) is indicated: • in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. • in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advance or metastatic breast cancer with disease progression following endocrine therapy.
BRU21033024NP	Betadine Antiseptic Ointment 10% w/w	• Cuts and bruises • Burns • Bacterial and Mycotic (fungal) skin infections eg. at groins, feet • Cold sores • Herpes simplex, Herpes genitalis • Disinfection of skin for catheterization.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21043025P	Nebilet Tablet	Hypertension Treatment of essential hypertension. Chronic heart failure (CHF) Treatment of stable mild and moderate chronic heart failure in addition to standard therapies in elderly patients ≥ 70 years.

BRU21043027P	Docetaxel Injection Concentrate 20mg/ml (Daxotel)	<u>Breast cancer</u> Docetaxel in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with: • operable node negative breast cancer. For patients with operable node-negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer. Docetaxel in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition. Docetaxel monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent. Docetaxel in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. <u>Non-small cell lung cancer</u> Docetaxel is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy. Docetaxel in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer, in patients who have not previously received chemotherapy for this condition. <u>Prostate cancer</u> Docetaxel in combination with prednisone or prednisolone is indicated for the treatment of patients with metastatic castration-resistant prostate cancer.

		Gastric adenocarcinoma Docetaxel in combination with cisplatin and 5 fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease. Ovarian Cancer Docetaxel is indicated for the treatment of metastatic carcinoma of the ovary after failure of first-line or subsequent chemotherapy. Squamous Cell Carcinoma of the Head and Neck Docetaxel is indicated as monotherapy in the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck after failure of a previous chemotherapy regimen. Docetaxel in combination with cisplatin and 5 fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.
BRU21043028NP	B.Braun 0.9% Sodium Chloride Intravenous Infusion B.P.	• Fluid and electrolyte substitution in hypochloraemic alkalosis, • Sodium deficiency, • Chloride losses, • Short-term intravascular volume substitution, • Hypotonic dehydration or isotonic dehydration, • Vehicle solution for compatible electrolyte concentrates and medicinal products, • Externally for wound irrigation and for moistening of wound tamponades and dressings.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21043029P	Pharmaniaga Phenytoin Sodium 250mg/5ml Injection	Phenytoin Sodium Injection is indicated for the control of status epilepticus of the tonic-clonic (grand mal) type and prevention and treatment of seizures occurring during or following neurosurgery.
BRU21043030P	Talzenna Capsule 0.25mg	TALZENNA is indicated for the treatment of adult patients with germline breast cancer susceptibility gene (BRCA) mutated human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer who have previously been treated with chemotherapy. These patients could have received chemotherapy in the neoadjuvant, adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments.
BRU21043031P	Talzenna Capsule 1mg	TALZENNA is indicated for the treatment of adult patients with germline breast cancer susceptibility gene (BRCA) mutated human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer who have previously been treated with chemotherapy. These patients could have received chemotherapy in the neoadjuvant, adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21043032P	Virox Tablet 400mg	**Herpes simplex virus infections** Treatment of herpes simplex virus infections of the skin and mucous membranes, including initial and recurrent genital herpes. Suppression (prevention of recurrence) of recurrent herpes simplex infections in immunocompetent patients. Prophylaxis of herpes simplex infections in immune-compromised patients. **Varicella (Chickenpox) and herpes zoster infections** Treatment of varicella (chickenpox) and herpes zoster (shingles) infections in immunocompromised and normally immune individuals. Studies have shown that early treatment of shingles with Acyclovir has a beneficial effect on pain and can reduce the incidence of post-herpetic neuralgia (zoster-associated pain).
BRU21043033P	Difflam Anti-Inflammatory Anti-Bacteria Lozenges (Honey Lemon)	For the temporary relief of painful conditions of the oral cavity including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post-orosurgical and periodontal procedures, pharyngitis, swelling, redness and inflammatory conditions.
BRU21053034P	Notrixum Injection 10mg/ml	Atracurium Besylate is a highly selective, competitive or non-depolarizing neuromuscular-blocking agent which is used as an adjunct to general anaesthesia to enable tracheal intubations to be performed and to relax skeletal muscles during surgery or controlled ventilation; to facilitate mechanical ventilation in Intensive Care Unit (ICU) patients.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21053035P	Farsorbid Injection 1mg/ml	Isosorbide dinitrate is indicated in the treatment of unresponsive left ventricular failure of various etiologies, including left ventricular failure secondary to acute myocardial infarction. It is also indicated in the management of severe or unstable angina pectoris.
BRU21053036NP	Zentel Tablet 200mg	Treatment of roundworm infection (ascariasis), whipworm infection (trichuriasis), hookworm disease (ancylostomiasis and necatoriasis), pinworm infection (enterobiasis), threadworm infection (strongyloidiasis), and tapeworm infection (hymenolepsiasis and taeniasis).
BRU21053038NP	Gelofusine® Solution for Infusion	As a colloidal volume substitute for, • prophylaxis and treatment of absolute and relative hypovolaemia (e.g. following shock due to haemorrhage or trauma, peri-operative blood losses, burns, sepsis) • prophylaxis of hypotension (e.g. in connection with induction of epidural or spinal anaesthesia) • haemodilution • extra-corporeal circulation (heart-lung machine, haemodialysis).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21053039P	Trulicity 0.75mg Solution For Injection In Pre-Filled Pen	Type 2 Diabetes Mellitus Trulicity is indicated for the treatment of patients 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications • in addition to other medicinal products for the treatment of diabetes.
BRU21053040P	Trulicity 1.5mg Solution For Injection In Pre-Filled Pen	Type 2 Diabetes Mellitus Trulicity is indicated for the treatment of patients 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise • as monotherapy when metformin is considered inappropriate due to intolerance or contraindications • in addition to other medicinal products for the treatment of diabetes.
BRU21053041P	Gemcitabine For Injection USP 1G (Gemita)	Gemcitabine is indicated for the treatment of locally advanced or metastatic non-small cell-lung cancer. Gemcitabine is indicated for the treatment of adult patients with locally advanced or metastatic adrenocarcinoma of the pancreas. Gemcitabine is indicated for patients with 5-FU refractory pancreatic cancer. Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/ neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21053042NP	Difflam HEXTRA™ Sore Throat Lozenges 2.4mg	As an antiseptic and local anaesthetic for the relief of sore throat and its associated pain.
BRU21053043NP	Cogesic Max Cream	COGESIC MAX Cream is indicated for the fast relief of Muscular & Joint Pains, Backache, Strains & Sprains and Leg Cramps.
BRU21073044P	Apo-Theo LA Tablet 200mg	APO-THEO LA (theophylline) tablets are indicated for the symptomatic treatment of reversible bronchospasm associated with asthma, chronic bronchitis, emphysema and related bronchospastic disorders.
BRU21073045NP	Rexom Mist. Magnesium Trisilicate	It is indicated for symptomatic relief of stomach upset associated with hyperacidity (heartburn, acid indigestion, and sour stomach); hyperacidity associated with gastric and duodenal ulcers and in the management of reflux esophagitis.
BRU21073046P	Iotim Eye Drops 0.5%	Iotim ED is indicated in the treatment of elevated intraocular pressure in patients with ocular hypertension or open angle glaucoma.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073047NP	Balsem Gosok – Balsem Merah Cap Betet	Relief of simple backache, stiff neck, rheumatism, stiff, strained, painful muscles, and itchiness caused by insect bites.
BRU21073048NP	Balsem Gosok – Balsem Hijau Cap Betet	Relief of simple backache, stiff neck, rheumatism, stiff, strained, painful muscles, and itchiness caused by insect bites.
BRU21073049NP	Salonpas	For relief of aches and pains associated with: • Muscle fatigue • Muscle pain • Stiff shoulder • Simple backache • Bruises • Sprains • Strains • Arthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073050P	Koact Tablet 625mg	Co-amoxiclav is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other beta-lactam antibiotic. Co-amoxiclav oral preparations are indicated for short-term treatment of bacterial infections at the following sites when amoxicillin resistant beta-lactamase producing strains are suspected as the cause. In other situations, amoxicillin alone should be considered. Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media. Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis, lobar and bronchopneumonia. Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis. Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections. Mixed infections caused by amoxicillin-susceptible organisms in conjunction with Co-amoxiclav-susceptible beta-lactamase-producing organisms may be treated with Co-amoxiclav. These infections should not require the addition of another antibiotic resistance to beta-lactamases.
BRU21073051NP	Guardian Fever & Pain Relief Tablet 500mg	Guardian fever & pain relief tablet is an analgesic and antipyretic agent which relieves fever, headache and muscular pain caused by cold and flu.
BRU21073052NP	B. Braun 5% Glucose Intravenous Infusion B.P.	• Carbohydrate solution for intravenous liquid therapy • Vehicle solution for compatible medicinal products

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073053NP	Infusol® M20	• Prophylaxis of acute renal failure. • Post operative oliguria. • In forced diuresis for elimination toxic substances via the kidneys. • For decreasing intracranial pressure in case of cerebral oedema.
BRU21073055P	UNIREN Gel	Treatment of: • Localized forms of soft-tissue rheumatism, e.g. tendovaginitis, shoulder-hand syndrome, bursitis, and peri-arthropathy. • Localized rheumatic disease, e.g. osteoarthritis of the spine and peripheral joints; • Post-traumatic inflammation of the tendons, ligaments, muscles, and joints, e.g. due to sprains, strains or bruises.
BRU21073056NP	BETADINE® Feminine Wash With Douching Apparatus	BETADINE® feminine wash is effective in: • Management of trichomonas vaginalis, vaginitis, monilial vaginitis and non-specific vaginitis; • Symptomatic relief of minor vaginal soreness, irritation, itching; • Cleansing and deodorizing after menstruation (Douching is not recommended during pregnancy); • Washing out vaginal medication, if so instructed by the physician; • Deodorizing and washing out the accumulations of normal secretions; • Removing contraceptive creams and jellies; • Cleansing the vaginal vault after sexual relations (Remember: It is cleanser, not a contraceptive); • Providing a refreshing feeling of being confidently clean.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073057P	Difflam Mouth Gel	Temporarily relieves painful inflamed conditions of the mouth, including mouth and denture ulcers and sore gum.
BRU21073058P	Pharmaniaga Labetalol Hydrochloride 25mg/5ml Injection	• Severe hypertension, including severe hypertension of pregnancy, when rapid control of blood pressure is essential. • Anaesthesia when a hypotensive technique is indicated. • Hypertensive episode following acute myocardial infarction.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073059P	Z Mox Oral Suspension 250mg/5ml	Z MOX is useful in the treatment of infections caused by amoxicillin susceptible organisms: Respiratory tract infections - Upper airways and ENT infections - Lower airways infections, e.g. acute and chronic bronchitis, pneumonia, lung abscess, pertussis (incubation period and early stages) Urogenital infections - Acute and chronic pyelonephritis, pyelitis, prostatitis, epididymitis - Cystitis, urethritis, asymptomatic bacteriuria during pregnancy - Gonorrhoea Gynaecologic infections (septic abortion, adnexitis, endometritis, etc.) Gastro-intestinal infections - typhoid fever, paratyphoid, particularly if complicated by septicemia (in combination with an aminoglycoside antibiotic); control of salmonella carriers - Shigellosis Infections of the biliary system (cholangitis, cholecystitis) Skin and soft tissue infections Leptospirosis Acute and latent listeriosis

		Unless parenteral treatment (e.g. with ampicillin) is required, Z MOX is also active in the conditions below: - Short-term (24 to 48 hrs) prophylactic treatment of patients undergoing surgery (e.g. in the oral cavity) - Endocarditis, e.g. enterococcal endocarditis (alone or in combination with an aminoglycoside antibiotic) - Bacterial meningitis (pending the outcome of susceptibility test; particularly in children) - Septicemias caused by amoxicillin-susceptible pathogens. Infections caused by pathogens with established penicillin G susceptibility should preferentially be treated with penicillin G.
BRU21073060NP	Nature’s Way Glucosamine HCL 1500mg	Nature's Way Glucosamine HCL 1500mg can help relieve symptoms of mild osteoarthritis such as mild joint pain, soreness, and stiffness by helping reduce mild inflammation in joints. Nature's Way Glucosamine HCL 1500mg helps support •Healthy joint function •Healthy joint cartilage growth •Healthy ligaments and tendons •Connective tissue health •Joint mobility and flexibility.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073061P	Hovid Hoftrex Injection 1g	For treatment of the following infections caused by susceptible organisms: • Bone and joint infections • Uncomplicated gonorrhoea • Intra-abdominal infections • Lyme disease • Meningitis • Otitis media • Female pelvic infections • Respiratory tract infections, particularly bacterial pneumonia • Bacterial septicaemia • Skin and soft tissue infections • Bacterial urinary tract infections For prophylaxis of: Post operative infections caused by susceptible organisms throughout the course of the surgical procedures.
BRU21073062NP	Wina Aqueous Cream	For topical application to the skin: As an emollient for the symptomatic relief of dry skin conditions. As a soap-substitute for skin washing.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073063NP	Dermoplex Bite And Sting Cream	Dermoplex Bite and Sting Cream can be used to provide soothing relief of itching and pain due to:- •Minor burns •Minor skin irritations •Insect and mosquito bites •Scrapes and abrasions •Rashes •Shaving •Pimples
BRU21073064NP	SALONPAS Patch	For relief of aches and pains associated with: •Muscle fatigue •Muscle pain •Stiff shoulder •Simple backache •Bruises •Sprains •Strains •Arthritis

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073065NP	Paracil Suspension 120mg/5ml	1. Relief of fever and discomfort associated with the common cold and flu. 2. Relief of teething pain, toothache and earache.
BRU21073066NP	Uphamol 650 Tablet	It can be used to relieve the symptoms of various types of headaches including migraine and tension-type headache. Uphamol 650 can also be used to relieve pain due to colds and flu and to reduce fever.
BRU21073067P	Ramtace Tablet 5mg	1. Hypertension. 2. Congestive heart failure. 3. Treatment of patients who within the first few days after an acute myocardial infarction have demonstrated clinical signs of congestive heart failure. 4. For reducing the risk of myocardial infarction, stroke, cardiovascular death or the need for revascularization procedures in patients ≥ 55 years who have clinical evidence of coronary artery disease, stroke or peripheral vascular disease. 5. For reducing the risk of myocardial infarction, stroke, cardiovascular death or revascularization procedures in diabetic patients ≥ 55 years with ≥ 1 of the following risk factors: Systolic blood pressure > 160 mm Hg or diastolic blood pressure > 90 mm Hg (or on antihypertensive treatment); total cholesterol > 5.2 mmol/L; HDL cholesterol < 0.9 mmol/L; current smoker; known microalbuminuria; any evidence of previous vascular disease. 6. Prevention of progressive renal failure in patients with persistent proteinuria.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073068P	Lecetam 500 Film-Coated Tablet	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalization in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of: • partial onset seizures with or without secondary generalization in adults, adolescents, and children from 1 month of age with epilepsy. • myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • primary generalized tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalized Epilepsy.
BRU21073069P	Fentanyl Kalceks 0.05mg/ml Solution For Injection	Fentanyl is a short acting opioid used: • as an intravenous analgesic agent in surgical procedures; • as an adjunct in the maintenance of general anaesthesia; • in combination with a neuroleptic agent in the technique of neuroleptanalgesia; • as a respiratory depressant/analgesic in patients requiring prolonged assisted ventilation; • for induction of anaesthesia.

BRUNEI DARUSSALAM MEDICINES CONTROL AUTHORITY
MINISTRY OF HEALTH, BRUNEI DARUSSALAM

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073070P	Leucovorin Kabi Injection USP 10mg/ml	Leucovorin Calcium Injection is indicated: a) To diminish the toxicity and counteract the effects of inadvertently administered over dosage of folic acid antagonists, b) As a rescue after high dose methotrexate therapy. c) In the treatment of megaloblastic anaemia due to sprue, nutritional deficiency, pregnancy and infancy when oral therapy is not possible and, d) For use in combination with fluorouracil to prolong survival in the palliative treatment of patients with advanced colorectal cancer.
BRU21073071NP	DifflamAB™ Sore Throat Lozenges (Honey Lemon)	For the symptomatic relief of mouth and throat infections.
BRU21073072P	Difflam Anti-Inflammatory 3mg Lozenges	For the temporary relief of painful conditions of the oral cavity including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post-orosurgical and periodontal procedures, pharyngitis, swelling, redness and in¬flammatory conditions.
BRU21073073NP	Dequadin Lozenges 0.25mg	For symptomatic relief of sore throat.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21073074P	Axcel Amlodipine-10mg Tablet	Amlodipine is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with the thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme inhibitor. Amlodipine is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/ vasoconstriction (Prinzmetal's or variant angina) or coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/ vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta blockers.
BRU21093075NP	Infusol® HM	Replacement of extracellular fluid loss (isotonic dehydration), sodium depletion, light metabolic acidosis and electrolyte substitution in burns.
BRU21093076NP	Daflon 1000mg Film-Coated Tablet	Treatment of symptoms related to venolymphatic insufficiency (heavy legs, pain, early morning restless legs). Treatment of functional symptoms related to acute hemorrhoidal

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21093077P	Avonox Tablet 10mg	Indications are limited to treatment of severe sleep disorders in the following cases: -Occasional insomnia -Transient insomnia
BRU21093078P	Ipraneb 500 (Ipratropium Bromide 500mcg/2ml Nebuliser Solution BP)	Maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. Used concomitantly with inhaled beta-agonists in the treatment of acute bronchospasm associated with chronic obstructive pulmonary disease including chronic bronchitis and asthma. IPRANEB is indicated, when used concomitantly with inhaled beta-agonists in the treatment of reversible airways obstruction as in acute and chronic asthma.
BRU21093079P	Enerzair® Breezhaler® 150mcg/50mcg/160mcg Inhalation Powder, Hard Capsule	Enerzair Breezhaler is indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.
BRU21093080P	Atectura® Breezhaler® 150mcg/80mcg Inhalation Powder, Hard Capsules	Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21093081P	Atectura® Breezhaler® 150mcg/160mcg Inhalation Powder, Hard Capsules	Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists.
BRU21093082P	Atectura® Breezhaler® 150mcg/320mcg Inhalation Powder, Hard Capsules	Atectura Breezhaler is indicated as a maintenance treatment of asthma in adults and adolescents 12 years of age and older not adequately controlled with inhaled corticosteroids and inhaled short-acting beta2-agonists.
BRU21093083P	Vastarel XR 80mg Prolonged-Release Hard Capsules	Trimetazidine is indicated in adults as add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled by or intolerant to first-line antianginal therapies.
BRU21093084NP	Lactus Syrup 66% w/v	1. Treatment of constipation: it encourages bowel movement by drawing water into the bowel from surrounding body tissues. This provides soft stool mass and increased bowel action. It may take up to 48 hours to take effect. 2. Helps in the treatment of hepatic encephalopathy: it reduces the amount of ammonia in the blood.

BRUNEI DARUSSALAM MEDICINES CONTROL AUTHORITY
MINISTRY OF HEALTH, BRUNEI DARUSSALAM

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21093085NP	Natural Wellness Aqueous Cream	As an emollient for the symptomatic relief of dry skin conditions As a soap substitute for skin washing.
BRU21093086P	Revcox 200mg Capsule	Management of acute pain in adults and for the treatment of primary dysmenorrhoea. Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. Relief of signs and symptoms of ankylosing spondylitis. For the management of low back pain.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21093087P	Rovas-10 Film-Coated Tablet 10mg	Rosuvastatin is indicated for patients with primary hypercholesterolemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin is indicated to treat patients with primary dysbetalipoproteinemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. Rosuvastatin also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. Rosuvastatin is also indicated in patients with homozygous familial hypercholesterolemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: Rosuvastatin is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, Rosuvastatin is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures.

		Rosuvastatin is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21093088P	Rovas-20 Film-Coated Tablet 20mg	Rosuvastatin is indicated for patients with primary hypercholesterolemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin is indicated to treat patients with primary dysbetalipoproteinemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. Rosuvastatin also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. Rosuvastatin is also indicated in patients with homozygous familial hypercholesterolemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: Rosuvastatin is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, Rosuvastatin is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures.

		Rosuvastatin is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.
BRU21093089NP	Shine J-Care Cream	Relief of joint and muscle pain, sprains, strains, pain associated with rheumatism and arthritis. Temporary relief of pain associated with musculoskeletal soreness and discomfort.
BRU21093090P	Flutinide Nasal Spray 50mcg/Dose	For prophylaxis and treatment of allergic rhinitis.
BRU21093091P	Hovid-Celecoxib Capsule 200mg	For the management of acute pain in adults and for the treatment of primary dysmenorrhoea. Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. Relief of signs and symptoms of ankylosing spondylitis. For the management of low back pain.
BRU21103092NP	Ammeltz Yoko Yoko	Stiffness, Muscular ache, Joint pain, Limb languor, Bruise, Sprain, Loin pain and Chilblain.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103093P	Truxima 100mg/10ml Concentrate For Solution For Infusion	Truxima® is indicated for the treatment of patients with relapsed or chemoresistant indolent B-cell non-Hodgkin's lymphomas. Truxima® is indicated for the treatment of patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin vincristine and prednisone) chemotherapy. Truxima® is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. Truxima® maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. Chronic Lymphocytic Leukaemia Truxima® is indicated in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. Rheumatoid Arthritis Truxima® in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumour necrosis factor (TNF) inhibitor therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103094P	Truxima 500mg/50ml Concentrate For Solution For Infusion	Truxima® is indicated for the treatment of patients with relapsed or chemoresistant indolent B-cell non-Hodgkin's lymphomas. Truxima® is indicated for the treatment of patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma (DLCL) in combination with CHOP (cyclophosphamide, doxorubicin vincristine and prednisone) chemotherapy. Truxima® is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. Truxima® maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy. Chronic Lymphocytic Leukaemia Truxima® is indicated in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL. Rheumatoid Arthritis Truxima® in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumour necrosis factor (TNF) inhibitor therapies.

BRU21103095P	Ogivri 440mg Powder For Concentrate For Solution For Infusion	Adjuvant Breast Cancer Ogivri™ is indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature [see Clinical Studies) breast cancer • as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel • as part of a treatment regimen with docetaxel and carboplatin • as a single agent following multi-modality anthracycline based therapy. Metastatic Breast Cancer Ogivri™ is indicated: • In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer. • As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease Metastatic Gastric Cancer Ogivri™ is indicated, in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.
BRU21103096P	Omeprazole-Otto	Omeprazole is the treatment of choice for conditions when oral administration is not possible: reflux esophagitis, duodenal ulcer, gastric ulcer, and Zollinger-Ellison syndrome.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103098P	ONRON 4 Solution For Injection 2mg/mL	Adults: Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, Prevention and treatment of post-operative nausea and vomiting (PONV). Paediatric Population: Management of chemotherapy-induced nausea and vomiting. Prevention and treatment of post-operative nausea and vomiting.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103099P	Textas 80 Concentrate For Solution For Infusion 20mg/ml	<u>Breast cancer</u> Docetaxel Injection in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with: • Operable node-positive breast cancer • Operable node-negative breast cancer For patients with operable node-negative breast cancer, adjuvant treatment should be restricted to patients eligible to receive chemotherapy according to internationally established criteria for primary therapy of early breast cancer. <u>Non-small cell lung cancer</u> Docetaxel Injection is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer. <u>Prostate cancer</u> Docetaxel Injection in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer. <u>Gastric adenocarcinoma</u> Docetaxel Injection in combination with Cisplatin and 5-fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease. <u>Head and neck cancer</u> Docetaxel Injection in combination with Cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103100P	ONRON 8 Solution For Injection 2mg/mL	Adults: Management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, Prevention and treatment of post-operative nausea and vomiting (PONV). Paediatric Population: Management of chemotherapy-induced nausea and vomiting. Prevention and treatment of post-operative nausea and vomiting.
BRU21103101P	Nisolon Tablet 5mg	Collagen diseases: (eg. rheumatoid arthritis, acute rheumatic fever, SLE). Allergic diseases: (such as severe bronchial asthma, intractable allergic rhinitis, exfoliative dermatitis, serum sickness, and other acute drug reactions). Generalised dermatosis having an allergic component (eg. contact dermatitis, neurodermatitis, allergic eczema). Acute ocular inflammatory disease involving structures in the posterior segment (such as uveitis, chorioretinitis in vital areas, sympathetic ophthalmia). Certain lymphatic neoplastic diseases (to induce temporary remission). Various chronic or recurrent diseases of unknown aetiology such as ulcerative colitis and nephrosis. Since Nisolon lacks significant mineralocorticoid activity in usual therapeutic doses, it is not adequate for acute adrenocortical insufficiency. Adrenocortical steroids, hydrocortisone and cortisone should be used. Whenever corticosteroid therapy is indicated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103102P	Prelica Capsule 75mg	Neuropathic pain Prelica is indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Prelica is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization. Generalized Anxiety Disorder Prelica is indicated for the treatment of Generalized Anxiety Disorder (GAD) in adults. Fibromyalgia Prelica is indicated for the management of fibromyalgia.
BRU21103103P	Prelica Capsule 150mg	Neuropathic pain Prelica is indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Prelica is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization. Generalized Anxiety Disorder Prelica is indicated for the treatment of Generalized Anxiety Disorder (GAD) in adults. Fibromyalgia Prelica is indicated for the management of fibromyalgia.

BRU21103104P	Zexate® Solution For Injection Or Infusion 25 mg/ml	Antineoplastic chemotherapy Methotrexate has a broad spectrum of antineoplastic activity. It is indicated for the treatment of breast cancer, gestational choriocarcinoma, and in patients with chorioadenoma destruens and hydatidiform mole. Methotrexate may be used in combination with other chemotherapeutic agents for the palliative treatment of acute leukaemias, particularly acute lymphoblastic leukaemia. It may also be used in the treatment of Burkitt lymphoma, advanced stages (III and IV, Petersa Staging System) of lymphosarcoma, especially in children, and in advanced cases of mycosis fungoides. High dose therapy In high-dose schedules, methotrexate may be effective alone or in combination therapy, in the treatment of epidermoid cancers of the head and neck, osteogenic sarcoma and bronchogenic carcinoma. Calcium folinate (leucovorin calcium) must be used in conjunction with high dose methotrexate therapy. Psoriasis chemotherapy Methotrexate may be of value in the symptomatic control of severe, recalcitrant, disabling psoriasis which is not adequately responsive to other forms of treatment. However, due to the high risk associated with its use, methotrexate should be used after the diagnosis has been definitely established, as by biopsy and/or after dermatologic consultation. Rheumatoid arthritis chemotherapy Management of severe, recalcitrant, active rheumatoid arthritis in adults not responding to, or intolerant of, an adequate trial of NSAIDs and one or more disease modifying drugs. Aspirin, NSAIDs and/or low dose steroids may be continued, although the possibility of increased toxicity with concomitant use of NSAIDs including salicylate has not been fully explored. Steroids may be reduced gradually in patients who respond to methotrexate.

		Combined use of methotrexate with gold, penicillamine, hydroxychloroquine, sulfasalazine or cytotoxic agents has not been studied and may increase the incidence of adverse effects. Rest and physiotherapy as indicated should be continued.
BRU21103105NP	Minyak Angin Menthol Oil (MAMO)	Helps to relieve headaches, blocked nose, insect bites, stomach ache and motion sickness.
BRU21103106NP	Shine Hepavite Forte Capsule	As an adjunct in the treatment of the following diseases such as chronic liver diseases, liver cirrhosis, fatty liver and intoxication by hepatotoxic substance.
BRU21103107NP	Gascovid Advance Liquid	Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn, indigestion occurring to the reflux of stomach contents, for instance, after gastric surgery, as a result of hiatus hernia, during pregnancy or accompanying reflux oesophagitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103108P	Pharmaniaga Bupivacaine Hydrochloride 0.5% w/v Injection	Bupivacaine Hydrochloride 0.5% w/v Injection are indicated for the production of local or regional anaesthesia and analgesia in individuals as follows: - **Surgical anaesthesia** • Epidural block for surgery • Field block (minor and major nerve blocks and infiltration) **Analgesia** • Continuous epidural infusion or intermittent bolus epidural administration for analgesia in postoperative pain or labour pain • Field block (minor nerve block and infiltration).
BRU21103109P	Iqnyde Tablet 100mg	Iqnyde is indicated for the treatment of erectile dysfunction in adult males, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103110P	Simvacor Film Coated Tablet 20mg	In patients at high risk of coronary events because of existing CHD, history of stroke or other cerebrovascular disease, simvastatin is indicated to: reduce the risk of total mortality by reducing CHD deaths, reduce the risk of non-fatal myocardial infarction and stroke, reduce the need for coronary and non-coronary revascularization procedures. HYPERLIPIDEMIA: As an adjunct to diet to reduce elevated total-C, LDL-C, Apo B, and TG, and to increase HDL-C in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate, Simvastatin, therefore, lowers the LDL-C/HDL-C and the total-C/HDL-C ratios. PEDIATRIC PATIENTS WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA: As an adjunct to diet to reduce total-C, LDL-C, TG, and Apo B levels in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with heterozygous familial hypercholesterolemia (HeFH). GENERAL RECOMMENDATIONS: Prior to initiating therapy with simvastatin, secondary causes of hypercholesterolemia (e.g. poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemias, obstructive liver disease, other drug therapy, alcoholism) should be identified and treated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103111P	Atswift 10 Tablet	Hypercholesterolaemia Atorvastatin Tablets is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin Tablets is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. Prevention of cardiovascular disease Atorvastatin Tablets is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥6, or premature family history of coronary heart disease. In adults with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin Tablet is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In adults with clinically evident coronary heart disease, atorvastatin is indicated to: - Reduce the risk of non-fatal myocardial infarction - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for CHF - Reduce the risk of angina.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103112P	Atswift 20 Tablet	Hypercholesterolaemia Atorvastatin Tablets is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin Tablets is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. Prevention of cardiovascular disease Atorvastatin Tablets is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥6, or premature family history of coronary heart disease. In adults with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin Tablet is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In adults with clinically evident coronary heart disease, atorvastatin is indicated to: - Reduce the risk of non-fatal myocardial infarction - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for CHF - Reduce the risk of angina.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103113NP	Octenisept® Antiseptic Solution	Wound treatment •Antiseptic treatment of traumatic, acute, chronic, surgical and burn wounds Mucous membrane antiseptic •Prior to diagnostic and surgical interventions in the anogenital (e.g. before obliteration of haemorrids), the urogenital area (e.g. before placing an intra-uterine device (IUD), the vaginal area, before prenatal, intranatal and postnatal manipulations) and in the oral cavity (e.g. before tooth extractions) •Before placing urinary tract catheters •For preop. skin antisepsis in the area close to mucous membranes.
BRU21103114P	Allergo-Comod Eye Drops	Indicated in acute and chronic allergic conjunctivitis including hay-fever conjunctivitis, vernal keratoconjunctivitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103115P	Privigen Solution For Infusion 10%	Replacement therapy in • *Primary immunodeficiency syndromes (PID)* such as: – congenital agammaglobulinaemia and hypogammaglobulinaemia – common variable immunodeficiency – severe combined immunodeficiency – Wiskott-Aldrich syndrome • *Myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infection* s • *Children with congenital AIDS and recurrent infections* Immunomodulation • *Immune thrombocytopenic purpura (ITP) in children or adults at high risk of bleeding or prior to surgical interventions to correct the platelet count* • *Guillain-Barré syndrome* • *Kawasaki disease* • *Chronic inflammatory demyelinating polyneuropathy (CIDP)* Allogeneic bone marrow transplantation

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103116PS1; BRU21103116PS2	Celmantin 10mg Film-Coated Tablet	CELMANTIN is indicated for patients with primary hypercholesterolaemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolaemia) as an adjunct to diet when response to diet and exercise is inadequate. CELMANTIN is indicated to treat patients with primary dysbetalipoproteinaemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. Rosuvastatin also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. CELMANTIN is also indicated in patients with homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: CELMANTIN is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, CELMANTIN is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures

		CELMANTIN is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year postmenarche, 10-17 years of age with heterozygous familial hypercholesterolaemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103117PS1; BRU21103117PS2	Celmantin 20mg Film-Coated Tablet	CELMANTIN is indicated for patients with primary hypercholesterolaemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolaemia) as an adjunct to diet when response to diet and exercise is inadequate. CELMANTIN is indicated to treat patients with primary dysbetalipoproteinaemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. Rosuvastatin reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. Rosuvastatin also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. CELMANTIN is also indicated in patients with homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: CELMANTIN is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, CELMANTIN is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures

		CELMANTIN is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year postmenarche, 10-17 years of age with heterozygous familial hypercholesterolaemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.
BRU21103118NP	Siang Pure Relief Cream	For relief of muscle pain.
BRU21103119NP	Hot Minyak Gosok Cap Betet (Parrot Brand Hot Medicated Oil)	Relieve flatulence, muscle pain, sprain, joint stiffness, itchiness caused by insects bites and warm the body
BRU21103122P	Pharmaniaga Ephedrine Hydrochloride 30mg/ml Injection	Treatment of bronchial spasm in asthma, adjunct to correct haemodynamic imbalances and treat hypotension in epidural and spinal anaesthesia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103123NP	Ainiron (Iron Sucrose Injection 20mg/ml)	AINIRON is indicated for the treatment of iron deficiency anaemia in the following indications:- •Where there is a clinical need for a rapid iron supply, •In patients who cannot tolerate oral iron therapy or who are non-compliant, •In active inflammatory bowel disease where oral iron preparations are ineffective. AINIRON should only be administered where the indication is confirmed by appropriate investigations (e.g. Hb, serum ferritin, serum iron).
BRU21103124NP	Eagle Medicated Oil	Helps to relieve symptoms of common cold, giddiness, motion sickness, nausea, muscle fatigue and itching due to mosquito & insect bites.
BRU21103125NP	Minyak Gandapura	Helps to relieve pains associated with muscles and joints, aching joints and sprains. This product is also good for warming up purposes for sports persons.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103126P	Rosuccord 10 Film-Coated Tablet 10mg	ROSUCCORD is indicated for patients with primary hypercholesterolaemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolaemia) as an adjunct to diet when response to diet and exercise is inadequate. ROSUCCORD is indicated to treat patients with primary dysbetalipoproteinaemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. ROSUCCORD reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. ROSUCCORD also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. ROSUCCORD is also indicated in patients with homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: ROSUCCORD is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, ROSUCCORD is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures. ROSUCCORD is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year postmenarche, 10-17 years of age with heterozygous familial hypercholesterolaemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103127P	Rosuccord 20 Film-Coated Tablet 20mg	ROSUCCORD is indicated for patients with primary hypercholesterolaemia and mixed dyslipidaemia (including Fredrickson Type IIa, IIb; and heterozygous familial hypercholesterolaemia) as an adjunct to diet when response to diet and exercise is inadequate. ROSUCCORD is indicated to treat patients with primary dysbetalipoproteinaemia (Fredrickson Type III hyper lipoproteinaemia) as an adjunct to diet when response to diet and exercise is inadequate. ROSUCCORD reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL-cholesterol, thereby enabling most patients to achieve relevant treatment guidelines. ROSUCCORD also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I. ROSUCCORD is also indicated in patients with homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis). Primary prevention of cardiovascular disease: ROSUCCORD is indicated in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥ 50 years old in men and ≥ 60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, ROSUCCORD is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures. ROSUCCORD is indicated in children and adolescents 10 to 17 years of age as an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year postmenarche, 10-17 years of age with heterozygous familial hypercholesterolaemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. Paediatric studies were conducted mainly in the non-Asian population and data on Asian children/adolescents is limited.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103128NP	NW Povidone Iodine 10% w/v Solution	Use to prevent and treat infections that may occur in minor scrapes and cuts.
BRU21103129NP	NW Calamine Lotion With 0.25% w/w Menthol	NW Calamine Lotion with 0.25% w/w Menthol is used to soothe and relieve nappy rashes, prickly heat, minor skin irritations, insect bites and sunburn, pruritic skin conditions.
BRU21103130P	Rekaxime Injection 500mg	Infections of the respiratory tract, including throat and nose; of the ear; of the kidneys and urinary tract; of the skin and soft tissues; of the bones and joints; of the genital organs, including gonorrhoea; of the abdominal region. Septicaemia, bacterial endocarditis, meningitis; for perioperative prophylaxis in patients who are at increased risk from infection, and for the prophylaxis of infections in patients with reduced resistance.

BRU21103131P	Surotin 10mg FC Tablet	• As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol (HDL-cholesterol ratio and triglycerides) and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of cardiovascular events in adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers such as an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease. Rosuvastatin is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, MI, unstable angina or arterial revascularization). • As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia). • Primary hypercholesterolaemia (Type IIa including heterozygous familial hypercholesterolaemia and severe non-familial hypercholesterolaemia). • Combined (mixed) dyslipidemia (Type IIb). • Homozygous familial hypercholesterolaemia where rosuvastatin is used either alone or as an adjunct to diet and other lipid lowering treatment such as apheresis. • As an adjunct therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels. • Paediatric Patients 10-17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH): As an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with HeFH if after an adequate trial of diet therapy the following findings are present: LDL-C >190 mg/dL or >160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or ≥2 other CVD risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103132P	Surotin 20mg FC Tablet	• As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol (HDL-cholesterol ratio and triglycerides) and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of cardiovascular events in adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers such as an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease. Rosuvastatin is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, MI, unstable angina or arterial revascularization). • As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia). • Primary hypercholesterolaemia (Type IIa including heterozygous familial hypercholesterolaemia and severe non-familial hypercholesterolaemia). • Combined (mixed) dyslipidemia (Type IIb). • Homozygous familial hypercholesterolaemia where rosuvastatin is used either alone or as an adjunct to diet and other lipid lowering treatment such as apheresis. • As an adjunct therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels. • Paediatric Patients 10-17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH): As an adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with HeFH if after an adequate trial of diet therapy the following findings are present: LDL-C >190 mg/dL or >160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or ≥2 other CVD risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103133P	Irstran® Film-Coated Tablet 150mg	1. For the treatment of essential hypertension. 2. For treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (> 300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Irbesartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103134P	Xolair 75mg/0.5ml Solution For Injection In Pre-Filled Syringe	Allergic Asthma Adults and adolescents (12 years of age and above) Xolair (omalizumab) is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). Children (6 to < 12 years of age) Xolair is indicated as add-on therapy to improve asthma control with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions. Chronic rhinosinusitis with nasal polyps (CRSwNP) Xolair is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with CRSwNP for whom therapy with INC does not provide adequate disease control. Chronic Spontaneous Urticaria (CSU) Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103135P	Xolair 150mg/ml Solution For Injection In Pre-filled Syringe	Allergic Asthma Adults and adolescents (12 years of age and above) Xolair (omalizumab) is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). Children (6 to < 12 years of age) Xolair is indicated as add-on therapy to improve asthma control with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions. Chronic rhinosinusitis with nasal polyps (CRSwNP) Xolair is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with CRSwNP for whom therapy with INC does not provide adequate disease control. Chronic Spontaneous Urticaria (CSU) Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.
BRU21103136P	Besanta 300mg Tablet	BESANTA® is indicated in adults for the treatment of essential hypertension. It is also indicated for the treatment of diabetic nephropathy in adult patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103137P	Besanta 150mg Tablet	BESANTA® is indicated in adults for the treatment of essential hypertension. It is also indicated for the treatment of diabetic nephropathy in adult patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.
BRU21103138P	Fucon Syrup 1mg/ml	Gastro-intestinal tract spasm, spasm and dyskinesia of the biliary system, genito-urinary tract spasm.
BRU21103139P	Orata 1 Film-Coated Tablet	Entecavir is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with: • Compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis. • Decompensated liver disease. For both compensated and decompensated liver disease, this indication is based on clinical trial data in nucleoside naïve patients with HBeAg positive and HBeAg negative HBV infection. With respect to patients with Lamivudine-refractory hepatitis B, see Dosage and Administration, Precaution and Mechanism of Action sections. Entecavir is also indicated for the treatment of chronic HBV infection in nucleoside naïve pediatric patients from 2 to <18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis. With respect to the decision to initiate treatment in pediatric patients, see Dosage and Administration, Precaution and Mechanism of Action sections

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103140P	Ericox 90mg Tablets	Etoricoxib is indicated for: • Acute and chronic treatment of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA). • Treatment of ankylosing spondylitis (AS). • Treatment of acute gouty arthritis. • Treatment of acute pain, including that related to primary dysmenorrhoea and minor dental procedures. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21103141P	Pharmaniaga Simvastatin Tablet 40mg	*Reductions in risk of coronary heart disease (CHD) mortality and cardiovascular events* In patients at high risk of coronary events because of existing coronary heart disease, diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease, simvastatin is indicated to: • Reduce the risk of total mortality by reducing CHD deaths. • Reduce the risk of non-fatal myocardial infarction and stroke. • Reduce the need for coronary and non-coronary revascularization procedures. *Hyperlipidemia* Simvastatin is indicated as an adjunct to diet to reduce elevated total plasma cholesterol (total-C), low-density lipoprotein (LDL-C), apolipoprotein B (Apo B), and triglycerides (TG) and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia, heterozygous familial hypercholesterolemia or combined (mixed) hyperlipidemia when response to diet and other nonpharmacological measures is inadequate. Simvastatin therefore, lowers the LDL-C/HDL-C and the total-C/HDL-C ratios. *Pediatric patients with heterozygous familial hypercholesterolemia* Simvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, TG, and Apo B levels in adolescent boys and girls who are at least one year post-menarche, 10-17 years of age, with heterozygous familial hypercholesterolemia (HeFH).
BRU21103142P	Irstran® Film-Coated Tablet 300mg	1. For the treatment of essential hypertension. 2. For treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (> 300 mg/day) in patients with type 2 diabetes and hypertension. In this population, Irbesartan reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end-stage renal disease (need for dialysis or renal transplantation).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123143P	Amoxigran Granules	For treatment of: • Ear, nose and throat infections caused by streptococci, pneumococci, nonpenicillinase – producing staphylococci and *H. influenzae* . • Genitourinary tract infections caused by *E. coli, P. mirabilis, S. faecalis* . • Skin and soft tissues infections caused by streptococci, nonpenicillinase - producing staphylococci and *E. coli* . • Anogenital and urethral gonorrhoea caused by *N. gonorrhoeae* .
BRU21123144P	Nalopril 5mg Tablet	• Treatment of hypertension • Treatment of symptomatic heart failure • Prevention of symptomatic heart failure in patients with asymptomatic left ventricular dysfunction (ejection fraction ≤ 35%)

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123145P	Flonoxin 400mg Tablet	Moxifloxacin tablets are indicated for treatment of adults (≥ 18 years of age) with the following bacterial infections caused by susceptible strains: • Acute bacterial rhinosinusitis* • Acute exacerbations of chronic obstructive pulmonary disease including chronic bronchitis* • Nosocomial pneumonia/Hospital-acquired pneumonia* • Acute otitis media* • External otitis* • Endocarditis* • Infection of cerebrospinal fluid* • Meningitis* • Septicaemia* • Uncomplicated acute cystitis / uncomplicated cystitis* • Prevention of exacerbations in women with recurring urinary tract infections* • Prevention of infection in surgical procedures in the urogenital system*,# • Pre-operative preparations for chronic cholesteatomatous otitis and chronic otitis spreading to bone * • Community acquired pneumonia • Mild to moderately severe inflammatory pelvic diseases (i.e. infections of the upper female genital tract, including salpingitis and endometritis) without an associated tubo-ovarian or pelvic abscess. Moxifloxacin is not recommended for monotherapy of mild to moderately severe inflammatory pelvic diseases. Preferably, they should be administered in combination with another suited antibiotic (e.g.: cephalosporin), due to the increasing resistance of Neisseria gonorrhoeae to moxifloxacin; that is, unless moxifloxacin-resistant Neisseria gonorrhoeae can be ruled out. • Complicated skin and skin structure infections • Complicated intraabdominal infections including polymicrobial such as abscesses Consideration should be given to official guidance on the appropriate use of antibacterial agents. *Flonoxin should be only used : • When Pseudomonas is considered AND the patient is allergic to antipseudomonal penicillins/ cephalosporins; • For resistant organisms with no other alternative antibiotics available. #Flonoxin should not be used >24 hours post operation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123146NP	Ranofer Injection 100mg/5ml	Ranofer is indicated for the treatment of iron deficiency anaemia in the following indications: • Where there is a clinical need for a rapid iron supply, • In patients who cannot tolerate oral iron therapy or who are non-compliant, • In active inflammatory bowel disease where oral iron preparations are ineffective. Ranofer should only be administered where the indication is confirmed by appropriate investigations (e.g. Hb, serum ferritin, serum iron).

BRU21123147P	Linezolid Sandoz Film-Coated Tablet 600mg	Linezolid formulations are indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms. Linezolid is active against Gram-positive bacteria only. Linezolid has no clinical activity against Gram-negative pathogens. Specific Gram-negative therapy is required if a concomitant Gram-negative pathogen is documented or suspected. Vancomycin-Resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia. Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and –resistant strains), or *Streptococcus pneumonia* (penicillin-susceptible strains). Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. Complicated skin and skin structure infections including diabetic foot infections, without concomitant osteomyelitis caused by *Staphylococcus aureus* (methicillin-susceptible and –resistant strains), *Streptococcus pyogenes* , or, *Streptococcus agalactiae* . Linezolid has not been studied in the treatment of decubitus ulcers. Combination therapy may be clinically indicated if the documented or presumptive pathogens include Gram-negative organisms. Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible only) or *Streptococcus pyogenes* . Community-acquired pneumonia caused by *Streptococcus pneumoniae* (penicillin-susceptible strains only), including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible strains only). Due to concerns about inappropriate use of antibiotics leading to an increase in resistant organisms, prescribers should carefully consider alternatives before initiating treatment with linezolid in the outpatient setting. Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to linezolid. Therapy may be instituted empirically while awaiting the results of these tests. Once these results become available, antimicrobial therapy should be adjusted accordingly.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123148P	Dexmedetomidine Kabi 0.1mg/ml Concentrate For Infusion	***Intensive Care Unit Sedation*** : Dexmedetomidine hydrochloride is indicated for sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting. Dexmedetomidine hydrochloride should be administered by continuous infusion not to exceed 24 hours. Dexmedetomidine hydrochloride has been continuously infused in mechanically ventilated patients prior to extubation, during extubation, and post-extubation. It is not necessary to discontinue Dexmedetomidine hydrochloride prior to extubation. **Procedural Sedation**: Dexmedetomidine hydrochloride is indicated for sedation of non-intubated patients prior to and/or during surgical and other procedures.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123149P	Rosuvastatin Sandoz 10mg Film-Coated Tablet	As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol: HDL-cholesterol ratio and triglycerides and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of Cardiovascular Events: In adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers e.g., an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease. Rosuvastatin Sandoz is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, myocardial infarction (MI), unstable angina, or arterial revascularization). As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (type III hyperlipoproteinemia). Primary hypercholesterolaemia. Combined (mixed) dyslipidemia (type IIb). Homozygous familial hypercholesterolaemia where Rosuvastatin Sandoz is used either alone or as an adjunct to diet, and other lipid-lowering treatment e.g., apheresis. As adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total-C and LDL-C to target levels.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123150P	Rosuvastatin Sandoz 20mg Film-Coated Tablet	As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol: HDL-cholesterol ratio and triglycerides and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: Prevention of Cardiovascular Events: In adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers e.g., an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease. Rosuvastatin Sandoz is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, myocardial infarction (MI), unstable angina, or arterial revascularization). As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (type III hyperlipoproteinemia). Primary hypercholesterolaemia. Combined (mixed) dyslipidemia (type IIb). Homozygous familial hypercholesterolaemia where Rosuvastatin Sandoz is used either alone or as an adjunct to diet, and other lipid-lowering treatment e.g., apheresis. As adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total-C and LDL-C to target levels.
BRU21123151P	GABTIN 300	GABTIN is an antiepileptic used as monotherapy or adjunctive therapy in the treatment of partial seizures with or without secondary generalisation. Gabapentin is also used in the treatment of neuropathic pain.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123152NP	Promag Tablet	Symptomatic relief of excess stomach acid associated with ulcers or dyspepsia such as heartburn, nausea, bloating and stomach pain.
BRU21123153P	Lydocan Injection 2%	To be used for most major nerve blocks, e.g. sciatic and retrobulbar.
BRU21123154P	Rahika 150mg Film-Coated Tablet	TABRECTA is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping.
BRU21123155P	Rahika 200mg Film-Coated Tablet	TABRECTA is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping.

		Rheumatoid Arthritis REMSIMA®, in combination with methotrexate (MTX), is indicated for: The reduction of signs and symptoms as well as the improvement in physical function in - patients with active disease when the response to disease modifying drugs, including methotrexate, has been inadequate. - patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. In these patient populations, a reduction in the rate of the progression of joint damage, as measured by x ray, has been demonstrated. **Crohn's Disease** REMSIMA® is indicated for: - Treatment of moderately to severely active Crohn s disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and an immunosuppressant: or who are intolerant to or have medical contraindications for such therapies. - Treatment of fistulising Crohn s disease, in patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). **Paediatric Crohn's Disease** REMSIMA® is indicated for: Treatment of severe, active Crohn s disease, in paediatric patients aged 6 to 17 years, who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. REMSIMA® has been studied only in combination with conventional immunosuppressive therapy. **Ulcerative Colitis** REMSIMA® is indicated for: Treatment of moderately to severely active ulcerative colitis in patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

BRU21123156P	Remsima Powder For Concentrate For Solution For Infusion 100mg/Vial	**Ulcerative Colitis** REMSIMA® is indicated for: Treatment of moderately to severely active ulcerative colitis in patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Paediatric Ulcerative Colitis** REMSIMA® is indicated for: Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. **Ankylosing Spondylitis** REMSIMA® is indicated for: Treatment of ankylosing spondylitis, in patients who have severe axial symptoms, elevated serological markers of inflammatory activity and who have responded inadequately to conventional therapy. **Psoriatic Arthritis** REMSIMA®, in combination with methotrexate, is indicated for: Treatment of active and progressive psoriatic arthritis in patients who have responded inadequately to disease-modifying anti-rheumatoid drugs. **Psoriasis** REMSIMA® is indicated for: Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen ultraviolet A (PUVA).

BRU21123157P	Herzuma 440mg Powder For Concentrate For Solution For Infusion	*Metastatic Breast Cancer (MBC)* Herzuma® is indicated for the treatment of patients with metastatic breast cancer who have tumors that overexpress HER2: a) as monotherapy for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease b) in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease c) in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer, not previously treated with trastuzumab. This indication is based on data from one Phase III trial which studied the use of Herzuma® in combination with anastrozole (see 3.1.2 Clinical/ Efficacy Studies). Experience with other aromatase inhibitors is limited. *Early Breast Cancer (EBC)* Herzuma® is indicated for the treatment of patients with HER2 positive early breast cancer. - following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). - following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel. - in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin. - in combination with neoadjuvant chemotherapy followed by adjuvant Herzuma® therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter. Herzuma® should only be used in patients whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay. *Metastatic Gastric Cancer (MGC)* Herzuma® in combination with capecitabine or 5-fluorouracil and cisplatin is indicated for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro- esophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Herzuma® should only be used in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123158P	Herzuma 150mg Powder For Concentrate For Solution For Infusion	*Metastatic Breast Cancer (MBC)* Herzuma® is indicated for the treatment of patients with metastatic breast cancer who have tumors that overexpress HER2: a) as monotherapy for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease b) in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease c) in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer, not previously treated with trastuzumab. This indication is based on data from one Phase III trial which studied the use of Herzuma® in combination with anastrozole (see 3.1.2 Clinical/ Efficacy Studies). Experience with other aromatase inhibitors is limited. *Early Breast Cancer (EBC)* Herzuma® is indicated for the treatment of patients with HER2 positive early breast cancer. - following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). - following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel. - in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin. - in combination with neoadjuvant chemotherapy followed by adjuvant Herzuma® therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter. Herzuma® should only be used in patients whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay. *Metastatic Gastric Cancer (MGC)* Herzuma® in combination with capecitabine or 5-fluorouracil and cisplatin is indicated for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro- esophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Herzuma® should only be used in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123159P	Pregeb Capsules 150mg	Neuropathic pain Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. Fibromyalgia Pregabalin is indicated for the management of fibromyalgia.
BRU21123160NP	Salonpas 30 Patch	For relief of aches and pains associated with: •Muscle fatigue • Muscle pain • Stiff shoulder • Simple backache •Bruises •Sprains •Strains • Arthritis

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123161P	Adrim Injection 50mg/25ml	ADRIM® has been used successfully to produce regression in neoplastic conditions such as: acute leukaemia, Wilms' tumour, neuroblastoma, soft tissue and bone sarcomas, breast carcinoma, lymphomas of both Hodgkin's and non-Hodgkin's type, bronchogenic (lung) carcinoma, thyroid carcinoma, hepatomas, ovarian carcinoma, etc. The main antitumour activities are listed below. ADRIM® is also indicated by intravesical administration in the primary management of non-metastatic carcinoma of the bladder. (Tis, T1, T2) (refer to PI).
BRU21123162P	Cymbalox 60mg Delayed-Release Capsules	Treatment of major depressive disorder. Management of Neuropathic pain associated with diabetic peripheral neuropathy in adults. Treatment of generalised anxiety disorder.
BRU21123163P	Cymbalox 30mg Delayed-Release Capsules	Treatment of major depressive disorder. Management of Neuropathic pain associated with diabetic peripheral neuropathy in adults. Treatment of generalised anxiety disorder.
BRU21123164NP	Three Legs Wintergreen Liniment	For symptomatic relief of strains, sprains and muscular pains.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123165P	Voritrop 50 Film-Coated Tablet 50mg	Voriconazole is a broad spectrum, triazole antifungal agent and is indicated as follows: - Treatment of invasive aspergillosis; - Treatment of candidemia in non-neutropenic patients; - Treatment of fluconazole-resistant serious invasive Candida infections (including C. krusei); - Treatment of serious fungal infections caused by Scedosporium spp. and Fusarium spp.; - Prophylaxis in patients ≥12 years old who are at high risk of developing invasive fungal infections. The indication is based on a study which includes patients ≥12 years old undergoing allogeneic haematopoietic stem cell transplantation.
BRU21123166P	Voritrop 200 Film-Coated Tablet 200mg	Voriconazole is a broad spectrum, triazole antifungal agent and is indicated as follows: - Treatment of invasive aspergillosis; - Treatment of candidemia in non-neutropenic patients; - Treatment of fluconazole-resistant serious invasive Candida infections (including C. krusei); - Treatment of serious fungal infections caused by Scedosporium spp. and Fusarium spp.; - Prophylaxis in patients ≥12 years old who are at high risk of developing invasive fungal infections. The indication is based on a study which includes patients ≥12 years old undergoing allogeneic haematopoietic stem cell transplantation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123167P	Entecavir Sandoz Film-Coated Tablet 0.5mg	Entecavir Sandoz is indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. The following points should be considered when initiating therapy with Entecavir Sandoz: • This indication is based on histologic, virologic, biochemical, and serologic responses in nucleoside-treatment- naïve and lamivudine-resistant adult patients with HBeAg-positive or HBeAg-negative chronic HBV infection with compensated liver disease. • Virologic, biochemical, serologic, and safety data are available from a controlled study in adult subjects with chronic HBV infection and decompensated liver disease. • Virologic, biochemical, serologic, and safety data are available for a limited number of adult subjects with HIV/HBV co-infection who have received prior lamivudine therapy.
BRU21123168P	Otagil 10 Film-Coated Tablet	<u>Treatment of hypercholesterolemia</u> Adults, adolescents and children aged 6 years or older with primary hypercholesterolemia (type IIa including heterozygous familial hypercholesterolemia) or mixed dyslipidemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolemia as an adjunct to diet and other lipid lowering treatment (e.g. LDL apheresis) or if such treatment are not appropriate. <u>Prevention of Cardiovascular Events</u> Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123169P	Otagil 20 Film-Coated Tablet	Treatment of hypercholesterolemia Adults, adolescents and children aged 6 years or older with primary hypercholesterolemia (type IIa including heterozygous familial hypercholesterolemia) or mixed dyslipidemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolemia as an adjunct to diet and other lipid lowering treatment (e.g. LDL apheresis) or if such treatment are not appropriate. Prevention of Cardiovascular Events Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU21123170P	RO-CAL 0.25mcg	Established postmenopausal osteoporosis. Renal osteodystrophy in patients with chronic renal failure, particularly those undergoing hemodialysis. Management of hypocalcemia and its clinical manifestations in patients with postsurgical hypoparathyroidism, idiopathic hypoparathyroidism, and pseudohypoparathyroidism. Vitamin D dependent rickets. Hypophosphatemic vitamin – D resistant rickets. Predialysis Patients : Management of secondary hyperparathyroidism and resultant metabolic bone disease in patients with moderate to severe chronic renal failure (Ccr 15 to 55 mL/min) not yet on dialysis. Dialysis Patients : Management of hypocalcemia and the resultant metabolic bone disease in patients undergoing chronic renal dialysis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123171P	Acetan Tablet 50mg	**Hypertension** ACETAN is indicated for the treatment of hypertension. **Hypertensive Patients with Left Ventricular Hypertrophy** ACETAN is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. **Nephropathy in Type 2 Diabetic Patients** Indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ≥300mg/g) in patients with type 2 diabetes and a history of hypertension. In this population, ACETAN reduces the rate of progression of nephropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation) or death.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123172P	Acetan Tablet 100mg	**Hypertension** ACETAN is indicated for the treatment of hypertension. **Hypertensive Patients with Left Ventricular Hypertrophy** ACETAN is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients. **Nephropathy in Type 2 Diabetic Patients** Indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ≥300mg/g) in patients with type 2 diabetes and a history of hypertension. In this population, ACETAN reduces the rate of progression of nephropathy as measured by the occurrence of doubling the serum creatinine or end stage renal disease (need for dialysis or renal transplantation) or death.
BRU21123173NP	B.Braun 0.9% Sodium Chloride & 5% Glucose Intravenous Infusion B.P	– Isotonic dehydration – Hypotonic dehydration – Chloride losses – Partial coverage of energy requirements – Vehicle solution for compatible electrolyte concentrates and medicinal products
BRU21123174P	Fucon Solution For Injection 20mg/ml	Fucon Solution for Injection 20mg/ml is indicated in acute spasm, as in renal or biliary colic, in radiology for differential diagnosis of obstruction. It is also indicated to reduce spasm and pain in pyelography, and in other diagnostic procedures where spasm may be a problem.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123175P	Flomist Aqueous Nasal Spray 50mcg	Flomist Aqueous Nasal Spray is indicated for the prophylaxis and treatment of seasonal allergic rhinitis including hayfever, and perennial rhinitis. Fluticasone propionate has potent anti-inflammatory activity but when used topically on the nasal mucosa has no detectable systemic activity.
BRU21123176P	Hepuri 0.5mg Film-Coated Tablets	Entecavir are indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum alanine aminotransferases (ALT or AST) or histological active disease. This indication is based on the reported histologic, virologic, biochemical, and serological response in: a) nucleoside treatment naive and lamivudine resistant adult patient with HBeAg positive and HBeAg negative HBV infection with compensated liver disease b) adult patent with chronic HBV infection and decompensated liver disease c) adult patient with HIV/HBV co infection who have received prior lamivudine therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU21123177P	Lebreta 2.5mg Tablets	• Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. • Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown estrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy). • First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer. • Treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antiestrogens. • Pre-operative therapy in postmenopausal women with localized hormone receptor positive breast cancer, to allow subsequent breast-conserving surgery in women not originally considered candidates for this type of surgery. Subsequent treatment after surgery should be in accordance with standard of care.
BRU22023178P	Bepen Injection 1.0MU	Benzylpenicillin is indicated for most wound infections, pyogenic infections of the skin, soft tissue infections and infections of the respiratory tract. It is also indicated for the following infections caused by penicillin-sensitive microorganisms: Generalised infections and septicaemia from susceptible bacteria. Acute and chronic osteomyelitis, sub-acute bacterial endocarditis and meningitis caused by susceptible organisms. Tetanus, actinomycosis, anthrax, rat-bite fever, listeriosis and severe Lyme disease. Complications secondary to gonorrhoea and syphilis (e.g. gonococcal arthritis or endocarditis, congenital syphilis and neurosyphilis). Diphtheria, brain abscesses and pasteurellosis. Consideration should be given to official local guidance (e.g. national recommendations) on the appropriate use of antibacterial agents. Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023179NP	Referis Iron Sucrose Injection USP 100mg/5ml	Referis is indicated for the treatment of iron deficiency in the following indications: • Where there is a clinical need for a rapid iron supply • In patients who cannot tolerate oral iron therapy or who are noncompliant • In active inflammatory bowel disease where oral iron preparations are ineffective • In chronic kidney disease when oral iron preparations are less effective The diagnosis of iron deficiency must be based on appropriate laboratory tests (e.g. Hb, serum ferritin, TSAT, serum iron, etc.) (Hb haemoglobin, TSAT transferrin saturation)
BRU22023180NP	Salonpas Hot Patch	For relief of aches, pains and inflammation associated with stiff shoulder, simple backache, muscle pain, bruises, sprains and joint pains.

		ADULTS **Rheumatoid Arthritis** AMGEVITA is indicated for reducing signs and symptoms and inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs. AMGEVITA can be used alone or in combination with methotrexate or other DMARDs. AMGEVITA, in combination with MTX, can also be used in the treatment of patients with recently diagnosed moderate to severely active rheumatoid arthritis who have not received methotrexate. **Psoriatic Arthritis** AMGEVITA is indicated for reducing signs and symptoms of active arthritis in adult patients with moderate to severe psoriatic arthritis when the response to previous DMARD therapy has been inadequate. AMGEVITA has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. AMGEVITA can be used alone or in combination with DMARDs. **Ankylosing Spondylitis** AMGEVITA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy. **Crohn's Disease** AMGEVITA is indicated for the treatment of moderate to severe active Crohn's disease in adults to reduce the signs and symptoms of the disease and to induce and maintain clinical remission in patients who have had an inadequate response to conventional therapies, or who have lost response to or are intolerant of infliximab. For induction treatment, AMGEVITA should be given in combination with corticosteroids. AMGEVITA can be given as monotherapy in case of intolerance to corticosteroids or when continued treatment with corticosteroids is inadequate.

BRU22023181P	Amgevita Solution For Injection In Prefilled Syringe 40mg/0.8ml	**Ulcerative Colitis** AMGEVITA is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Plaque Psoriasis** AMGEVITA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Hidradenitis Suppurativa** AMGEVITA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** AMGEVITA is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. **PEDIATRICS** **Juvenile Idiopathic Arthritis** *Polyarticular Juvenile Idiopathic Arthritis* AMGEVITA in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA), in patients 2 years of age and older, who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs 23 (DMARDS). AMGEVITA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate (for the efficacy in monotherapy see CLINICAL STUDIES). AMGEVITA has not been studied in patients aged less than 2 years.

		Enthesitis-Related Arthritis AMGEVITA is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. **Pediatric Crohn's Disease** AMGEVITA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients, 6 years of age and older, with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. **Pediatric Plaque Psoriasis** AMGEVITA is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Adolescent Hidradenitis Suppurativa** AMGEVITA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Uveitis** AMGEVITA is indicated for the treatment of chronic non-infectious anterior uveitis in pediatric patients 2 years of age and older who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. **Pediatric Ulcerative Colitis** AMGEVITA is indicated for inducing and maintaining clinical remission in pediatric patients 5 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

		ADULTS **Rheumatoid Arthritis** AMGEVITA is indicated for reducing signs and symptoms and inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs. AMGEVITA can be used alone or in combination with methotrexate or other DMARDs. AMGEVITA, in combination with MTX, can also be used in the treatment of patients with recently diagnosed moderate to severely active rheumatoid arthritis who have not received methotrexate. **Psoriatic Arthritis** AMGEVITA is indicated for reducing signs and symptoms of active arthritis in adult patients with moderate to severe psoriatic arthritis when the response to previous DMARD therapy has been inadequate. AMGEVITA has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. AMGEVITA can be used alone or in combination with DMARDs. **Ankylosing Spondylitis** AMGEVITA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy. **Crohn's Disease** AMGEVITA is indicated for the treatment of moderate to severe active Crohn's disease in adults to reduce the signs and symptoms of the disease and to induce and maintain clinical remission in patients who have had an inadequate response to conventional therapies, or who have lost response to or are intolerant of infliximab. For induction treatment, AMGEVITA should be given in combination with corticosteroids. AMGEVITA can be given as monotherapy in case of intolerance to corticosteroids or when continued treatment with corticosteroids is inadequate.

BRU22023182P	Amgevita Solution For Injection In Prefilled Autoinjector 40mg/0.8ml	**Ulcerative Colitis** AMGEVITA is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Plaque Psoriasis** AMGEVITA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. **Hidradenitis Suppurativa** AMGEVITA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** AMGEVITA is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. **PEDIATRICS** **Juvenile Idiopathic Arthritis** *Polyarticular Juvenile Idiopathic Arthritis* AMGEVITA in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA), in patients 2 years of age and older, who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs 23 (DMARDS). AMGEVITA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate (for the efficacy in monotherapy see CLINICAL STUDIES). AMGEVITA has not been studied in patients aged less than 2 years.

		Enthesitis-Related Arthritis AMGEVITA is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. **Pediatric Crohn's Disease** AMGEVITA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients, 6 years of age and older, with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. **Pediatric Plaque Psoriasis** AMGEVITA is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Adolescent Hidradenitis Suppurativa** AMGEVITA is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Pediatric Uveitis** AMGEVITA is indicated for the treatment of chronic non-infectious anterior uveitis in pediatric patients 2 years of age and older who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. **Pediatric Ulcerative Colitis** AMGEVITA is indicated for inducing and maintaining clinical remission in pediatric patients 5 years of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023183P	Forvic 300 Film-Coated Tablet	*HIV-1 infection* Tenofovir disoproxil is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults. Tenofovir disoproxil is also indicated for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents, aged 12 to < 18 years. The choice of Tenofovir disoproxil to treat antiretroviral-experienced patients with HIV-1 infection should be based on individual viral resistance testing and/or treatment history of patients. *Hepatitis B infection* Tenofovir disoproxil is indicated for the treatment of chronic hepatitis B in adults with: • compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis. • evidence of Lamivudine-resistant hepatitis B virus. • decompensated liver disease. Tenofovir disoproxil is indicated for the treatment of chronic hepatitis B in adolescents 12 to < 18 years of age with: • compensated liver disease and evidence of immune active disease, i.e. active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis.
BRU22023184P	Haemostop Injection 100mg/ml	For local fibrinolysis as epistaxis, prostatectomy, cervical conization, and dental extraction in patients with coagulopathies. Hereditary angioneurotic edema. General fibrinolysis after major surgery.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023185P	Letimble 10mg Tablets	*Primary hypercholesterolaemia* Ezetimibe, administered alone, or with an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia. Ezetimibe, administered in combination with fenofibrate, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B and non-HDL-C in patients with mixed hyperlipidemia. *Prevention of Cardiovascular Events* Ezetimibe, administered with a statin, is indicated to reduce the risk of cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, hospitalization for unstable angina, or need for revascularization), in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS). *Homozygous Familial Hypercholesterolaemia (HoFH)* Ezetimibe, administered with a statin, is indicated for patients with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis). *Homozygous Sitosterolaemia (Phytosterolaemia)* Ezetimibe is indicated for the reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolaemia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023186P	Imaccord 400 Film Coated Tablet	**Imaccord** is indicated for the • treatment of adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML) (for paediatric use see section DOSAGE AND ADMINISTRATION). • treatment of adult and paediatric patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy (for paediatric use see section DOSAGE AND ADMINISTRATION). • treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy. • treatment of adult patients with relapsed or refractory Ph+ ALL as monotherapy. • treatment of adult patients with Kit+ (CD117) unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST). • adjuvant treatment of adult patients following complete gross resection of Kit+ GIST. The effectiveness of Imaccord is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in relapsed or refractory adult Ph+ ALL, on objective response rates in unresectable and/or metastatic GIST and on recurrence free survival in adjuvant GIST. Except in newly diagnosed chronic phase CML there are no controlled trials demonstrating increased survival.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023187P	Imaccord 100 Film Coated Tablet	**Imaccord** is indicated for the • treatment of adult and paediatric patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML) (for paediatric use see section DOSAGE AND ADMINISTRATION). • treatment of adult and paediatric patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy (for paediatric use see section DOSAGE AND ADMINISTRATION). • treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy. • treatment of adult patients with relapsed or refractory Ph+ ALL as monotherapy. • treatment of adult patients with Kit+ (CD117) unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST). • adjuvant treatment of adult patients following complete gross resection of Kit+ GIST. The effectiveness of Imaccord is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in relapsed or refractory adult Ph+ ALL, on objective response rates in unresectable and/or metastatic GIST and on recurrence free survival in adjuvant GIST. Except in newly diagnosed chronic phase CML there are no controlled trials demonstrating increased survival.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023188P	Pharmaniaga Dermasole Ointment 0.1% w/w	Betamethasone is a potent topical corticosteroid indicated for adults, elderly and children over 1 year for the relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses. These include the following: -Atopic dermatitis (including infantile atopic dermatitis) -Nummular dermatitis (discoid eczema) -Prurigo nodularis -Psoriasis (excluding widespread plaque psoriasis) -Lichen simplex chronicus (neurodermatitis) and lichen planus -Seborrhoeic dermatitis -Irritant or allergic contact dermatitis -Discoid lupus erythematosus -Adjunct to systemic steroid therapy in generalized erythroderma, -Insect bite reactions -Miliara (prickly heat)
BRU22023189P	Amdepin 5 Tablet	•Hypertension •Chronic stable anginal pectoris •Vasospastic (Prinzmetal's) angina

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023190P	Amdepin 10 Tablet	•Hypertension •Chronic stable anginal pectoris •Vasospastic (Prinzmetal's) angina
BRU22023191P	Copan Injection 1ml Amp	Spasm of the gastrointestinal tract, biliary spasm, renal spasm, diagnostic aid in radiology.
BRU22023192P	Lygaba Capsule 75mg	*Neuropathic Pain* : Treatment of neuropathic pain in adults. *Epilepsy* : As adjunctive therapy in adults with partial seizures with or without secondary generalisation. *Generalised Anxiety Disorder* : Treatment of Generalised Anxiety Disorder (GAD) in adults. *Fibromyalgia* : Management of fibromyalgia.
BRU22023193P	Ternolol 50 Film-Coated Tablet	For treatment of hypertension, angina pectoris, acute myocardial infarction and cardiac arrhythmias.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023194P	Hosolvon Elixir 4mg/5ml (Sugar Free)	Secretolytic therapy in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport.
BRU22023195P; BRU22023195PS2	Mavenclad Tablet 10mg	MAVENCLAD is indicated for the treatment of relapsing-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023196P	Imbruvica® 140mg Film-Coated Tablets	IMBRUVICA is indicated for the treatment of adult patients with mantle cell lymphoma (MCL). IMBRUVICA as a single agent or in combination with rituximab or obinutuzumab or venetoclax is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with lymphocytic leukaemia (CLL) who have received at least one prior therapy. IMBRUVICA as a single agent is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with WM. IMBRUVICA is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023197P	Imbruvica® 280mg Film-Coated Tablets	IMBRUVICA is indicated for the treatment of adult patients with mantle cell lymphoma (MCL). IMBRUVICA as a single agent or in combination with rituximab or obinutuzumab or venetoclax is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with lymphocytic leukaemia (CLL) who have received at least one prior therapy. IMBRUVICA as a single agent is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with WM. IMBRUVICA is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22023198P	Imbruvica® 420mg Film-Coated Tablets	IMBRUVICA is indicated for the treatment of adult patients with mantle cell lymphoma (MCL). IMBRUVICA as a single agent or in combination with rituximab or obinutuzumab or venetoclax is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with lymphocytic leukaemia (CLL) who have received at least one prior therapy. IMBRUVICA as a single agent is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy. IMBRUVICA in combination with rituximab is indicated for the treatment of adult patients with WM. IMBRUVICA is indicated for the treatment of adult patients with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.
BRU22033199P	Amsubac 1.5g Injection	For infections caused by susceptible microorganisms. Typical indications are upper and lower respiratory tract infections including sinusitis, otitis media and epiglottitis; bacterial pneumonias; urinary tract infections and pyelonephritis; intra-abdominal infections including peritonitis, cholecystitis, endometritis and pelvic cellulitis; bacterial septicaemia; skin, soft tissue, bone and joint infections and gonococcal infections. Ampicillin sodium & Sulbactam sodium may also be administered preoperatively to reduce the incidence of postoperative wound infections in patients undergoing abdominal or pelvic surgery, in which peritoneal contamination may be present. In termination of pregnancy or caesarean section, Ampicillin sodium & Sulbactam sodium may be used prophylactically to reduce postoperative sepsis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22033200P	Xylocon 0.025% Nasal Drops	Rhinitis acuta, sinusitis, eustachitis and otitis media.
BRU22033201P	Xylocon 0.05% Nasal Drops	Rhinitis acuta, sinusitis, eustachitis and otitis media.
BRU22033202NP	Salonpas 30 Hot Patch	For relief of aches and pains associated with: •Muscle fatigue •Muscle pain •Stiff shoulder •Simple backache •Bruises •Sprains •Strains •Arthritis
BRU22033203P	GPO-A-Flu (Oseltamivir Capsules 75mg)	GPO-A-FLU™ (oseltamivir capsules) is used for the symptomatic treatment and the prophylaxis of influenza A or B virus infection in adults and adolescents 13 years of age or older. The World Health Organization (WHO) recommends that oseltamivir be available for the treatment of suspected avian influenza A (H5N1) respiratory infections in individuals involved in mass poultry culling operations.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22033204P	Iobrim Eye Drops	Brimonidine Eye Drops are effective for lowering intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension. Brimonidine Eye Drops may also be used as adjunctive therapy when intraocular pressure (IOP) is not adequately controlled by a topical beta-blocking agent. There is no known cure for glaucoma. Treatment with Brimonidine Eye Drops (as with any other therapy) aims to preserve visual field through decrease of IOP.
BRU22033205P	Pharmaniaga Erythromycin Suspension 200mg	Erythromycin is used in the treatment of infections due to susceptible organisms; it is often used as an alternative to penicillin in infections due to Gram-positive cocci, especially Streptococci, and *Listeria monocytogenes* . In penicillin sensitive patients it is given in place of penicillin in the prophylaxis of endocarditis and in the treatment of syphilis. For the treatment of otitis media caused by *Haemophilus influenzae* it may be given in combination with sulphonamide. Erythromycin may be given as an adjunct to antitoxin in the treatment of diphtheria or used alone to eradicate the carrier state. In the prevention of pertussis, it may be used in non- or partially immune patients. It is used in infections due to *Mycoplasma pneumoniae* and *Chlamydia trachomatis* in Legionnaires' disease, in enteritis due to *Campylobacter* spp., chancroid and similarly to tetracycline, in the treatment of severe acne vulgaris.
BRU22033206P	Mycofit 500 Tablets 500mg	Mycophenolate Mofetil is indicated for: • prophylaxis of acute organ rejection and treatment of refractory organ rejection in patients receiving allogeneic renal transplants. • prophylaxis of acute organ rejection and increased graft and patient survival in patients receiving allogeneic cardiac transplants. • prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplants. Mycophenolate Mofetil should be used concomitantly with cyclosporin and corticosteroids.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22033207P	Zynomax Tablet 250mg	Zynomax is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes pharyngitis, including the prophylaxis of rheumatic fever. Zynomax is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of Zynomax and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, Zynomax is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis. It is also indicated in the treatment of chancroid due to Haemophilus ducreyi and uncomplicated genital infection due to non-multiresistant Neisseria gonorrhoea; concurrent infection with Treponema pallidum should be excluded.
BRU22033208P	Urief 4mg Film-Coated Tablets	Bladder outlet obstruction associated with benign prostatic hyperplasia in patients ≥ 50 years.
BRU22033209P	Mycofit 250 Capsules 250mg	Mycofit is indicated for: • Prophylaxis of acute organ rejection and treatment of refractory organ rejection in patients receiving allogeneic renal transplants. • Prophylaxis of acute organ rejection and increased graft and patient survival in patients receiving allogeneic cardiac transplants. • Prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplants. Mycofit should be used concomitantly with cyclosporin and corticosteroids.

BRU22033210P	Pharmaniaga Dopamine Hydrochloride 40mg/ml Injection	Dopamine hydrochloride is indicated for the correction of haemodynamic imbalances present in the shock syndrome due to myocardial infarctions, trauma, endotoxic septicaemia, open heart surgery, renal failure and chronic cardiac decompensation as in congestive failure. *Poor Perfusion of Vital Organs* : Urine flow appears to be one of the better diagnostic signs by which adequacy of vital organ perfusion can be monitored. Nevertheless, the physician should also observe the patient for signs of reversal of confusion or comatose condition. In a number of oliguric or anuric patients, administration of dopamine hydrochloride has resulted in an increase in urine flow which in some cases reached normal levels. Dopamine hydrochloride may also increase urine flow in patients whose output is within normal limits and thus may be of value in reducing the degree of pre-existing fluid accumulation. It should be noted that at doses above those optimal for the individual patient, urine flow may decrease, necessitating reduction of dosage. Concurrent administration of dopamine hydrochloride and diuretic agents may produce an additive or potentiating effect. *Low Cardiac Output* : Increased cardiac output is related to the direct inotropic effect of dopamine hydrochloride on the myocardium. Increased cardiac output at low or moderate doses appears to be related to a favourable prognosis. In many instances, the renal fraction of the total cardiac output has been found to increase. Increase in cardiac output produced by dopamine hydrochloride is not associated with substantial decreases in systemic vascular resistance (SVR) as may occur with isoproterenol. *Hypotension* : Hypotension due to inadequate cardiac output can be managed by administration of low to moderate doses of dopamine hydrochloride which have little effect on SVR. At high therapeutic doses, the alpha adrenergic activity of dopamine hydrochloride becomes more prominent and thus may correct hypotension due to diminished SVR. It is suggested that the physician administer dopamine hydrochloride as soon as a definite trend toward decreased systolic and diastolic pressure becomes evident.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22043211NP	Daneuron Tablet	DANEURON promotes effectively the treatment of pain due to disturbance of the peripheral nerves such as lumbago, neuritis, polyneuritis, post-herpetic neuralgia. It is also effective in the treatment of hyperemesis gravidarum and during the convalescent period of disease.
BRU22043212NP	Three Legs Septyc-Kare Antiseptic Spray 1% w/v	As an antiseptic for treatment of skin lesions, cuts, abrasions, infected wounds and burns.
BRU22043213P	Carbopa 10mg/ml Injection	Carboplatin is indicated in the treatment of advanced stage ovarian cancer of epithelial origin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22043214P	Amtas 5 (Amlodipine Tablets 5mg)	<u>Hypertension</u> Amlodipine is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme (ACE) inhibitor. <u>Coronary Artery Disease</u> *Chronic Stable Angina* Amlodipine is indicated for the symptomatic treatment of chronic stable angina. Amlodipine may be used alone or in combination with other antianginal drugs. *Vasospastic Angina (Prinzmetal's or variant angina)* Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy, or in combination with other antianginal drugs. *Angiographically Documented Coronary Artery Disease* In patients with recently documented coronary artery disease (CAD) by angiography and without heart failure or an ejection fraction <40%, amlodipine is indicated to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure.
BRU22043215P	Celcox 200mg Capsules	? For the management of acute pain in adults and for the treatment of primary dysmenorrhea. ? Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. ? Relief of signs and symptoms of ankylosing spondylitis. ? For the management of low back pain.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22043216P	Gemibine-200 Gemcitabine For Injection USP 200mg	Gemcitabine is indicated for the treatment of advanced bladder cancer (muscle invasive Stage IV tumours with or without metastases) in combination with cisplatin. Gemcitabine is indicated for treatment of adult patients with locally advanced or metastatic adenocarcinoma of the pancreas. Gemcitabine, in combination with cisplatin is indicated as first line treatment of patients with locally advanced (inoperable Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer (NSCLC). Gemcitabine is indicated for the palliative treatment of adult patients with locally advanced or metastatic NSCLC. Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.
BRU22043217P	Pharmaniaga Co-Amoxiclav Suspension 228mg	It is indicated for the treatment of the following infections: a) Upper & lower respiratory tract infections – sinusitis, otitis media, bronchitis. b) Skin and soft tissue infections – boils, abscesses, cellulitis, wound infections. c) Genitounrinary tract infections – cystitis, urethritis, pyelonephritis. d) Bone & joint infections – osteomyelitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22043218P	Lorviqua 25mg Film-Coated Tablet	LORVIQUA as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor. LORVIQUA as monotherapy is indicated for the treatment of adult patients with ALK positive advanced NSCLC whose disease has progressed after: • alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or • crizotinib and at least one other ALK TK1.
BRU22043219P	Lorviqua 100mg Film-Coated Tablet	LORVIQUA as monotherapy is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously not treated with an ALK inhibitor. LORVIQUA as monotherapy is indicated for the treatment of adult patients with ALK positive advanced NSCLC whose disease has progressed after: • alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy; or • crizotinib and at least one other ALK TK1.
BRU22043220P	Uniquin (Hydroxychloroquine Sulfate 200mg Film Coated Tablet)	Treatment of rheumatoid arthritis, juvenile chronic arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22043221P	Atorvon 10mg Film-Coated Tablets	***Hypercholesterolaemia*** : Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides in patients with primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia, or combined (mixed) hyperlipidaemia (Fredrickson Types IIa and IIb) when response to diet and other non-pharmacological measures is inadequate. Atorvastatin is also indicated as an adjunct to diet and other non-dietary measures in reducing elevated total cholesterol, LDL-cholesterol and apolipoprotein B in patients with homozygous familial hypercholesterolaemia when response to these measures is inadequate. ***Prevention of cardiovascular disease*** : Atorvastatin is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥ 55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥ 6, or premature family history of coronary heart disease. In patients with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk of revascularization procedures • Reduce the risk of hospitalization of CHF • Reduce the risk of angina

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22043222P	Caditor 10 Film-Coated Tablets	**<u>Hypercholesterolaemia</u>** Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. **<u>Prevention of cardiovascular disease</u>** Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22043223P	Caditor 20 Film-Coated Tablets	**Hypercholesterolaemia** Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. **Prevention of cardiovascular disease** Prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.
BRU22043224NP	Rexom Winamol 500mg Tablet	For relief of fever. For relief from mild-to-moderate pain including: Headache, Migraine Muscle ache, Dysmenorrhea, Sore throat, Musculoskeletal pain, Fever and pain after vaccination, Pain after dental procedures / tooth extraction, Toothache, Pain of osteoarthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22043225NP	B. Braun Water for Injection B.P.	Preparation and dilution of parenteral preparations.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22043226P	Rosmi 10 Tablet	**Hyperlipidemia and Mixed Dyslipidemia** ROSUVASTATIN is indicated as adjunctive therapy to diet to reduce elevated Total-C, LDL-C, ApoB, nonHDL-C, and triglycerides and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and nonpharmacological interventions alone has been inadequate. **Pediatric Patients 10 to 17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH)** Adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. **Hypertriglyceridemia** ROSUVASTATIN is indicated as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia. **Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia)** ROSUVASTATIN is indicated as an adjunct to diet for the treatment of patients with Dysbetalipoproteinemia (Type III Hyperlipoproteinemia). **Homozygous Familial Hypercholesterolemia** ROSUVASTATIN is indicated as adjunctive therapy to other lipid-lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia. **Slowing of the Progression of Atherosclerosis** ROSUVASTATIN is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.

		Primary Prevention of Cardiovascular Disease In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age > 50 years old in men and > 60 years old in women, hsCRP > 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, ROSUVASTATIN is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures **Limitations of Use** ROSUVASTATIN has not been studied in Fredrickson Type I and V dyslipidemias.

BRU22043227P	Rosmi 20 Tablet	**Hyperlipidemia and Mixed Dyslipidemia** ROSUVASTATIN is indicated as adjunctive therapy to diet to reduce elevated Total-C, LDL-C, ApoB, nonHDL-C, and triglycerides and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and nonpharmacological interventions alone has been inadequate. **Pediatric Patients 10 to 17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH)** Adjunct to diet to reduce Total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C > 190 mg/dL or > 160 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. **Hypertriglyceridemia** ROSUVASTATIN is indicated as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia. **Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia)** ROSUVASTATIN is indicated as an adjunct to diet for the treatment of patients with Dysbetalipoproteinemia (Type III Hyperlipoproteinemia). **Homozygous Familial Hypercholesterolemia** ROSUVASTATIN is indicated as adjunctive therapy to other lipid-lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia. **Slowing of the Progression of Atherosclerosis** ROSUVASTATIN is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.

		Primary Prevention of Cardiovascular Disease In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age > 50 years old in men and > 60 years old in women, hsCRP > 2 mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, ROSUVASTATIN is indicated to: • reduce the risk of stroke • reduce the risk of myocardial infarction • reduce the risk of arterial revascularization procedures **Limitations of Use** ROSUVASTATIN has not been studied in Fredrickson Type I and V dyslipidemias.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22063228P	Atorvon 20mg Film-Coated Tablets	***Hypercholesterolaemia*** : Atorvastatin is indicated as an adjunct to diet for reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B, and triglycerides in patients with primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia, or combined (mixed) hyperlipidaemia (Fredrickson Types IIa and IIb) when response to diet and other non-pharmacological measures is inadequate. Atorvastatin is also indicated as an adjunct to diet and other non-dietary measures in reducing elevated total cholesterol, LDL-cholesterol and apolipoprotein B in patients with homozygous familial hypercholesterolaemia when response to these measures is inadequate. ***Prevention of cardiovascular disease*** : Atorvastatin is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥ 55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥ 6, or premature family history of coronary heart disease. In patients with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin is indicated to: • Reduce the risk of myocardial infarction • Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to: • Reduce the risk of non-fatal myocardial infarction • Reduce the risk of fatal and non-fatal stroke • Reduce the risk of revascularization procedures • Reduce the risk of hospitalization of CHF • Reduce the risk of angina

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22063229P	Siranalen 75mg Capsules	<u>Neuropathic pain</u> Siranalen is indicated for the treatment of neuropathic pain, which includes diabetic peripheral neuropathy and post-herpetic neuralgia in adults. <u>Epilepsy</u> Siranalen is indicated as adjunctive therapy of partial seizures, with or without secondary generalization, in adults. <u>Generalised Anxiety Disorder</u> Siranalen is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.
BRU22063230P	YSP Knowful Injection 200mg/ml	1. Treatment of the elderly with some degree of cerebral functional impairment such as loss of memory, a lack of concentration or alertness and vertigo. 2. Indicated for patients suffering from myoclonus of cortical origin, irrespective of aetiology and should be used in combination with other anti-myoclonic therapies. 3. Used in the treatment of sickle-cell vaso-occlusive crises.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22063231P	Entacapone HEC 200mg Film-Coated Tablets	Entacapone is indicated as an adjunct to standard preparations of levodopa/benserazide or levodopa/carbidopa for use in adult patients with Parkinson's disease and end-of-dose motor fluctuations, who cannot be stabilised on the levodopa combinations.
BRU22063232P	Vytan Tablet 80mg	**Hypertension** Treatment of hypertension. **Heart failure** Treatment of heart failure (NYHA class II-IV) in patients receiving usual therapy (such as diuretics, digitalis) who are intolerant to ACE inhibitors. Valsartan improves morbidity in these patients, primarily via reduction in hospitalization for heart failure. Valsartan also slows the progression of heart failure, improves NYHA functional class, ejection fraction and signs and symptoms of heart failure and improves quality of life versus placebo. **Post-myocardial infarction** Valsartan is indicated to improve survival following myocardial infarction in clinically stable patients with signs, symptoms or radiological evidence of left ventricular failure and/or with left ventricular systolic dysfunction.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22063233P	Vytan Tablet 160mg	**Hypertension** Treatment of hypertension. **Heart failure** Treatment of heart failure (NYHA class II-IV) in patients receiving usual therapy (such as diuretics, digitalis) who are intolerant to ACE inhibitors. Valsartan improves morbidity in these patients, primarily via reduction in hospitalization for heart failure. Valsartan also slows the progression of heart failure, improves NYHA functional class, ejection fraction and signs and symptoms of heart failure and improves quality of life versus placebo. **Post-myocardial infarction** Valsartan is indicated to improve survival following myocardial infarction in clinically stable patients with signs, symptoms or radiological evidence of left ventricular failure and/or with left ventricular systolic dysfunction.

BRU22063234P	Stelara Solution for Injection In Single-Use Vial 45mg/0.5ml	**Plaque Psoriasis** ***(via subcutaneous administration only)*** STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A) (see *Pharmacodynamic Properties*). **Pediatric Plaque Psoriasis** ***(via subcutaneous administration only with single-use vial)*** STELARA is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies (see *Pharmacodynamic Properties*). **Psoriatic Arthritis (PsA)** ***(via subcutaneous administration only)*** STELARA alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate (see *Pharmacodynamic Properties*). **Crohn's Disease** ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies (see *Pharmacodynamic Properties*).

		Ulcerative Colitis ***(via intravenous administration for induction dosing, and via subcutaneous administration for maintenance dosing)*** STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies (see *Pharmacodynamic Properties*).
BRU22063235P	Piri Syrup	For symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, and allergic conjunctivitis due to inhalant allergens and foods. Symptomatic treatment of mild, uncomplicated allergic skin manifestation of urticaria and angioedema.
BRU22063236NP	Cardin Orodispersible Tablet	Conditions where modification of platelet behaviour is considered beneficial, including transient ischaemic attacks, secondary prevention of myocardial infarction, and for prophylaxis against stroke, vascular occlusion and deep vein thrombosis.
BRU22083237P	Allercrom Eye Drops 2% w/v	Prevention and relief of the ocular symptoms that appear with allergic conjunctivitis and seasonal conjunctivitis.
BRU22083238NP	Inhaler Lang	**Eagle Inhaler** helps clear a blocked nose that come with colds and influenza.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22083239P	Spizef Tablet 250mg	Upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis. Lower respiratory tract infections for example, pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis. Genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis. Skin and soft-tissue infections for example, furunculosis, pyoderma, and impetigo. Gonorrhoea, acute uncomplicated gonococcal urethritis and cervicitis.

BRU22083240P	Tecentriq® Concentrate For Solution For Infusion 840mg/14ml	**Early-stage non-small cell lung cancer** Tecentriq as monotherapy is indicated as adjuvant treatment following complete resection for adult patients with Stage II to IIIA (7th edition of the UICC/AJCC-staging system) non-small cell lung cancer (NSCLC) whose tumours have PD-L1 expression on ≥ 50% of tumour cells (TC) and whose disease has not progressed following platinum-based adjuvant chemotherapy (see Section 3.1.2 Clinical / Efficacy Studies). **Metastatic non-small cell lung cancer** Tecentriq, in combination with Avastin, paclitaxel and carboplatin, is indicated for the treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) who had not received prior chemotherapy. Tecentriq as monotherapy is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving Tecentriq. Tecentriq, in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumor aberrations. Tecentriq as monotherapy is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have a PD-L1 expression ≥ 50% tumor cells (TC) or ≥ 10% tumor-infiltrating immune cells (IC) and who do not have EGFR or ALK genomic tumor aberrations. **Small cell lung cancer** Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).

		Triple-negative breast cancer Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression of ≥1% on IC, and who have not received prior chemotherapy for metastatic disease. **Hepatocellular carcinoma** Tecentriq, in combination with Avastin, is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.
BRU22083241P	Herpesan Gel 2% w/w	Treatment of Lip Sores, Mouth Ulcers and Orofacial Lesions caused by virus infections.
BRU22083242NP	Rowatanal Cream	For the treatment of haemorrhoids and proctitis (anal irritation).
BRU22083243NP	Rowarolan Powder	For the treatment of minor cuts, abrasions, bed sores, leg ulcers and similar conditions.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22083244P	Diabetmin XR 500mg Tablet	Metformin is used in the treatment of non-insulin-dependent diabetes mellitus (type 2) in adults, not responding to exercise and dietary modification. Diabetmin may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.
BRU22083245P	Zynomax Powder for Oral Suspension 200mg/5ml	Zynomax is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes pharyngitis, including the prophylaxis of rheumatic fever. Zynomax is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of Zynomax and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, Zynomax is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis. It is also indicated in the treatment of chancroid due to Haemophilus ducreyi and uncomplicated genital infection due to non-multiresistant Neisseria gonorrhoea; concurrent infection with Treponema pallidum should be excluded.
BRU22083246P	Febuton Film-Coated Tablet 80mg	Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis). Febuton is indicated in adults.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22093247NP	Hexidine Solution 0.2% w/v	Hexidine Mouthwash is an antimicrobial solution which inhibits the formation of dental plaque. It is indicated as an aid in the treatment and prevention of gingivitis and in the maintenance of oral hygiene, particularly in situations where tooth brushing cannot be adequately employed (e.g. following oral surgery, in mentally or physically handicapped patients).
BRU22093248P	Pregatas-150 Capsules 150mg	<u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised Anxiety Disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Neuropathic pain</u> Pregabalin is indicated for the treatment of neuropathic pain which includes diabetic peripheral neuropathy and post-herpetic neuralgia in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22093249P	Pregatas-75 Capsules 75mg	Epilepsy Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. Neuropathic pain Pregabalin is indicated for the treatment of neuropathic pain which includes diabetic peripheral neuropathy and post-herpetic neuralgia in adults. Fibromyalgia Pregabalin is indicated for the management of fibromyalgia.
BRU22093250NP	Promag Oral Suspension	Symptomatic relief of excess stomach acid associated with ulcers or dyspepsia such as heartburn, nausea, bloating and stomach pain.
BRU22093251P	Candefar 16	- Treatment of essential hypertension in adults - Treatment of adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction < 40%) as add-on therapy to Angiotensin Converting Enzyme (ACE) inhibitors or when ACE inhibitors are not tolerated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22093252P	Letero (Letrozole Tablets 2.5mg)	• Adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. • Adjuvant treatment of postmenopausal women with early breast cancer (positive or unknown oestrogen or progesterone receptor status) who have received 5 years of adjuvant tamoxifen therapy (extended adjuvant therapy). • First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer. • Treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status, who have previously been treated with antioestrogens. • Pre-operative therapy in postmenopausal women with localized hormone receptor positive breast cancer, to allow subsequent breast-conserving surgery in women not originally considered candidates for this type of surgery. Subsequent treatment after surgery should be in accordance with standard of care.
BRU22093254P	Calquence® Capsules 100mg	Calquence as monotherapy or in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). Calquence as monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22093255P	Ibrance Film-Coated Tablets 75mg	IBRANCE is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.
BRU22093256P	Ibrance Film-Coated Tablets 100mg	IBRANCE is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22093257P	Ibrance Film-Coated Tablets 125mg	IBRANCE is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or • fulvestrant in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.
BRU22093258P	TS-ONE OD Tablet 25	TS-ONE® is indicated in adults • For the treatment of advanced gastric cancer when given in combination with cisplatin. • For post operative adjuvant chemotherapy for locally advanced (stage II (excluding T1), IIIA or IIIB) gastric cancer. • For the treatment of locally advanced or metastatic pancreatic cancer when given as monotherapy. • For the treatment of locally advanced or metastatic non-small cell lung cancer when given in combination with carboplatin. • For the treatment of metastatic colorectal cancer when given in combination with oxaliplatin as first-line treatment or in combination with irinotecan as second-line treatment. • For the treatment of HER2-negative metastatic breast cancer when given as monotherapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22093259P	TS-ONE OD Tablet 20	TS-ONE® is indicated in adults • For the treatment of advanced gastric cancer when given in combination with cisplatin. • For post operative adjuvant chemotherapy for locally advanced (stage II (excluding T1), IIIA or IIIB) gastric cancer. • For the treatment of locally advanced or metastatic pancreatic cancer when given as monotherapy. • For the treatment of locally advanced or metastatic non-small cell lung cancer when given in combination with carboplatin. • For the treatment of metastatic colorectal cancer when given in combination with oxaliplatin as first-line treatment or in combination with irinotecan as second-line treatment. • For the treatment of HER2-negative metastatic breast cancer when given as monotherapy.
BRU22113260NP	Panadol Caplet 500mg Optizorb Formulation	Paracetamol is an analgesic and an antipyretic. Relief of fever. Relief of headache, migraine, sore throat, fever and toothache.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22113261P	Eperon 1mg Film-Coated Tablets	Eperon is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. Eperon alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. Eperon is also effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Risperidone is indicated for the short-term treatment of persistent aggression in patients with moderate to severe dementia of the Alzheimer's type unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others. Eperon is indicated for the treatment of behavioural disorders associated with autism (eg irritability, social withdrawal, stereotypic behaviour, hyperactivity and inappropriate speech) in children and adolescents. Eperon is also indicated for bipolar mania. Adjunctive therapy: Eperon is indicated as adjunctive therapy to mood stabilizers in the treatment of manic episodes associated with bipolar disorders. These episodes are characterized by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviors. Monotherapy: Eperon is indicated in the treatment of acute manic episodes associated with bipolar 1 disorder. The effectiveness of Eperon for more than 12 weeks of treatment of an acute episode, and for the prevention of new manic episodes has not been established. Eperon is indicated in the treatment of conduct and other disruptive behavior disorders in children (over 5 years), adolescents and adults with subaverage intellectual functioning or mental retardation in whom destructive behaviors (e.g. aggression, impulsivity and self-injurious behaviors) are prominent.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22113262NP	Healthy Care High Strength Vitamin B12 1000mcg	**Healthy Care Vitamin B12 1000mcg** has been specially formulated to promote energy production and helps to relieve tiredness and fatigue. **Other benefits**: • Supports blood vessel health. • Supports heart health and healthy cardiovascular system function. • Helps relieve symptoms of stress.
BRU22113263P	Tremfya® One-Press® 100mg/ml Solution For Injection In Pre-Filled Pen	**Plaque Psoriasis** TREMFYA is indicated for the treatment of adults ~~patients~~ with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis** TREMFYA, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. **Palmoplantar pustulosis** TREMFYA is indicated for the treatment of moderate to severe palmoplantar pustulosis (PPP) in adult patients who do not adequately respond to conventional therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22113264P	Neufar 150 Capsule	Neuropathic Pain Pregabalin is indicated for the treatment of peripheral neuropathic pain in adults. Epilepsy Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22113265P	Midazolam Kalceks 5mg/ml Solution For Injection/Infusion	Midazolam Kalceks is a short-acting sleep-inducing drug that is indicated as follows: **In adults** • CONSCIOUS SEDATION before or during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia - Induction of anaesthesia - As a sedative component in combined anaesthesia • SEDATION IN INTENSIVE CARE UNITS **In paediatric** • CONSCIOUS SEDATION before or during diagnostic or therapeutic procedures with or without local anaesthesia • ANAESTHESIA - Premedication before induction of anaesthesia • SEDATION IN INTENSIVE CARE UNITS For dosage recommendation in specific age range see section 4.2 below, Table 1.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22113266P	Femcord Solution For Injection 250mg/5ml	Femcord is indicated for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy, or with disease relapse on or after adjuvant antiestrogen therapy, or disease progression on antiestrogen therapy. <u>Combination therapy with palbociclib</u> Femcord is indicated in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women with disease progression following endocrine therapy. <u>Combination therapy with abemaciclib</u> Femcord is indicated in combination with abemaciclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women with disease progression after endocrine therapy. <u>Combination therapy with ribociclib</u> Femcord is indicated in combination with ribociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in postmenopausal women as initial endocrine based therapy or following disease progression on endocrine therapy.

BRU22113267P	YSP Tidact 150mg/ml Solution For Injection	Clindamycin has been shown to be effective in the treatment of the following infections when caused by susceptible anaerobic bacteria: susceptible strains of gram positive aerobic bacteria such as streptococci, staphylococci and pneumococci; and susceptible strains of *Chlamydia trachomatis* . a) Upper respiratory infections including tonsillitis, pharyngitis, sinusitis, otitis media and scarlet fever. b) Lower respiratory infection including bronchitis, pneumonia, empyema and lung abscess. c) Skin and soft tissue infections including acne, furuncles, cellulitis, impetigo, abscesses, and wound infections, specific skin and soft tissue infections caused by susceptible organisms like erysipelas and paranychia (panaritium) d) Bone and joint infections including osteomyelitis and septic arthritis. e) Gynecological infections including endometritis, cellulitis, vaginal cuff infection and tubo-ovarian abscess, salpingitis, and pelvic inflammatory disease when given in conjunction with an antibiotic of appropriate gram negative spectrum. In cases of cervicitis due to *Chlamydia trachomatis* , single drug therapy with clindamycin has been shown to be effective in eradicating the organism. f) Intra-abdominal infections including peritonitis and abdominal abscess when given in conjunction with an antibiotic of appropriate gram negative aerobic spectrum. g) Septicemia and endocarditis – the effectiveness of clindamycin in the treatment of selected cases of endocarditis has been documented when clindamycin is determined to be bactericidal to the infecting organism by in vitro testing of appropriate achievable serum concentrations. h) Dental infections such as periodontal abscess and periodontitis. i) Toxoplasmic encephalitis in patients with AIDS. In patients who are intolerant to conventional treatment, clindamycin in combination with pyrimethamine has been shown to be efficacious. j) *Pneumocystis jiroveci* (previously classified as *Pneumocystis carinii*) pneumonia in patients with AIDS. In patients who are intolerant to, or do not respond adequately to conventional treatment, clindamycin may be used in combination with primaquine. Clindamycin phosphate, when used concurrently with an aminoglycoside antibiotic such as gentamicin or tobramycin, has been shown to be effective in preventing peritonitis or intra-abdominal abscess after bowel perforation and bacterial contamination secondary to trauma. In-vitro susceptibility to clindamycin has been shown for the following organisms: *B.melaninogenicus, B.disiens, B.bivius, Peptostreptococcus spp., G. vaginalis, M.mulieris, M.curtisii and Mycoplasma hominis* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22113268P	Azith (Powder For Oral Suspension 200mg/5ml)	Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, azithromycin is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated in the treatment of chancroid due to *Haemophilus ducreyi* ; and uncomplicated genital infection due to non-multiresistant *Neisseria gonorrhoea* ; concurrent infection with *Treponema pallidum* should be excluded. Azithromycin is indicated, either alone or in combination with rifabutin, for prophylaxis against *Mycobacterium avium-intracellulare complex* (MAC) infection, an opportunistic infection prevalent in patients with advanced human immunodeficiency virus (HIV). Azithromycin is indicated in combination with ethambutol for the treatment of disseminated MAC (DMAC) infection in patients with advanced HIV infection.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU22113272P	Skyrizi Solution For Injection In Pre-Filled Syringe 150mg/ml	**Plaque Psoriasis** Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Psoriatic Arthritis** Skyrizi, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).
BRU22113273P	Skyrizi Solution For Injection In Pre-Filled Pen 150mg/ml	**Plaque Psoriasis** Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Psoriatic Arthritis** Skyrizi, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23013274P	Olumiant 2mg Film-Coated Tablets	<u>Rheumatoid arthritis</u> Baricitinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate (see sections 4.4, 4.5 and 5.1 for available data on different combinations). <u>Atopic dermatitis</u> Baricitinib is indicated for the treatment of moderate to severe atopic dermatitis in adult and paediatric patients 2 years of age and older who are candidates for systemic therapy. <u>Alopecia areata</u> Baricitinib is indicated for the treatment of severe alopecia areata in adult patients (see section 5.1).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23013275P	Olumiant 4mg Film-Coated Tablets	<u>Rheumatoid arthritis</u> Baricitinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate (see sections 4.4, 4.5 and 5.1 for available data on different combinations). <u>Atopic dermatitis</u> Baricitinib is indicated for the treatment of moderate to severe atopic dermatitis in adult and paediatric patients 2 years of age and older who are candidates for systemic therapy. <u>Alopecia areata</u> Baricitinib is indicated for the treatment of severe alopecia areata in adult patients (see section 5.1).
BRU23013276P	Bisodac-HF 5mg Tablets	For 5mg & 10mg • Treatment of high blood pressure (hypertension) • Treatment of coronary heart disease (angina pectoris) • Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.
BRU23013277P	Bisodac-HF 2.5mg Tablets	For 2.5mg • Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23013278P	Gemibine-1000 Gemcitabine For Injection USP 1000mg	Gemcitabine is indicated for the treatment of advanced bladder cancer (muscle invasive Stage IV tumours with or without metastases) in combination with cisplatin. Gemcitabine is indicated for treatment of adult patients with locally advanced or metastatic adenocarcinoma of the pancreas. Gemcitabine, in combination with cisplatin is indicated as first line treatment of patients with locally advanced (inoperable Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer (NSCLC). Gemcitabine is indicated for the palliative treatment of adult patients with locally advanced or metastatic NSCLC. Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated.
BRU23013279P	Qilu Palonosetron Hydrochloride Injection 0.25mg/5ml	Palonosetron Hydrochloride Injection is indicated for **Chemotherapy-Induced Nausea and Vomiting** ***Adults and Paediatric Patients 1 month of Age and Older*** • the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy. • the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23013280P	PeBarin® (75mg Capsule)	*Neuropathic pain* Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. *Epilepsy* Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. *Generalised anxiety disorder* Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.
BRU23013281P	PeBarin® (150mg Capsule)	*Neuropathic pain* Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. *Epilepsy* Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. *Generalised anxiety disorder* Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23013282P	Liobac Tablet 10mg	**Liobac** is indicated for the alleviation of spasticity of the skeletal muscles in multiple sclerosis and other spastic conditions occurring from spinal cord diseases of infectious, degenerative, traumatic, neoplastic or unknown origin (e.g. spastic spinal paralysis, amyotrophic lateral sclerosis, syringomyelia, transverse myelitis, traumatic paraplegia or paraparesis, and compression of the spinal cord), muscle spasticity of cerebral origin, especially where due to infantile cerebral palsy. Because of the likelihood of intolerance, **Liobac** is less suitable for spasticity due to cerebrovascular accident or degenerative or neoplastic brain disease, but it may be tried if administered cautiously.
BRU23013283P	Pitomate 25mg Tablet	*Epilepsy* PITOMATE is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy. PITOMATE is indicated as adjunctive therapy for adults and children aged 2 years and above with partial onset seizures or generalized tonic-clonic seizures. PITOMATE is also indicated in adults and children as adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome. *Migraine* PITOMATE is indicated in adults for the prophylaxis of migraine headache. The usefulness of PITOMATE in the acute treatment of migraine headache has not been studied.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23013284P	Pitomate 50mg Tablet	*Epilepsy* PITOMATE is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy. PITOMATE is indicated as adjunctive therapy for adults and children aged 2 years and above with partial onset seizures or generalized tonic-clonic seizures. PITOMATE is also indicated in adults and children as adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome. *Migraine* PITOMATE is indicated in adults for the prophylaxis of migraine headache. The usefulness of PITOMATE in the acute treatment of migraine headache has not been studied.
BRU23013285P	Pitomate 100mg Tablet	*Epilepsy* PITOMATE is indicated as monotherapy in patients with newly diagnosed epilepsy or for conversion to monotherapy in patients with epilepsy. PITOMATE is indicated as adjunctive therapy for adults and children aged 2 years and above with partial onset seizures or generalized tonic-clonic seizures. PITOMATE is also indicated in adults and children as adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome. *Migraine* PITOMATE is indicated in adults for the prophylaxis of migraine headache. The usefulness of PITOMATE in the acute treatment of migraine headache has not been studied.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23013286NP	Trovite IV Injection	For the rapid treatment of severe vitamin deficiencies which can occur in association with: alcoholism; Wernicke's encephalopathy and Korsa-Koff's psychosis; subacute confusional delirium or amnesic states; specific deficiency syndrome-pellagra, beri-beri, anorexia nervosa; parenteral nutrition, severe malnutrition.
BRU23013287P	Monem 1g Powder For Injection	Meropenem is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem: Pneumonias including hospital acquired pneumonias, Urinary Tract Infection, Intra abdominal Infections, Gynaecological Infections, such as endometritis and pelvic inflammatory diseases, Bacterial Meningitis, Septicaemia, and Empiric treatment for presumed infections in patients with febrile neutropenia used as monotherapy or in combination with anti-viral or anti-fungal agents. Meropenem has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.
BRU23013288P	Kertet 20 Tablet	Leflunomide is indicated for the treatment of adult patients with: - active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD) - active psoriatic arthritis Recent or concurrent treatment with hepatotoxic or hematotoxic DMARDs (e.g. Methotrexate) may result in an increased risk of serious adverse reactions; therefore, the initiation of Leflunomide treatment has to be carefully considered regarding these benefit/risk aspects. Moreover, switching from Leflunomide to another DMARD without following the washout procedure may also increase the risk of serious adverse reactions even for a long time after the switching.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23013289P	Pontevia 120mg Solution For Injection In Pre-Filled Syringe	PONTEVIA is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month.
BRU23013290P	Pontevia 120mg Solution For Injection In Pre-Filled Pen	PONTEVIA is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month.
BRU23013291P	Norphenadol® Tablet	Tension headache, occipital headaches associated with spasm of skeletal muscles in the region of the head and neck. Acute and traumatic conditions of the limbs and trunk: sprains, strains, whiplash injuries, acute torticollis, prolapsed intervertebral disc.
BRU23013292P	Sisalon 50 Tablet	Sertraline is indicated for the treatment of: - Major depressive episodes. Prevention of recurrence of major depressive episodes - Panic disorder, with or without agoraphobia - Obsessive compulsive disorder (OCD) in adults and pediatric patients aged 6-17 years - Social anxiety disorder - Post traumatic stress disorder (PTSD)

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23013293P	Pharmaniaga Isoniazid Tablet 100mg	Isoniazid is used primarily in conjunction with other anti-tuberculosis drugs in the treatment of all forms of tuberculosis. Isoniazid is also used in the treatment of tuberculosis meningitis and non-tuberculosis mycobacterium infections.
BRU23023294NP	Siang Pure Oil Formula 1	Bottle: Inhale or rub over for relief of dizziness, faint, muscle pains, insect bites and itches. Ball Tip: Rub over for relief of itches from insect bites.
BRU23023295NP	Ferrovit Capsule	For patients with anemia or pregnant women with anemic symptoms.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23023296P	Gemtero 1g (Gemcitabine For Injection 1g)	• Gemcitabine is indicated for the treatment of locally advanced or metastatic non-small cell-lung cancer • Gemcitabine is indicated for the treatment of adult patients with locally advanced or metastatic adrenocarcinoma of the pancreas. Gemcitabine is indicated for patients with 5-FU refractory pancreatic cancer • Gemcitabine is indicated for the treatment of patients suffering from bladder cancer, at the invasive stage • Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated • Gemcitabine, in combination with carboplatin, is indicated for the treatment of patients with recurrent epithelial ovarian carcinoma, who have relapse > 6 months, following platinum-base therapy
BRU23023297P	Prega-75 (Pregabalin Hard Capsules 75mg)	**Neuropathic Pain:** Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. **Epilepsy:** As adjunctive therapy in adults with partial seizures with or without secondary generalisation. **Generalised Anxiety Disorder:** Treatment of Generalised Anxiety Disorder (GAD) in adults. **Fibromyalgia**: Management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23023298P	Prega-150 (Pregabalin Hard Capsules 150mg)	**Neuropathic Pain:** Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. **Epilepsy:** As adjunctive therapy in adults with partial seizures with or without secondary generalisation. **Generalised Anxiety Disorder:** Treatment of Generalised Anxiety Disorder (GAD) in adults. **Fibromyalgia**: Management of fibromyalgia.
BRU23023299P	Pharmaniaga Co-Amoxiclav Tablet 625mg	It is indicated for the treatment of the following infections: a) Upper & lower respiratory tract infections – sinusitis, otitis media, bronchitis. b) Skin and soft tissue infections – boils, abscesses, cellulitis, wound infections. c) Genitourinary tract infections – cystitis, urethritis, pyelonephritis. d) Bone & joint infections – osteomyelitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23023300P	Flumazenil Kabi 0.1mg/ml Solution For Injection	Flumazenil 0.1mg/ml injection is indicated for the complete or partial reversal of the central sedative effects of benzodiazepines. It may therefore be used in anaesthesia and in intensive care in the following situations: In anaesthesia - Termination of hypnosedative effects in general anaesthesia induced and/or maintained with benzodiazepines in hospitalized patients. - Reversal of benzodiazepine sedation in short-term diagnostic and therapeutic procedures in ambulatory patients and hospitalized patients. In intensive care situations: - For diagnosis of intoxication with benzodiazepines or to rule out such intoxication. - As a diagnostic measure in unconsciousness unknown origin to differentiate between involvement of benzodiazepines, other drugs or brain damage. - For specific reversal of the central effects of benzodiazepines in drug overdose (return to spontaneous respiration and consciousness in order to render intubation unnecessary or allow extubation).
BRU23023301P	Afstyla 250 IU Powder And Solvent For Solution For Injection	*AFSTYLA* is indicated in adults and pediatrics with hemophilia A (congenital factor VIII deficiency) for: • Control and prevention of bleeding episodes, • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes. • Perioperative prophylaxis (surgical prophylaxis)

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23023302P	Afstyla 500 IU Powder And Solvent For Solution For Injection	*AFSTYLA* is indicated in adults and pediatrics with hemophilia A (congenital factor VIII deficiency) for: • Control and prevention of bleeding episodes, • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes. • Perioperative prophylaxis (surgical prophylaxis)
BRU23023303P	Covee Cream 1% w/w	Covee is indicated for the treatment of fungal skin infections such as dermatophytoses (athlete's foot, ringworm), pityriasis versicolour, fungal infection of the tissue adjacent to nails and skin folds and erythrasma (skin redness/irritation).
BRU23023304P	YSP Pulin Injection 5mg/ml	Adult population This product is indicated in adults for: - Prevention of post-operative nausea and vomiting - Symptomatic treatment of nausea and vomiting, including nausea and vomiting induced by migraine attacks - Prevention of radiotherapy-induced nausea and vomiting Pediatric population This product is indicated in children aged 1 to 18 years for: - Prevention of delayed chemotherapy-induced nausea and vomiting as a second-line option - Prevention of post-operative nausea and vomiting as a second-line option

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23023305P	Idaman Pharma Diazepam Tablet 5mg	1) Treatment of anxiety. 2) Treatment of acute alcohol withdrawal symptoms. 3) Indicated for preoperative procedures to relieve anxiety and tension. 4) Indicated as an adjunct prior to endoscopic procedures. 5) Indicated as short-term (7-14 days) adjunctive therapy in convulsive disorder. 6) Indicated as an adjunct for the treatment of skeletal muscle spasm. 7) Treatment of familial, senile or essential action tremors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23023306P	Amlocord 5 Tablet 5mg	**Hypertension** Amlodipine is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme (ACE) inhibitor. **Coronary Artery Disease** *Chronic Stable Angina* Amlodipine is indicated for the symptomatic treatment of chronic stable angina. Amlodipine may be used alone or in combination with other antianginal drugs. *Vasospastic Angina (Prinzmetal's or variant angina)* Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy, or in combination with other antianginal drugs. *Angiographically Documented Coronary Artery Disease* In patients with recently documented coronary artery disease (CAD) by angiography and without heart failure or an ejection fraction <40%, amlodipine is indicated to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure.
BRU23053307P	Tiaryt Injection	Serious rhythm disorders when the oral route is not appropriate, namely: • Atrial rhythm disorders, with rapid ventricular rhythm. • Wolf-Parkinson-White syndrome tachycardia. • Documented symptomatic and disabling ventricular rhythm disorders.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23053308P	Valoin Injection	Valoin is indicated for the treatment of epileptic patients who would normally be maintained on oral sodium valproate, and for whom oral therapy is temporarily not possible.
BRU23053309P	Bendamustine Hydrochloride 2.5mg/ml Powder For Concentrate For Solution For Infusion	First-line treatment of chronic lymphocytic leukaemia (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate. Indolent non-Hodgkin's lymphomas as monotherapy in patients who have progressed during or within 6 months following treatment with rituximab or a rituximab containing regimen. Front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment.
BRU23053310P	Mixagrip Extra Caplet	MIXAGRIP is a cold preparation to alleviate and relieve any influenza symptoms, such as sneezing, catarrh, nasal congestion, muscle pain, headache/dizziness and fever.

BRU23053311P	Cefmex 1g Powder For Injection	**Adult**: Cefmex is indicated in adults for the treatment of the following infections when caused by susceptible strains of bacteria: Lower respiratory tract infections (including pneumonia and bronchitis). Urinary tract infections (both complicated, including pyelonephritis and uncomplicated infections). Skin and skin structure infections. Intra-abdominal infections (including peritonitis and biliary tract infections). Gynecological infections. Septicemia. Empiric treatment in febrile neutropenic patients. **Pediatrics**: Cefmex is indicated in pediatric patients for treatment of infections when caused by susceptible bacteria: Pneumonia Urinary tract infections (both complicated and uncomplicated, including pyelonephritis) Skin and skin structure infections Septicemia Empiric treatment in febrile neutropenia. Culture and susceptibility studies should be performed when appropriate to determine susceptibility of the causative organism(s) to cefepime. Empiric therapy with Cefmex may be instituted before results of susceptibility studies are known; however, once these results become available, the antibiotic treatment should be adjusted accordingly. Because of its broad spectrum of bactericidal activity against gram-positive and gram-negative bacteria, Cefmex can be used as monotherapy prior to identification of the causative organism(s). In patients who are at risk of mixed aerobic-anaerobic infection, particularly if bacteria not susceptible to cefepime may be present, concurrent initial therapy with anti-anaerobic agent is recommended before the causative agents may or may not be necessary, depending on the susceptibility profile.

		By intravenous or intramuscular injection when oral therapy is not feasible: Adrenocortical insufficiency: Dexamethasone phosphate Injection has predominantly glucocorticoid activity with low mineralocorticoid activity. Therefore, it does not offer complete replacement therapy, and its use must be supplemented with salt and/or desoxycorticosterone. When so supplemented, Dexamethasone Phosphate Injection is indicated in the impairment of all adrenocortical activity, as in Addison's disease or following bilateral adrenalectomy that requires replacement of both glucocorticoid and mineralocorticoid activity. **Relative Adrenocortical Insufficiency:** In the relative adrenocortical insufficiency that may occur following cessation of long-term therapy with suppressive doses of adrenocortical hormones, mineralocorticoid secretion may be unimpaired. Replacement with a hormone that acts predominantly as a glucocorticoid may be sufficient to restore adrenocortical function. When immediate support is mandatory, Dexamethasone Phosphate Injection may be effective within minutes after administration and can be life-saving. **Pre-operative and Post-operative support:** Patients undergoing bilateral adrenalectomy, or hypophysectomy, or any other surgical procedure when adrenocortical reserve is doubtful, and in post-operative shock unresponsive to conventional therapy. **Non-supportive Thyroiditis:** Shock: Injection Dexamethasone Phosphate is recommended for the adjunctive therapy of shock where high (Pharmacological) doses of corticosteroids are needed; severe shock of haemorrhagic, traumatic or surgical origin. Treatment with Injection Dexamethasone Phosphate is an adjunct, to and not a substitute for, specific or supportive measures that the patient may require. **Rheumatic Disorders:** As adjunctive therapy for short-term administration to support the patient during an acute episode or exacerbation in: Post-traumatic osteoarthritis; synovitis of osteoarthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); acute subacute bursitis; epicondylitis; acute nonspecific tenosynovitis; acute gouty arthritis; psoriatic arthritis; ankylosing arthritis; ankylosing spondylitis. **Collagen disease**: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus; acute rheumatic carditis. **Dermatological Disease:** Pemphigus; severe erythema multiforme (Stevens Johnson Syndrome); exfoliative dermatitis; bullous dermatitis herpetiformis; severe seborrhoeic dermatitis; severe psoriasis; mycosis fungoides.

BRU23053312P	Penatone Injection 4mg/ml (2ml Ampoule)	**Allergic states:** Control of severe of incapacitating allergic conditions intractable to adequate trials of conventional treatment in: bronchial asthma; contact dermatitis; atopic dermatitis; serum sickness; seasonal or perennial allergic rhinitis; drug hypersensitivity reactions; urticarial transfusion reactions; acute noninfectious laryngeal oedema; anaphylaxis (epinephrine is the drug of first choice). **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis; keratitis; allergic corneal marginal ulcers; herpes zoster ophthalmicus; iritis, iridocyclitis; chorioretinitis; diffuse posterior uveitis and choroiditis; optic neuritis; sympathetic ophthalmia; anterior segment inflammation. **Gastrointestinal diseases:** To support the patient during a critical period of disease in: ulcerative colitis (systemic therapy); regional enteritis (systemic therapy); regional enteritis (systemic therapy). **Respiratory Disease: Symptomatic sarcoidosis:** Loeffler's syndrome not manageable by other means; Berylliosis; fulminating or disseminated pulmonary tuberculosis when concurrently accompanied by appropriate antituberculous chemotherapy; aspiration pneumonitis. **Haematological Disorders:** Acquired (autoimmune) haemolytic anaemia; idiopathic thrombocytopenic purpura in adults (I.V. only, I.M. administration is contraindicated); secondary thrombocytopenia in adults; erythroblastopenia (R.B.C. anaemia); congenital (erythroid) hypoplastic anaemia. **Neoplastic Diseases:** For palliative management of: hypercalcaemia associated with cancer; leukamias and lymphomas in adults; acute leukamia of childhood. **Oedematous States:** To induce diuresis or remission of proteinuria in the nephrotic syndrome without uraemia of the idiopathic type, or that due to lupus erythematosus. **Cerebral oedema:** Dexamethasone Phosphate Injection may be used to treat patients with cerebral oedema from various causes: (a) associated with primary or metastatic brain tumours, (b) associated with neurosurgery, (c) associated with head injury or pseudo-tumour cerebri, (d) associated with cerebral vascular accident (acute stroke) involving the cerebral cortex. It may be used also in the preoperative preparation of patients with increased intracranial pressure secondary to brain tumours or for pallation of patients with inoperable or recurrent brain neoplasms. Use of Dexamethasone Phosphate Injection in cerebral oedema is not a substitute for careful neurological evaluation and definitive management such as neurosurgery or other specific therapy.

		Diagnostic Testing of Adrenocortical Hyperfunction **Neonatal respiratory distress syndrome; antenatal prophylaxis:** Use of Dexamethasone Phosphate Injection in mothers at high risk for premature delivery has been shown to reduce the incidence of neonatal respiratory distress syndrome. **By intra-articular or soft-tissue injection:** As adjunctive therapy for short-term administration (to support patient during an acute episode or exacerbation) in: synovitis of osteoarthritis; rheumatoid arthritis; acute and subacute bursitis; acute gouty arthritis; epicondylitis; acute non-specific tenosynovitis; post-traumatic osteoarthritis. **By intralesional injection: Keloids:** localised hypertrophic, infiltrated, inflammatory lesions of: lichen planus, psoriatic plaques, granuloma annulare, and lichen simplex chronicus (neurodermatitis); discoid lupus erythematosus; necrobiosis lipoidica diabeticorum; alopecia areata; may also be useful in cystic tumours of an aponeurosis or tendon (ganglia).
BRU23053313P	Azacitidine Seacross 25mg/ml Powder For Suspension For Injection	Azacitidine Seacross is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with: • intermediate-2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS), • chronic myelomonocytic leukaemia (CMML) with 10-29% marrow blasts without myeloproliferative disorder, • acute myeloid leukaemia (AML) with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification, • AML with >30% marrow blasts according to the WHO classification.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23053314P	YSP Tren Injection 100mg/ml	1. Bleeding tendencies in which systemic hyperfibrinolysis is considered to be involved. (Leukemia, aplastic anemia, purpura, etc., abnormal bleeding during or after operation.) 2. Abnormal bleeding in which local hyperfibrinolysis is considered to be involved. (Pulmonary hemorrhage, nasal hemorrhage, vaginal hemorrhage, renal hemorrhage, abnormal bleeding during or after prostate surgery.) 3. Symptoms, such as erythema, swelling or pruritus in the following diseases: Eczema or similar conditions, urticaria, drug eruptions or toxicoderma. 4. Symptoms, such as pharyngalgia, redness, hyperemia or swelling in the following diseases: Tonsillitis, pharyngolaryngitis. 5. Pain in the oral cavity or mucosal aphtha in cases of stomatitis.
BRU23053315P	MenQuadfi – Meningococcal Vaccine, Solution For Injection In 0.5ml Vial	MenQuadfi is indicated for active immunisation of individuals from the age of 12 months and older against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y. The use of this vaccine should be in accordance with available official recommendations.
BRU23053316P	Naldebain® Extended Release Injection 75mg/ml	**NALDEBAIN** is indicated for the relief of moderate to severe acute postsurgical pain.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23053317P	RINVOQ® 30mg Extended-Release Tablets	<u>Atopic dermatitis</u> RINVOQ® is indicated for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. <u>Ulcerative Colitis</u> RINVOQ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent. <u>Crohn's disease</u> RINVOQ is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.
BRU23053318NP	Viquprin Tablet	VIQUPRIN is used as a platelet aggregation inhibitor in patients following aortocoronary by-pass surgery, to prevent graft occlusion. Conditions where modification of platelet behaviour is considered beneficial, including transient ischaemic attacks, secondary prevention of myocardial infarction, and for prophylaxis against stroke, vascular occlusion and deep vein thrombosis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23053319NP	Salonpas Jet Spray	For relief of aches and pains associated with: ▪ Muscle fatigue ▪ Muscle pain ▪ Backache ▪ Stiff shoulder ▪ Joint pain ▪ Strains ▪ Sprains ▪ Bruises ▪ Arthritis

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23053320P	Amlocord 10 Tablet 10mg	**Hypertension** Amlodipine is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme (ACE) inhibitor. **Coronary Artery Disease** *Chronic Stable Angina* Amlodipine is indicated for the symptomatic treatment of chronic stable angina. Amlodipine may be used alone or in combination with other antianginal drugs. *Vasospastic Angina (Prinzmetal's or variant angina)* Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy, or in combination with other antianginal drugs. *Angiographically Documented Coronary Artery Disease* In patients with recently documented coronary artery disease (CAD) by angiography and without heart failure or an ejection fraction <40%, amlodipine is indicated to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23053321P	Rabirox Capsule 200mg	• For the management of acute pain in adults and for the treatment of primary dysmenorrhea. • Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. • Relief of signs and symptoms of ankylosing spondylitis. • For the management of low back pain (200 mg only).
BRU23053322P	Rabirox Capsule 400mg	• For the management of acute pain in adults and for the treatment of primary dysmenorrhea. • Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis. • Relief of signs and symptoms of ankylosing spondylitis.
BRU23063323P	Motidom Tablet	Domperidone is indicated for the relief of the symptoms of nausea and vomiting. This includes: • Nausea and vomiting of functional, organic, infectious or dietary origin. • Nausea and vomiting induced by: - radiotherapy or drug therapy - dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson's disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23063324NP	Healthy Care Super Hair Skin & Nail Capsules	Maintain collagen formation and enhance healthy hair, skin and strong nails.
BRU23063325P	Gluvox (Metformin HCl Film-Coated Tablet 500mg)	• Type 2 Diabetes Mellitus [monotherapy or in combination with other antidiabetic drugs (including insulin)] • Type 2 Diabetes Mellitus [reduction in risk or delay of onset]
BRU23063326P	Nevox XR	• **NEVOX XR** is indicated in patients 17 years of age and older. • **NEVOX XR**, as monotherapy, is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. • **NEVOX XR** may be used concomitantly with a Sulfonylurea or Insulin to improve glycemic control in adults (17 years of age and older).
BRU23063327P	Difflam Forte Anti-Inflammatory Throat Spray 0.3% w/v	Difflam® Forte Anti-Inflammatory Throat Spray 0.3% w/v is indicated for the temporary relief of painful conditions of the mouth and throat including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, pharyngitis, swelling, redness, inflammatory conditions, post orosurgical and periodontal procedures.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23063328P	Pitasor 2 Tablet	Indicated for the reduction of elevated total cholesterol (TC) and LDL-C, in adults, adolescents and children aged 6 years or older with primary hypercholesterolemia, including heterozygous familial hypercholesterolemia, and combined (mixed) dyslipidaemia, when response to diet and other non-pharmacological measures is inadequate.
BRU23063329P	Pharmaniaga Dermapro Cream 0.05% w/w	Clobetasol is indicated for short-term treatment of inflammation and/or pruritus associated with acute and chronic corticosteroid-responsive skin disorders.
BRU23063330P	Pradox 50 Tablet	***Epilepsy*** Monotherapy in adults, adolescents and children over 6 years of age with partial seizures with or without secondary generalized seizures, and primary generalized tonic-clonic seizures. Adjunctive therapy in children aged 2 years and above, adolescents and adults with partial onset seizures with or without secondary generalization or primary generalized tonic-clonic seizures and for the treatment of seizures associated with Lennox-Gastaut syndrome. ***Migraine*** Topiramate is indicated in adults for the prophylaxis of migraine headache after careful evaluation of possible alternative treatment options. Topiramate is not intended for acute treatment.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23063331P	Pharmaniaga Diphenhydramine Expectorant	Cough, nasal and bronchial congestion.
BRU23063332P	Bilkate 5 Tablet	<u>Hypertension</u> Treatment of essential hypertension. <u>Chronic heart failure (CHF)</u> Treatment of stable mild to moderate chronic heart failure (CHF) in addition to standard therapies in elderly patients ≥70 years.
BRU23063333P	Celxib 400 Capsule	- For the management of acute pain in adults and For the treatment of primary dysmenorrhea - Relief of the acute and chronic pain and inflammation of rheumatoid arthritis and osteoarthritis - Relief of signs and symptoms of ankylosing spondylitis

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23063334P	Gonal-F 150IU/0.24ml (11mcg/0.24ml) Solution For Injection In Pre-Filled Pen	<u>In adult women</u> • Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate. • Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer.

BRU23063335P	DARZALEX Faspro™ 1,800mg Solution For Injection	**Multiple Myeloma** DARZALEX FASPRO is indicated for the treatment of adult patients with multiple myeloma: • in combination with lenalidomide and dexamethasone - in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. - in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. • in combination with bortezomib, melphalan, prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. • in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant • in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. • in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy. • in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. • as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. **Light chain (AL) amyloidosis** DARZALEX FASPRO is indicated in combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adult patients with newly diagnosed systemic AL amyloidosis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23063336P	Inhixa 2000 IU/0.2ml Solution For Injection In Pre-Filled Syringe	Inhixa is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure, respiratory insufficiency, severe infections or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Prevention of thrombus formation in extra corporeal circulation during haemodialysis. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23063337P	Inhixa 4000 IU/0.4ml Solution For Injection In Pre-Filled Syringe	Inhixa is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure, respiratory insufficiency, severe infections or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Prevention of thrombus formation in extra corporeal circulation during haemodialysis. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI).
BRU23063338P	Inhixa 6000 IU/0.6ml Solution For Injection In Pre-Filled Syringe	Inhixa is indicated in adults for: • Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery. • Prophylaxis of venous thromboembolic disease in medical patients with an acute illness (such as acute heart failure, respiratory insufficiency, severe infections or rheumatic diseases) and reduced mobility at increased risk of venous thromboembolism. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. • Prevention of thrombus formation in extra corporeal circulation during haemodialysis. • Acute coronary syndrome: - Treatment of unstable angina and Non ST-segment elevation myocardial infarction (NSTEMI), in combination with oral acetylsalicylic acid. - Treatment of acute ST-segment elevation myocardial infarction (STEMI) including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23063339P	Enerzair® Breezhaler® 150/50/80mcg Inhalation Powder, Hard Capsules	Enerzair Breezhaler is indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.
BRU23063340P	Remabrex 200mg Capsules	**REMABREX** is indicated for: • Relief of the signs and symptoms of OA (osteoarthritis), RA (rheumatoid arthritis), and AS (ankylosing spondylitis). • Short treatment of acute pain in adults following surgery or musculoskeletal injury.
BRU23063341P	Caeseva Film-Coated Tablet 800mg	CAESEVA is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. CAESEVA is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease (CKD) not on dialysis with serum phosphorus ≥ 1.78 mmol/l. CAESEVA should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D3 or one of its analogues to control the development of renal bone disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23073342P	Rosucor Tablets 10mg	Mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and exercise is inadequate. Homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) when response to diet and exercise is inadequate.
BRU23073343P	Rosucor Tablets 20mg	Mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and exercise is inadequate. Homozygous familial hypercholesterolaemia, either alone or as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) when response to diet and exercise is inadequate.
BRU23073344P	Fusix Injection 20mg/2ml	Frusemide is indicated in the treatment of edema associated with congestive heart failure, hepatic cirrhosis and renal disease (including nephrotic syndrome). It is also indicated as an adjunct in the treatment of acute pulmonary edema and hypertensive crisis.
BRU23073345NP	Oracue Gel	ORACUE helps to relieve pain, inflammation, and to treat minor infection due to common mouth ulcers, cold sores, denture and sore spots, as well as mouth ulcers and sore spots due to orthodontic devices. To help to fight minor mouth infection and healing of sore spots and ulcers due to dentures and orthodontic devices. Oracue helps to relieve and soothe teething.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23073346P	Vastinor Tablet 10mg	Treatment of hypercholesterolaemia Adults, adolescents and children aged 6 years or older with primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate. Prevention of Cardiovascular Events Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23073347P	Atswift 40 Tablet	**Hypercholesterolaemia** Atorvastatin Tablets is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in adults, adolescents and children aged 10 years or older with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (Corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate. Atorvastatin Tablets is also indicated to reduce total-C and LDL-C in adults with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable. **Prevention of cardiovascular disease** Atorvastatin Tablets is indicated to reduce the risk of myocardial infarction in adult hypertensive patients without clinically evident coronary heart disease, but with at least three additional risk factors for coronary heart disease such as age ≥ 55 years, male sex, smoking, left ventricular hypertrophy, other specified abnormalities on ECG, microalbuminia or proteinuria, ratio of plasma total cholesterol to HDL-cholesterol ≥ 6, or premature family history of coronary heart disease. In adults with type 2 diabetes and without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, Atorvastatin Tablet is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke In adults with clinically evident coronary heart disease, atorvastatin is indicated to: - Reduce the risk of non-fatal myocardial infarction - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for CHF - Reduce the risk of angina

		Treatment: Doxycycline is indicated for treatment of the following infections: • Rocky Mountain spotted fever, typhus fever and the typhus group; • Q fever, rickettsial pox and tick fevers caused by *Rickettsiae* ; • Respiratory infections caused by *Mycoplasma pneumoniae* ; • Psittacosis caused by *Chlamydia psittaci* ; • Lymphogranuloma venereum, caused by *Chlamydia trachomatis* ; • Uncomplicated urethral, endocervical or rectal infections in adults caused by *Chlamydia trachomatis* ; • Trachoma caused by *Chlamydia trachomatis* although the infectious agent is not always eliminated, as judged by immunofluorescence; • Inclusion conjunctivitis caused by *Chlamydia trachomatis* may be treated with oral doxycycline alone or with a combination of topical agents; • Granuloma inguinale (donovanosis) caused by *Calymmatobacterium granulomatis* ; • Early (Stage 1) Lyme disease caused by *Borrelia burgdorferi* ; • Louse-borne relapsing fever caused by *Borrelia recurrentis* ; • Tick-borne relapsing fever caused by *Borrelia duttonii* ; • Non-gonococcal urethritis (NGU) caused by *Ureaplasma urealyticum (T-Mycoplasma)* . Doxycycline is also indicated for the treatment of infections caused by the following gram-negative microorganisms: • *Acinetobacter* species; • *Bacteroides* species; • *Fusobacterium* species; • Brucellosis caused by *Brucella* species (in conjunction with streptomycin); • Plague caused by *Yersinia pestis* ; • Tularemia caused by *Francisella tularensis* ; • Bartonellosis caused by *Bartonella bacilliformis* ; • *Campylobacter fetus* .

BRU23073348P	Pharmaniaga Doxycycline Capsule 100mg	Because many strains of the following groups of microorganisms have been shown to be resistant to tetracyclines, culture and susceptibility testing are recommended. Doxycycline is indicated for treatment of infections caused by the following gram-negative microorganisms, when bacteriologic testing indicates appropriate susceptibility to the drug: • *Shigella* species; • Uncomplicated gonorrhea caused by *Neisseria gonorrhoeae* ; • Respiratory infections caused by *Haemophilus influenzae* ; • Respiratory and urinary infections caused by *Klebsiella species* ; • *Escherichia coli* ; • *Enterobacter aerogenes* ; • *Moraxella catarrhalis* . Doxycycline is indicated for treatment of infections caused by the following gram-positive microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug: • *Streptococcus* species: A certain percentage of strains of *Streptococcus pyogenes* and *Streptococcus faecalis* have been found to be resistant to tetracycline drugs. Tetracyclines should not be used for streptococcal infections unless the organism has been demonstrated to be sensitive. • For upper respiratory infections due to group A beta-hemolytic streptococci, penicillin is the usual drug of choice, including prophylaxis of rheumatic fever. This includes: - Upper respiratory tract infections caused by *Streptococcus pneumoniae* ; Respiratory, skin and soft-tissue infections caused by *Staphylococcus aureus* . Tetracyclines are not the drug of choice in the treatment of staphylococcal infections.

		When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of: • Actinomycosis caused by *Actinomyces* species; • Infections caused by *Clostridium* species; • Syphilis caused by *Treponema pallidum* and yaws caused by *Treponema pertenue* ; • Listeriosis caused by *Listeria monocytogenes* ; • Vincent's infection (acute necrotizing ulcerative gingivitis) caused by *Leptotrichia buccalis* (formerly, *Fusobacterium fusiform*). <u>Adjunctive treatment</u> In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides. In severe acne caused by *acne vulgaris* , doxycycline may be useful adjunctive therapy. <u>Treatment and Prophylaxis</u> Doxycycline is indicated for the prophylaxis and treatment of the following infections: • Malaria caused by *Plasmodium falciparum* (in areas with chloroquine-resistant *P. falciparum*). • Leptospirosis caused by genus *Leptospira* . • Cholera caused by *Vibrio cholerae* . <u>Prophylaxis</u> Doxycycline is indicated as prophylaxis in the following conditions: • Scrub typhus caused by Rickettsia *tsutsugamushi* ; • Traveler's diarrhea caused by enterotoxigenic *Escherichia coli* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23093349NP	Peppermint Field Inhaler	Peppermint Field Inhaler provides symptomatic relief of nasal congestion and dizziness.
BRU23093350P	Meropenem Kabi 1g, Powder For Solution For Injection Or Infusion	Meropenem IV is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem: -pneumonias and nosocomial pneumonias -urinary tract infections -intra-abdominal infections -gynaecological infections, such as endometritis and pelvic inflammatory disease -bacterial meningitis -septicaemia -empiric treatment, for presumed infections in patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents Meropenem IV has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.
BRU23093351NP	Axcel Paracetamol-500 Tablet	Paracetamol is used to relieve fever and mild to moderate pain associated with conditions such as headache, migraine, backache, toothache, aches due to the colds and flu, muscular rheumatism and dysmenorrhea.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23093352P	Vultin 300 Capsule	<u>Epilepsy</u> Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above. Gabapentin is indicated as monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above. <u>Treatment of peripheral neuropathic pain</u> Gabapentin is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.
BRU23093353P	Ondavell Injection 4mg/2ml	***Adults*** Ondansetron injection is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. Ondansetron is also indicated for the prevention and treatment of post-operative nausea and vomiting. **Paediatric Population** **Injection and oral formulations:** Ondansetron is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting; IV injection is recommended for this purpose.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23093354P	Ondavell Film-Coated Tablet 8mg	**Adults** Ondansetron is indicated to manage nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. Ondansetron is also indicated for the prevention of post-operative nausea and vomiting. **Paediatric Population** Ondansetron is indicated to manage nausea and vomiting induced by cytotoxic chemotherapy.
BRU23093355P	Novorin Injection 10mg/ml	Calcium Folinate is indicated a) To diminish the toxicity and counteract the action of folic acid antagonists such as methotrexate in cytotoxic therapy and overdose in adults and children. In cytotoxic therapy, this procedure is commonly known as 'Calcium Folinate Rescue'. b) In combination with 5-fluorouracil in cytotoxic therapy.
BRU23093356P	Vastinor Tablet 20mg	Treatment of hypercholesterolaemia Adults, adolescents and children aged 6 years or older with primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate. Prevention of Cardiovascular Events Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23093357P	Kemocarb Solution For Injection 10mg/ml	Carboplatin is used as initial chemotherapy of advanced ovarian carcinoma in combination with other approved chemotherapeutic agents. Carboplatin is used as palliative treatment of patients with ovarian carcinoma recurrent after prior chemotherapy, including patients who have been previously treated with cisplatin.
BRU23093358P	Imiquad Cream (Imiquimod Cream USP 5% w/w)	Imiquimod cream is indicated for: 1. Treatment of external genital and perianal warts/condyloma accuminata in adults. 2. Treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adults. 3. Treatment of biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) in immunocompetent adults, with a maximum tumor diameter of 2.0 cm, located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured. The histological diagnosis of superficial basal cell carcinoma should be established prior to treatment, since safety and efficacy of imiquimod cream have not been established for other types of basal cell carcinomas, including nodular and morpheaform (fibrosing or sclerosing) types.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23093359P	Bioxitide 25/250mcg/Dose HFA Inhalation Aerosol	**Asthma (Reversible Obstructive Airways Disease)** Bioxitide™ is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: • Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** Bioxitide™ is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU23093360P	Novomin Syrup 15mg/5ml	**Novomin** has anti-emetic properties and is used for the prevention and treatment of nausea and vomiting, such as in travel or motion sickness.
BRU23103361P	Isoniazid 300mg Tablets	Isoniazid Tablets BP 300 mg is indicated for the treatment of tuberculosis, caused by *Mycobacterium tuberculosis* .
BRU23103362P	Cosyrel 10mg/5mg Film-Coated Tablet	Cosyrel 10mg/5mg are indicated as substitution therapy for treatment of hypertension and/or stable coronary artery disease (in patients with a history of myocardial infarction and/or revascularisation) and/or stable chronic heart failure with reduced systolic left ventricular function in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23103363P	Cosyrel 10mg/10mg Film-Coated Tablet	Cosyrel 10mg/10mg are indicated as substitution therapy for treatment of hypertension and/or stable coronary artery disease (in patients with a history of myocardial infarction and/or revascularisation) in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level.
BRU23103364P	Cosyrel 5mg/10mg Film-Coated Tablet	Cosyrel 5mg/10mg are indicated as substitution therapy for treatment of hypertension and/or stable coronary artery disease (in patients with a history of myocardial infarction and/or revascularisation) in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level.
BRU23103365P	Cosyrel 5mg/5mg Film-Coated Tablet	Cosyrel 5mg/5mg are indicated as substitution therapy for treatment of hypertension and/or stable coronary artery disease (in patients with a history of myocardial infarction and/or revascularisation) and/or stable chronic heart failure with reduced systolic left ventricular function in adult patients adequately controlled with bisoprolol and perindopril given concurrently at the same dose level.
BRU23103366P	Herbesser R200 Sustained Release Capsule	- Essential hypertension (mild to moderate) - Angina pectoris, variant angina pectoris

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23103367P	Abiranat Tablets 250mg	Abiraterone acetate tablets are indicated with prednisone or prednisolone for: • the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT) (see section 5.1). • the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated (see section 5.1). • the treatment of mCRPC in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen.
BRU23103368P	Biosone 100mcg Per Dose HFA Inhalation Aerosol	Indicated for the prophylactic management of mild, moderate or severe asthma.
BRU23103369P	Claritrox 250 Tablet	Treatment of infections due to susceptible organisms of the upper respiratory tract infections (e.g. streptococcal pharyngitis/tonsillitis, acute maxillary sinusitis), lower respiratory tract infections (e.g. bronchitis, pneumonia), acute otitis media, skin and skin structure infections (e.g. impetigo, folliculitis, cellulitis, abscesses).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23103370P	Maforan 1mg Tablet	**MAFORAN** is indicated for: • Prophylaxis and/or treatment of venous thrombosis and its extension, and pulmonary embolism. • Prophylaxis and/or treatment of the thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement. • Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction in patients with poor LV function.
BRU23103371P	Maforan 2mg Tablet	**MAFORAN** is indicated for: • Prophylaxis and/or treatment of venous thrombosis and its extension, and pulmonary embolism. • Prophylaxis and/or treatment of the thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement. • Reduction in the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction in patients with poor LV function.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23103372P	Zithronam Powder For Oral Suspension 200mg/5ml	Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in skin and soft tissue infections, in acute otitis media and in upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis. (Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin is generally effective in the eradication of streptococci from the oropharynx, however, data establishing the efficacy of azithromycin and the subsequent prevention of rheumatic fever are not available at present.) In sexually transmitted diseases in men and women, azithromycin is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* . It is also indicated in the treatment of chancroid due to *Haemophilus ducreyi* ; and uncomplicated genital infection due to non-multiresistant *Neisseria gonorrhoea* ; concurrent infection with *Treponema pallidum* should be excluded.
BRU23103373P	Afzoline XL 10 Tablet	Treatment of the functional symptoms of benign prostatic hypertrophy (BPH). For information on use in acute urinary retention (AUR) related to BPH (see section *Dosage and Administration and Mechanism of Action-Pharmacology*).
BRU23103374P	Salvado 1 Capsule	Primary immunosuppression in liver and kidney allograft recipients and liver and kidney allograft rejection resistant to conventional immunosuppressive agents.
BRU23103375P	Elonza-100 Tablet	Indicated in adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23103376P	Nervica 75 Capsule	Neuropathic Pain Indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder Indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.
BRU23103377P	Nervica 150 Capsule	Neuropathic Pain Indicated for the treatment of peripheral and central neuropathic pain in adults. Epilepsy Indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Generalised Anxiety Disorder Indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.
BRU23113378P	Herbesser Tablet 30mg	-Angina pectoris, variant angina pectoris -Essential hypertension (mild to moderate)

BRU23113379P	Fluclonazole Kabi 2mg/ml Solution For Infusion	Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. 1. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g. pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole Kabi can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. 2. Systemic candidiasis, including candidemia, disseminated candidiasis and other forms of invasive candidal infection. These include infections of the peritoneum, endocardium, eye and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 3. Mucosal candidiasis. These include oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of oropharyngeal candidiasis in patients with AIDS. 4. Genital candidiasis. Vaginal candidiasis, acute or recurrent and prophylaxis to reduce the incidence of recurrent vaginal candidiasis (3 or more episodes a year). Candidal balanitis. 5. Prevention of fungal infections in patients with malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy. 6. Dermatomycosis including tinea pedis, tinea corporis, tinea cruris, tinea versicolor, and dermal candida infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23113380P	Candesartan HCT Sandoz 16mg/12.5mg Tablet	Hypertension when a monotherapy is not sufficiently effective.

BRU23113381P	Fraizeron 300mg/2ml Solution For Injection In Pre-Filled Pen	**Plaque psoriasis** Fraizeron is indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy. **Hidradenitis Suppurativa (HS)** Fraizeron is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Psoriatic arthritis** Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Axial spondyloarthritis (axSpA)** **Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)** Fraizeron is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. **Non-radiographic axial spondyloarthritis (nr-axSpA)** Fraizeron is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).

		Juvenile idiopathic arthritis (JIA) **Enthesitis-related arthritis (ERA)** Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active enthesitis-related arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. **Juvenile psoriatic arthritis (JPsA)** Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active juvenile psoriatic arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.
BRU23113383NP	Winmyco Antiseptic Cream 0.1%	For the treatment of minor wounds and burns.
BRU23113384P	Kanolone Oral Base	Kanolone® Oral Base is for local application. It is for adjunctive treatment and for the temporary relief of symptoms associated with oral inflammatory lesions and ulcerative lesions resulting from trauma.
BRU23113385P	Zirin Softgel Capsules 10mg	Adults: Symptomatic treatment of seasonal allergic rhinitis, perennial allergic rhinitis and urticaria of allergic origin.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23113386P	Lonsurf Film-Coated Tablet 15mg/6.14mg	**Metastatic Colorectal Cancer** Lonsurf® is indicated for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. **Metastatic Gastric Cancer** Lonsurf® is indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.
BRU23113387P	Lonsurf Film-Coated Tablet 20mg/8.19mg	**Metastatic Colorectal Cancer** Lonsurf® is indicated for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. **Metastatic Gastric Cancer** Lonsurf® is indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23113388P	Mianserin-Remedica 30mg Film-Coated Tablets	Depressive illness, particularly with anxiety.
BRU23113389P	Atorvastatin 40mg Film-Coated Tablet	Atorvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. Atorvastatin is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Atorvastatin can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.
BRU23113390P	Atorvastatin 20mg Film-Coated Tablet	Atorvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. Atorvastatin is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Atorvastatin can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU23113391P	Atorvastatin 10mg Film-Coated Tablet	Atorvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. Atorvastatin is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, Atorvastatin can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.
BRU23113392P	Ceftriaxone-Zhijun 1g (Ceftriaxone Sodium Powder For Injection)	CEFTRIAXONE-ZHIJUN is indicated in the treatment of the following infections caused by pathogens sensitive to ceftriaxone, e.g.: -Sepsis; -Meningitis; -Infections of the bones, joints, soft tissue, skin and of wounds; -Infections in patients with impaired defense mechanisms; -Respiratory tract infections, particularly pneumonia; -Genital infections, including gonorrhea; -Peri-operative prophylaxis of infections associated with surgery.
BRU23113393P	Cerator 400 Extended-Release Tablet	Indicated in the treatment of peripheral vascular disease, including intermittent claudication and rest pain.

BRU23113394P	Phesgo Solution For Subcutaneous Injection 600mg/600mg/10ml	**Early Breast Cancer (EBC)** Phesgo is indicated for use in combination with chemotherapy for the: • neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer (*see 3.1.2 Clinical studies*). This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival. • adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence (*see 3.1.2 Clinical Studies*) **Metastatic Breast Cancer (MBC)** Phesgo is indicated for use in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.
BRU23113395P	Phesgo Solution For Subcutaneous Injection 1200mg/600mg/15ml	**Early Breast Cancer (EBC)** Phesgo is indicated for use in combination with chemotherapy for the: • neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer (*see 3.1.2 Clinical studies*). This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall survival. • adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence (*see 3.1.2 Clinical Studies*) **Metastatic Breast Cancer (MBC)** Phesgo is indicated for use in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24013396P	Paxus (Paclitaxel) Injection USP 100mg/16.7ml	1. **PAXUS** is indicated as first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy **PAXUS** is indicated in combination with cisplatin. 2. **PAXUS** is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
BRU24013397P	Zynor Tablet 5mg	**Hypertension**: Zynor is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of Zynor, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin converting enzyme inhibitor. **Myocardial Ischemia**: Zynor is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Zynor may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but vasospastic/vasoconstrictive has not been confirmed. Zynor may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta blockers.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24013398P	Zynor Tablet 10mg	**Hypertension**: Zynor is indicated for the first line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of Zynor, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin converting enzyme inhibitor. **Myocardial Ischemia**: Zynor is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Zynor may be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but vasospastic/vasoconstrictive has not been confirmed. Zynor may be used alone, as monotherapy, or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta blockers.
BRU24013399P	Valgan 450 (Valganciclovir 450mg Film Coated Tablet)	Valganciclovir is indicated: • For the treatment of cytomegalovirus (CMV) retinitis is acquired immunodeficiency syndrome (AIDS) patients. • For the prevention of CMV disease in CMV-negative patients who have received a solid organ transplant from a CMV-positive donor.
BRU24013400P	Zoledronic Acid 4mg/5ml Concentrate For Solution For Infusion	- Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone. - Treatment of adult patients with tumour-induced hypercalcaemia (TIH).

BRU24013401P	Zanaflox Eye Drop 0.5% w/v	Zanaflox is indicated for the treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of the following organisms: **<u>Gram-positive bacteria</u>**: *Corynebacterium species* * *Microbacterium species* *Micrococcus luteus* * [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains] *Staphylococcus aureus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus epidermidis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus haemolyticus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus hominis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains] *Staphylococcus warneri* * [including erythromycin resistant strains] *Streptococcus mitis* * [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains] *Streptococcus pneumoniae* [including penicillin, erythromycin, gentamicin, tetracycline and/or trimethoprim resistant strains] *Streptococcus viridans* [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains]

		Gram-negative bacteria: *Acinetobacter species* *Haemophilus "alconae"* [including ampicillin resistant strains] *Haemophilus influenzae* [including ampicillin resistant strains] *Klebsiella pneumoniae** *Moraxella catarrhalis** *Pseudomonas aeruginosa** Other microorganisms: *Chlamydia trachomatis* * Efficacy for this organism was studied in fewer than 10 infections. Preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required).
BRU24013402P	Arite Beclometasone 100mcg/Actuation Metered Dose Inhaler	For prophylactic management of asthma.
BRU24013403NP	Ridped Lotion	For the treatment of head lice and scabies.
BRU24013404NP	Win-Aid Antiseptic Cream 0.5% w/w	Win-Aid Antiseptic Cream is for the treatment of cuts, abrasions, burns and wounds.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24013405P	Voltaren 12 Hours Emulgel 2% Gel	For the relief of pain, inflammation and swelling in the following situations: – soft-tissue injuries: trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains, bruises and backache (sports injuries); – localised forms of soft tissue rheumatism such as tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthropathy; – and for the symptomatic treatment of osteoarthritis of small and medium-sized joints located close to the skin such as the finger joints or knee joints.
BRU24013406P	Bioxitide 25/125mcg/Dose HFA Inhalation Aerosol	**Asthma (Reversible Obstructive Airways Disease)** Bioxitide™ is indicated in the regular treatment of reversible obstructive airways disease (ROAD), including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include: • Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids. • Patients who are symptomatic on current inhaled corticosteroid therapy. • Patients on regular bronchodilator therapy who require inhaled corticosteroids. **Chronic Obstructive Pulmonary Disease (COPD)** Bioxitide™ is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
BRU24013407P	Glix Tablet 5mg	For control of hyperglycaemia and its associated symptomology in patients with non-insulin dependent diabetes mellitus after an adequate trial of dietary therapy has proved unsatisfactory.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24013408P	Bralon 5 Tablet	<u>Symptomatic treatment of chronic stable angina pectoris</u> Ivabradine is indicated for the symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm and heart rate ≥ 70 bpm. Ivabradine is indicated: - in adults unable to tolerate or with a contra-indication to the use of beta-blockers - or in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose. <u>Treatment of chronic heart failure</u> Ivabradine is indicated in chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥ 75 bpm, in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated.
BRU24013409P	RINVOQ® 45mg Extended-Release Tablets	<u>Ulcerative Colitis</u> RINVOQ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent. <u>Crohn's disease</u> RINVOQ is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24013410P	Xofluza Film-Coated Tablets 40mg	*Treatment of Influenza* Xofluza is indicated for the treatment of acute uncomplicated influenza in patients aged 12 and above who have been symptomatic for no more than 48 hours and who are: • otherwise healthy, or • at high risk of developing influenza-related complications (see section 3.1.2 Clinical/ Efficacy Studies). *Prophylaxis of Influenza* Xofluza is indicated for the post-exposure prophylaxis of influenza in individuals aged 12 and above. **Limitations of Use** Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Xofluza (see section 3.1.2 Clinical/Efficacy Studies, Resistance Monitoring during Clinical Development).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24013411P	Saxenda® 6mg/ml, Solution For Injection In Pre-Filled Pen	<u>Adults</u> Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of • ≥30 kg/m^2 (obesity), or • ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. Treatment with Saxenda® should be discontinued after 12 weeks on the 3.0 mg/day dose if patients have not lost at least 5% of their initial body weight. <u>Adolescents (≥12 years)</u> Saxenda® can be used as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients from the age of 12 years and above with: • obesity (BMI corresponding to ≥30 kg/m^2 for adults by international cut-off points)* and • body weight above 60 kg. Treatment with Saxenda® should be discontinued and re-evaluated if patients have not lost at least 4% of their BMI or BMI z score after 12 weeks on the 3.0 mg/day or maximum tolerated dose. *IOTF BMI cut-off points for obesity by sex between 12–18 years (refer to PI).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24033412PS1; BRU24033412PS2	Erysaa Prefilled Syringe 2000IU/0.5ml	ERYSAA® is an erythropoiesis-stimulating agent (ESA) indicated for: i. Treatment of anaemia associated with chronic renal failure in adult haemodialysis and predialysis patients and paediatric patients on haemodialysis. ii. To facilitate autologous blood collection within a predeposit program and decrease the risk of receiving allogeneic blood transfusions in patients with hematocrits of 33 - 39%, who are scheduled for major elective surgery and are expected to require more blood than that which can be obtained through autologous blood collection techniques in the absence of Epoetin alfa.
BRU24033413P	Erysaa Prefilled Syringe 4000IU/0.4ml	ERYSAA® is an erythropoiesis-stimulating agent (ESA) indicated for: i. Treatment of anaemia associated with chronic renal failure in adult haemodialysis and predialysis patients and paediatric patients on haemodialysis. ii. To facilitate autologous blood collection within a predeposit program and decrease the risk of receiving allogeneic blood transfusions in patients with hematocrits of 33 - 39%, who are scheduled for major elective surgery and are expected to require more blood than that which can be obtained through autologous blood collection techniques in the absence of Epoetin alfa.

BRU24033414P	Zopam Injection 10mg/2ml	*Adults* Diazepam is an anxiolytic, anticonvulsant and central muscle-relaxant. Diazepam is used to relieve anxiety and provide sedation in severe acute anxiety or agitation and for the management of agitation associated with delirium tremens. Diazepam is used to relieve acute muscle spasm and tetanus. Acute convulsions including status epilepticus, also convulsions due to poisoning and febrile convulsions. As an adjunct during endoscopy, in dentistry, surgery, radiology. Cardiac catheterisation, cardioversion, used pre-operatively to relieve anxiety, provide sedation, light anaesthesia and anterograde amnesia. *Paediatric patients* Diazepam Injection is used: • to treat status epilepticus, convulsions due to poisoning, and febrile convulsions; • to treat tetanus; • as a pre-operative medication or premedication. The suitability of treatment with Diazepam Injection in this population may need to be assessed on a case-to-case basis. *General* Diazepam Injection contains propylene glycol and ethanol. This should be taken into consideration when use of a parenteral benzodiazepine is indicated, especially when used in high volumes (e.g., continuous infusion of high doses to treat tetanus or status epilepticus) and/or when used in patients at risk of developing propylene glycol toxicity.
BRU24033415NP	Panaflex Hot Patch	For the temporary relief of muscular and joint pain e.g. due to simple backache, strains, sprains.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24033416P	Biomol™ 100mcg/Dose HFA Metered Dose Inhaler	Biomol™ 100mcg/dose HFA Metered Dose Inhaler provides short-acting (4 to 6 hour) bronchodilation with fast onset (within 5 minutes) in reversible airway obstruction. It is particularly suitable for the relief and prevention of asthma symptoms. It should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure). Biomol™ 100mcg/dose HFA Metered Dose Inhaler is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.
BRU24033417P; BRU24033417PS2	Fentanyl Citrate Injection 0.1mg/2ml	Fentanyl is indicated: • For use as an opioid analgesic supplement in general or regional anesthesia, • For administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia, and as an adjunct in the maintenance of general and regional anesthesia. • For use as an anesthetic agent with oxygen in selected high-risk patients undergoing major surgery.
BRU24033418P	Candefar 8	- Treatment of essential hypertension in adults. - Treatment of adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction < 40%) as add-on therapy to Angiotensin Converting Enzyme (ACE) inhibitors or when ACE inhibitors are not tolerated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24033419P	Crystorvas Tablet 20mg	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-Cholesterol, apolipoprotein B and triglycerides and to increase HDL-Cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Fredrickson Type IV) and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction to total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident coronary heart disease but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, CRYSTORVAS is indicated to : - Reduce the risk of myocardial infarction - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, CRYSTORVAS is indicated to : - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to : - Reduce the risk of non-fatal myocardial infarction - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for CHF - Reduce the risk of angina

		Pediatric Patient (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C and apo B levels in boys and postmenarchal girls 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dl or b. LDL-C remains ≥ 160 mg/dl and : • There is a positive family history of premature cardiovascular disease or • Two or more other CVD risk factors are present in the pediatric patient
BRU24033420P	Monem 500mg Powder For Injection	Meropenem is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem: Pneumonias including hospital acquired pneumonias, Urinary Tract Infection, Intra abdominal Infections, Gynaecological Infections, such as endometritis and pelvic inflammatory diseases, Bacterial Meningitis, Septicaemia, and Empiric treatment for presumed infections in patients with febrile neutropenia used as monotherapy or in combination with anti-viral or anti-fungal agents. Meropenem has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24033421P	Dayvus 50 Tablet	Vildagliptin is indicated in the treatment of type 2 diabetes mellitus in adults: As monotherapy - In patients inadequately controlled by diet and exercise alone and for whom Metformin is inappropriate due to contraindications or intolerance. As dual oral therapy in combination with - Metformin, in patients with insufficient glycemic control despite maximal tolerated dose of monotherapy with Metformin - A sulfonylurea, in patients with insufficient glycemic control despite maximal tolerated dose of Sulphonylurea and for whom Metformin is inappropriate due to contraindications or intolerance - A Thiazolidinedione, in patients with insufficient glycemic control and for whom the use of a Thiazolidinedione is appropriate As triple oral therapy in combination with - A Sulfonylurea and Metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. Vildagliptin is also indicated for use In combination with insulin (with or without Metformin) when diet and exercise plus a stable dose of insulin do not result in adequate glycaemic control.
BRU24033422P	Latanost Eye Drops 0.005%	• Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, chronic angle closure glaucoma and ocular hypertension. • Reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24033423P	Erleada 60mg Film-Coated Tablets	ERLEADA® is indicated: • in adult men for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease. • in adult men for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).
BRU24033424PS1; BRU24033424PS2	Fasenra 30mg Solution For Injection In Pre-Filled Pen	<u>Asthma</u> FASENRA is indicated as an add-on maintenance treatment in adult patients from 18 years with severe eosinophilic asthma characterised by the following criteria: • At least two exacerbations in the past 12 months on the current standard therapy (high-dose inhaled corticosteroids plus long-acting bronchodilators) and/or need for treatment with systemic corticosteroids. • Eosinophil count in the blood of ≥0.3 G/L (corresponding to ≥300 cells/µL). <u>Eosinophilic granulomatosis with polyangiitis (EGPA)</u> FASENRA is indicated as an add-on treatment for adult patients with relapsing or refractory eosinophilic granulomatosis with polyangiitis. For detailed information about the patient populations investigated in trials, please see 'Clinical Efficacy'.

		Rheumatoid Arthritis Hyrimoz is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Hyrimoz can be used alone or in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs). **Psoriatic Arthritis** Hyrimoz is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. Hyrimoz can be used alone or in combination with disease modifying anti-rheumatic drugs. **Axial Spondyloarthritis** **Ankylosing Spondylitis** Hyrimoz is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Non-radiographic Axial spondyloarthritis (Axial Spondyloarthritis without radiographic evidence of AS)** Hyrimoz is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis (nr-axSpA) but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. **Plaque Psoriasis** Hyrimoz is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate.

BRU24033425P	Hyrimoz 40mg/0.8ml Solution For Injection In Pre-Filled Pen	**Crohn's Disease** Hyrimoz is indicated for the treatment of moderately to severely active Crohn's Disease in adult patients who have inadequate response to conventional therapy. Hyrimoz is also indicated for treatment in adult patients with moderately to severely active Crohn's Disease who have lost response to or are intolerant to infliximab. **Ulcerative colitis** Hyrimoz is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6- mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Hidradenitis Suppurativa** Hyrimoz is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy. **Uveitis** Hyrimoz is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. **Paediatrics** **Juvenile idiopathic arthritis** **Polyarticular Juvenile Idiopathic Arthritis** Hyrimoz in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients aged above 2 years old who had an inadequate response to one or more disease modifying anti-rheumatic drugs (DMARDs). Hyrimoz can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

		Enthesitis-Related Arthritis Hyrimoz is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. **Paediatric Crohn's Disease** Hyrimoz is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (6 to 17 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindication for such therapies. **Paediatric Plaque Psoriasis** Hyrimoz is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. **Paediatric Uveitis** Hyrimoz is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate. **Adolescent Hidradenitis Suppurativa** Hyrimoz is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adolescents from 12 years of age with an inadequate response to conventional systemic hidradenitis suppurativa (HS) therapy. **Paediatric Ulcerative Colitis** Hyrimoz is indicated for treatment of moderately to severely active ulcerative colitis in patients aged 6 years and above who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24043426P	Idelvion 500IU Powder & Solvent For Solution For Injection	IDELVION is indicated in children and adults with Hemophilia B (congenital Factor IX deficiency) for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes
BRU24043427P	Enclor Ear Drops 5% w/v	Enclor ear drops are indicated in the treatment of bacterial otitis externa by *Escherichia coli, Haemophilus Influenzae, staphylococci, Morax-Axenfeld diplobacillus, Proteus morgani* and *Pseudomonas pyocyanea* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24043428P	Remedica Co-Amoxiclav 625mg Film-Coated Tablet	Remedica Co-Amoxiclav is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other beta-lactam antibiotics. Remedica Co-Amoxiclav should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. Remedica Co-Amoxiclav oral presentations for twice daily dosing, are indicated for short-term treatment of bacterial infections at the following sites: • *Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media.* • *Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis, lobar and bronchopneumonia.* • *Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis.* • *Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections.* • *Bone and joint infections e.g. osteomyelitis.* • *Dental infections e.g. dentoalveolar abscess* • *Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis.* Susceptibility to Remedica Co-Amoxiclav will vary with geography and time (see *Pharmacological Properties, Pharmacodynamics* for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.
BRU24043429NP	Panaflex Cool Patch	For the temporary relief of muscular and joint pain e.g. due to simple backache, strains, sprains.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24043430P	Motidom Oral Suspension 1mg/ml	Domperidone is indicated for the relief of the symptoms of nausea and vomiting. This includes: • Nausea and vomiting of functional, organic, infectious or dietary origin. • Nausea and vomiting induced by: - radiotherapy or drug therapy - dopamine agonists (such as L-dopa and bromocriptine) used in the treatment of Parkinson's disease.

BRU24043431P	Flugal 150mg Capsule	Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. 1. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g., pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. ***Flugal*** ® can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. 2. Systemic candidiasis, including candidemia, disseminated candidiasis and other forms of invasive candidal infection. These include infections of the peritoneum. endocardium, eye and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 3. Mucosal candidiasis, these include oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of oropharyngeal candidiasis in patients with AIDS. 4. Genital candidiasis, vaginal candidiasis, acute or recurrent, and prophylaxis to reduce the incidence of recurrent vaginal candidiasis (3 or more episodes a year), candidal balanitis. 5. Prevention of fungal infections in patients with malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy. 6. Dermatomycosis including tinea pedis, tinea corporis, tinea cruris, tinea vesicolor, and dermal candida infections.
BRU24043432P	Latacom (Latanoprost 0.005% + Timolol 0.5%) Eye Drops	Reduction of intraocular pressure (IOP) in patients with open-angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24043433P	Evenity Solution For Injection In Pre-Filled Syringe 105mg/1.17ml	Postmenopausal Osteoporosis EVENITY is indicated for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture.
BRU24043434NP	Cafuroid Tablet	Cafuroid is used for the treatment of: • Symptoms related to venolymphatic insufficiency, such as heavy legs, pain, early morning restless leg. • Functional symptoms related to acute hemorrhoidal attack.
BRU24043435NP	SteriPrep Antiseptic Solution	For antiseptic skin preparation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24043436P	Lecetam Oral Solution	Levetiracetam is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy. Levetiracetam is indicated as adjunctive therapy • in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents, children and infants from 1 month of age with epilepsy. • in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with Juvenile Myoclonic Epilepsy. • in the treatment of primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with Idiopathic Generalised Epilepsy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24043437P	Flucozole 50mg Capsule	Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. 1. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g., pulmonary, cutaneous). Normal hosts and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS. 2. Systemic candidiasis, including candidemia, disseminated candidiasis and other forms of invasive candidal infections. These include infections of the peritoneum, endocardium, eye, and pulmonary and urinary tracts. Patients with malignancy, in intensive care units, receiving cytotoxic or immunosuppressive therapy, or with other factors predisposing to candidal infection may be treated. 3. Mucosal candidiasis. These include oropharyngeal, esophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated. Prevention of relapse of oropharyngeal candidiasis in patients with AIDS. 4. Genital candidiasis. Vaginal candidiasis, acute or recurrent, and prophylaxis to reduce the incidence of recurrent vaginal candidiasis (three or more episodes a year). Candidal balanitis. 5. Prevention of fungal infections in patients with malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy or radiotherapy. 6. Dermatomycosis, including tinea pedis, tinea corporis, tinea cruris, tinea versicolor, and dermal Candida infections.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24053438P	Vytocor 10mg/40mg Tablet	***Prevention of Cardiovascular Events*** VYTOCOR is indicated to reduce the risk of cardiovascular events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, hospitalization for unstable angina, or need for revascularization), in patients with coronary heart disease (CHD) and history of acute coronary syndrome (ACS), either previously treated with a statin or not. ***Primary Hypercholesterolemia*** VYTOCOR is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and non-high density lipoprotein cholesterol (non- HDL-C), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidaemia. ***Homozygous Familial Hypercholesterolemia (HoFH)*** VYTOCOR is indicated for the reduction of elevated total-C and LDL-C levels in patients with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24053439P	Crystorvas Tablet 40mg	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol, LDL-Cholesterol, apolipoprotein B and triglycerides and to increase HDL-Cholesterol in patients with primary hypercholesterolemia (heterozygous familial and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson Types IIa and IIb), elevated serum triglyceride levels (Fredrickson Type IV) and for patients with dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction to total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident coronary heart disease but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease, CRYSTORVAS is indicated to : - Reduce the risk of myocardial infarction - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking or hypertension, CRYSTORVAS is indicated to : - Reduce the risk of myocardial infarction - Reduce the risk of stroke In patients with clinically evident coronary heart disease, atorvastatin is indicated to : - Reduce the risk of non-fatal myocardial infarction - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for CHF - Reduce the risk of angina

		Pediatric Patient (10-17 years of age) Atorvastatin is indicated as an adjunct to diet to reduce total-C and apo B levels in boys and postmenarchal girls 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: a. LDL-C remains ≥ 190 mg/dl or b. LDL-C remains ≥ 160 mg/dl and : • There is a positive family history of premature cardiovascular disease or • Two or more other CVD risk factors are present in the pediatric patient
BRU24053440P	Musafen Tablet 10mg	Spasticity of the skeletal muscles in multiple sclerosis. Spastic conditions occurring in spinal cord diseases of infectious, degenerative, traumatic, neoplastic or unknown origin, e.g. spastic spinal paralysis, amyotrophic lateral sclerosis, syringomyelia, transverse myelitis, traumatic paralplegia or paraparesis and compression of the spinal cord; muscle spasm of cerebral origin, especially where due to infantile cerebral palsy. In spasticity due to caerebrovascular accident or degenerative or neoplastic brain disease, Musafen tablet is less suitable owing to the likelihood of intolerance, but it may be tried if administered cautiously. Not recommended in Parkinsons Disease or spasticity arising from strokes.
BRU24053441P	Vaxcel Pantoprazole 40mg Injection	Short term use for symptomatic improvement and healing of gastrointestinal diseases which require a reduction in acid secretion: - Duodenal ulcer - Gastric ulcer - Moderate and severe reflux esophagitis - Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24053442P	Prednisyn Tablet 5mg	Rheumatic fever, rheumatoid arthritis, allergic diseases, nephrotic syndrome, bronchial asthma, and other corticosteroid-indicated conditions.
BRU24053443PS1; BRU24053443PS2	Tolcord 2 Film-Coated Tablet 2mg	Tolterodine is indicated for the treatment of overactive bladder with symptoms of urinary urgency, frequency, and/or urge incontinence.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24053444PS1; BRU24053444PS2	Acoloft 50 Sertraline Film-Coated Tablet 50mg	Sertraline is indicated for the treatment of symptoms of depression, including depression accompanied by symptoms of anxiety, in patients with or without a history of mania. Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of depression or recurrence of further depressive episodes. Sertraline is also indicated for the treatment of obsessive compulsive disorder (OCD). Following initial response, sertraline has been associated with sustained efficacy, safety and tolerability in up to 2 years of treatment of OCD. Sertraline is indicated for the treatment of panic disorder, with or without agoraphobia. Sertraline is indicated for the treatment of post-traumatic stress disorder (PTSD). Sertraline is indicated for the treatment of social phobia (social anxiety disorder). Sertraline is indicated for the treatment of pre-menstrual dysphoric disorder (PMDD). Sertraline is not indicated for use in children and adolescents under 18 years of age (see section 4.4 – Special Warnings and Precautions for Use).
BRU24053445P	Accoquin Film-Coated Tablet 200mg	Treatment of rheumatoid arthritis, juvenile chronic arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24053446P	Healol Salbutamol Inhaler (Salbutamol 100mcg/Dose)	Indicated for the relief and prevention of asthma symptoms. It should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognized by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure). Indicated as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.
BRU24053447P	Ammi Votara Emulsion Gel	Symptomatic relief and treatment of soft-tissue rheumatism, e.g. tendovaginitis, shoulder-hand syndrome, bursitis and periarthropathy; rheumatic diseases e.g. osteoarthritis of the spine and peripheral joints; post-traumatic inflammation of the tendons, ligaments, muscles and joints. e.g. due to sprains, strains or bruises.
BRU24053448P	Koselugo® Hard Capsules 10mg	Koselugo as monotherapy is indicated for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and above.
BRU24053449P	Koselugo® Hard Capsules 25mg	Koselugo as monotherapy is indicated for the treatment of symptomatic, inoperable plexiform neurofibromas (PN) in paediatric patients with neurofibromatosis type 1 (NF1) aged 3 years and above.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24063450NP	Salonpas Spray	For relief of aches and pains associated with: • Muscle fatigue • Muscle pain • Stiff shoulder • Simple backache • Bruises • Sprains • Strains • Arthritis
BRU24063451P	Dulox 30 (Duloxetine Hydrochloride Delayed Release Capsules 30mg)	Treatment of major depressive disorder. Management of neuropathic pain associated with diabetic peripheral neuropathy in adults. Treatment of generalized anxiety disorder.
BRU24063452P	Lenangio 10 (Lenalidomide Hard Capsules 10mg)	Lenangio® as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation. Lenangio® in combination with dexamethasone is indicated for the treatment of previously untreated multiple myeloma patients who are not eligible for transplant. Lenangio® in combination with dexamethasone is indicated for the treatment of multiple myeloma in patients who have received at least one prior therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24063453P	Lenangio 25 (Lenalidomide Hard Capsules 25mg)	Lenangio® as monotherapy is indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation. Lenangio® in combination with dexamethasone is indicated for the treatment of previously untreated multiple myeloma patients who are not eligible for transplant. Lenangio® in combination with dexamethasone is indicated for the treatment of multiple myeloma in patients who have received at least one prior therapy.
BRU24063454P	Nordipine Tablet 10mg	First line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, β-adrenoceptor-blocking agent or an angiotensin-converting enzyme inhibitor. Amlodipine is indicated for the first line treatment of myocardial ischemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of coronary vasculature. Amlodipine may be used where the clinical presentation suggests a possible vasospastic / vasoconstrictive component but where vasospasm/vasoconstriction has not been confirmed. Amlodipine may be used alone, as monotherapy or in combination with other anti anginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of β-blockers.
BRU24063455P	Winadryl Expectorant Syrup	For the relief of cough and congestion in the chest and nasal passages. It helps to loosen viscous mucous and expectorate stubborn phlegm.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24083456P	Troypofol (Propofol Emulsion For I.V. Injection Or Infusion 1% w/v)	Propofol is a short-acting intravenous anaesthetic agent suitable for induction and maintenance of general anaesthesia. Propofol may also be used for sedation of ventilated patients receiving intensive care. Propofol may also be used for sedation for surgical and diagnostic procedures.
BRU24083457P	Amtas-10 Tablet 10mg	<u>Hypertension</u> Amlodipine is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of amlodipine, which has been used in combination with a thiazide diuretic, alpha blockers, beta adrenoceptor blocking agent, or an angiotensin-converting enzyme (ACE) inhibitor. <u>Coronary Artery Disease</u> *Chronic Stable Angina* Amlodipine is indicated for the symptomatic treatment of chronic stable angina. Amlodipine may be used alone or in combination with other antianginal drugs. *Vasospastic Angina (Prinzmetal's or variant angina)* Amlodipine is indicated for the treatment of confirmed or suspected vasospastic angina. Amlodipine may be used as monotherapy, or in combination with other antianginal drugs. *Angiographically Documented Coronary Artery Disease* In patients with recently documented coronary artery disease (CAD) by angiography and without heart failure or an ejection fraction <40%, amlodipine is indicated to reduce the risk of hospitalization due to angina and to reduce the risk of a coronary revascularization procedure.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24083458P	Guardian Anti-Fungal Cream 1% w/w	For treatment of skin fungal infections including ringworm (tinea corporis), athlete's foot (tinea pedis), jock itch (tinea cruris), white spot (tinea versicolor) and candidiasis (topical).
BRU24083459P	Promethiol Syrup	Symptomatic treatment of troublesome, non-productive cough, particularly occurring at night.
BRU24083460P	Hydrine Capsule 500mg	Melanoma, resistant chronic myelocytic leukemia, and recurrent, metastatic, or inoperable carcinoma of the ovary. Hydroxyurea used concomitantly with irradiation therapy is intended for use in the loc al control of primary squamous cell (epidermoid) carcinomas of the head and neck, excluding the lip.
BRU24083461P	Caridine Syrup 0.5mg/ml	**CARIDINE SYRUP** is indicated for the rapid relief of symptoms associated with allergic rhinitis, such as sneezing, nasal discharge and itching, congestion/stuffiness, as well as ocular itching, tearing and redness. **CARIDINE SYRUP** is also indicated for the relief of symptoms associated with urticaria such as the relief of itching and the size and number of hives.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24083462P	Renaxin 5mg Film-Coated Tablets	Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome.
BRU24083463P	Goutric 80mg Film Coated Tablets	Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis). Goutric is indicated in adults.
BRU24083464P	Calquence 100mg Film-Coated Tablets	CALQUENCE as monotherapy or in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL). CALQUENCE as monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24083465NP	Mili Suspension 250mg/5ml (Raspberry Flavour)	For fever and relief of mild to moderate pain.
BRU24093466P	B.S. Tablet	Treatment of infections caused by susceptible organisms, as in: respiratory tract infections, urinary tract infections, gastro-intestinal tract infections, including typhoid and paratyphoid fever; cholera; skin and soft tissues infections; brucellosis (generally in combination with other agents), septicaemia due to sensitive organisms, nocardiosis, mycetoma (except when caused by the true fungi). For South American blastomycosis, **BS** is suppressive but not curative.
BRU24093467P	Tadaccord 20 - Tadalafil Film Coated Tablet USP 20mg	For 5mg & 20mg: Treatment of erectile dysfunction (ED) in adult males. In order for tadalafil to be effective for the treatment of ED, sexual stimulation is required. For 5mg only: Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). If Tadaccord is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks. For 5mg only: Treatment of erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia (ED/BPH). Tadaccord is not indicated for use by women.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24093468P	Tadaccord 5 - Tadalafil Film Coated Tablet USP 5mg	For 5mg & 20mg: Treatment of erectile dysfunction (ED) in adult males. In order for tadalafil to be effective for the treatment of ED, sexual stimulation is required. For 5mg only: Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). If Tadaccord is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks. For 5mg only: Treatment of erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia (ED/BPH). Tadaccord is not indicated for use by women.
BRU24093469P	Genessa 250mg Film Coated Tablets	Genessa is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating mutations of EGFR-TK.
BRU24093470P	Kalten 5mg Tablet	In management of hypertension, it may be used alone or in combination with other antihypertensive agent.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24093471P	Rosuvor Film-Coated Tablet 20mg	Rosuvor Tablet (rosuvastatin calcium) is indicated as an adjunct to diet, at least equivalent to the Adult Treatment Panel lll (ATP lll TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol: HDL-cholesterol ratio and triglycerides and for increasing HDL-C, in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: • Prevention of Cardiovascular Events. In adult patients with an increased risk of atherosclerotic cardiovascular disease based on the presence of cardiovascular disease risk markers such as an elevated hsCRP level, age, hypertension, low HDL-C, smoking or a family history of premature coronary heart disease, Rosuvor Tablet is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, MI, unstable angina, or arterial revascularization). • Rosuvor Tablet is indicated as an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia). • Combined (mixed) dyslipidemia (Type IIb). • Homozygous familial hypercholesterolaemia where Rosuvor Tablet is used either alone or as an adjunct to diet and other lipid lowering treatment such as apheresis. • Rosuvor Tablet is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.

BRU24093472P	Spiro 25mg Tablet	***Essential Hypertension*** Spironolactone, when used alone, is effective in lowering both systolic and diastolic blood pressure. Spironolactone improves the hypotensive action of thiazide diuretics while at the same time reducing or preventing potassium loss due to the thiazide. Spironolactone enhances the effectiveness of other antihypertensive agents such as beta blockers, vasodilators, etc. ***As Adjunctive Therapy in Malignant Hypertension*** ***In Diuretic-induced Hypokalaemia When Other Measures Are Considered Inappropriate or Inadequate*** ***Prophylaxis of Hypokalaemia in Patients Taking Digitalis When Other Measures Are Considered Inadequate or Inappropriate*** ***Oedematous Disorders, Such as Oedema and Ascites of Congestive Cardiac Failure, Cirrhosis of the Liver, Nephrotic Syndrome*** ***Congestive Cardiac Failure*** Spironolactone, when used alone, is effective in the management of oedema and sodium retention associated with congestive cardiac failure. Spironolactone may be used in combination with a thiazide or other conventional diuretics for achieving diuresis in patients whose oedema is resistant to a thiazide or other conventional diuretics. Unlike conventional diuretics Spironolactone does not produce hypokalaemia. When administered with a thiazide or other conventional diuretics, Spironolactone offsets hypokalaemia induced by these diuretics. The prevention of potassium loss is particularly important in the treatment of digitalised patients since digitalis intoxication may be precipitated if hypokalaemia is induced by conventional diuretic therapy.

		Hepatic Cirrhosis with Ascites and Oedema Spironolactone, when used alone, is frequently adequate for the relief of ascites and oedema associated with hepatic cirrhosis. Spironolactone provides a mild and even diuresis and prevents excessive potassium excretion caused by thiazide diuretics thus avoiding possible precipitation of hepatic coma. ***Nephrotic Syndrome*** Although glucocorticoids, whose anti-inflammatory activity appears to benefit the primary pathologic process in the renal glomerulus, should probably be employed first, Spironolactone either alone or in combination with a conventional diuretic is useful for inducing diuresis ***Diagnosis and Treatment of Primary Hyperaldosteronism*** Spironolactone may be used to establish the diagnosis of primary hyperaldosteronism by therapeutic trial. Spironolactone may also be used for the short term pre-operative treatment of patients with primary hyperaldosteronism, long term maintenance therapy for patients with discrete aldosterone producing adrenal adenomas who are judged to be poor operative risks (or who decline surgery), and the long-term maintenance therapy for patients with bilateral micro or macronodular adrenal hyperplasia (idiopathic hyperaldosteronism). ***Hirsutism*** Spironolactone is effective in the treatment of females with hirsutism, an androgen related increase in facial and body hair. A reduction in hair growth, hair shaft diameter and hair pigmentation are seen. Use of Spironolactone should be considered only after all other alternatives of non-drug therapy has been explored. For women of child-bearing age, see Contraindications, Precautions & Fertility, pregnancy and lactation.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24093473P	Asolan Tablet 0.5mg	**Anxiety States (Anxiety Neuroses)**: Symptoms which occur in such patients include anxiety, tension, agitation, insomnia, apprehension, irritability and / or autonomic hyperactivity resulting in a variety of somatic complaints. **Mixed Anxiety-Depression**: Symptoms of both anxiety and depression occur simultaneously in such patients. **Neurotic or Reactive Depression**: Such patients primarily exhibit a depressed mood or a pervasive loss of interest or pleasure. Symptoms of anxiety, psychomotor agitation and insomnia are usually present. Other characteristics include appetite disturbances, changes in weight, somatic complaints, cognitive disturbances, decreased energy, feeling of worthlessness or guilt or thoughts of death or suicide. **Anxiety states, mixed anxiety-depression or neurotic depression associated with other diseases**, eg. the chronic phase of alcohol withdrawal and functional or organic disease, particularly certain gastrointestinal, cardiovascular or dermatological disorders. **Panic related disorders**: Alprazolam is indicated in the treatment of panic disorder with or without some phobic avoidance. Alprazolam is also indicated for the blocking or attenuation of panic attacks and phobias in patients who have agoraphobia with panic attacks. The effectiveness of alprazolam in the treatment of anxiety, anxiety associated with depression and neurotic (reactive) depression for long-term use exceeding six months has not been established by systematic clinical trials; however, patients with panic-related disorders have been effectively treated for up to eight months. The physician should periodically reassess the usefulness of the drug for the individual patient.
BRU24093474NP	Dimectal Powder For Oral Suspension 3g	• Treatment of acute diarrhoea in adults and children above 2 years, in addition to oral rehydration. • Symptomatic treatment of chronic functional diarrhoea in adults. • Symptomatic treatment of pain associated with functional bowel diseases in adults.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24093475P	Atenol Film Coated Tablet 50mg	i) Hypertension ii) Angina pectoris iii) Cardiac arrhythmias iv) Myocardial infarction – Early and late intervention
BRU24093476P	Arilift 15mg Tablets	I. For the treatment of acute episodes of schizophrenia and for maintenance of clinical improvement during continuation therapy. II. For the treatment of acute manic episodes associated with Bipolar I Disorder.
BRU24093477P	Arilift 10mg Tablets	I. For the treatment of acute episodes of schizophrenia and for maintenance of clinical improvement during continuation therapy. II. For the treatment of acute manic episodes associated with Bipolar I Disorder.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24093478P	Clavamox 500 Amoxicillin 500mg with Clavulanic Acid 125mg Film-Coated Tablets	Clavamox is indicated for the treatment of the following infections in adults and children: • Acute bacterial sinusitis (adequately diagnosed) • Acute otitis media • Acute exacerbations of chronic bronchitis (adequately diagnosed) • Community-acquired pneumonia • Cystitis • Pyelonephritis • Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis. • Bone and joint infections, in particular osteomyelitis. • Consideration should be given to official guidance on the appropriate use of antibacterial agents.
BRU24093479P	Eurythmic 50mg/ml Injection	Treatment of severe rhythm disturbances especially the following: Atrial arrythmia with rapid ventricular rhythm, tachycardia associated with Wolff-Parkinson-White syndrome and ventricular rhythm disorders. Cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock. Amiodarone I.V. is to be used where a rapid response is required or where oral administration is not possible.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24103480P	Xelcol (1 MIU Of Colistimethate Sodium Powder For Solution For Injection Or Infusion)	Xelcol is indicated in the treatment of the following infections where sensitivity testing suggests that they are caused by susceptible bacteria: Intravenous administration for the treatment of some serious infections caused by Gram negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contra-indicated or may be ineffective because of bacterial resistance.
BRU24103481PS1; BRU24103481PS2	Parsabiv Solution For Injection 2.5mg/0.5ml	Parsabiv is indicated for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy.
BRU24103482PS1; BRU24103482PS2	Parsabiv Solution For Injection 5mg/ml	Parsabiv is indicated for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24103483P	Pregal 75mg Capsule	<u>Neuropathic pain</u> Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. <u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised Anxiety Disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24103484P	Pregal 150mg Capsule	<u>Neuropathic pain</u> Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults. <u>Epilepsy</u> Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation. <u>Generalised Anxiety Disorder</u> Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults. <u>Fibromyalgia</u> Pregabalin is indicated for the management of fibromyalgia.
BRU24103485P	Ondrin Injection 4mg/2ml	**Adults** Ondrin injection is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. Ondrin injection is also indicated for the prevention and treatment of post-operative nausea and vomiting. **Paediatric Population** Ondrin injection is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting; IV injection is recommended for this purpose.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24103486P	Rivoxan 20 Tablet	• Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. • Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.
BRU24123487P	Streptokinase Karma 1 500 000	Streptokinase Karma is indicated in adults. Acute myocardial infarction: within 12 hours of onset with persistent ST-segment elevation or recent left bundle-branch block. Note: No statement on therapy outcome can be made for administration beyond the time window indicated above.
BRU24123488P	New Obimin Tablet	Vitamin and mineral supplements for pregnant and lactating women.
BRU24123492P	ALPHAGAN P Ophthalmic Solution 0.1%	ALPHAGAN® P is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
BRU24123493P	Safrosyn S Tablet 275mg	Naproxen sodium is indicated in the relief of mild to moderate pain including post partum pain, pain following IUD insertion, post-operative pain and pain due to orthopedic surgery, for the treatment of primary dysmenorrhea and for the relief (prophylaxis) of migraine headache. It is also indicated for the treatment of the signs and symptoms of mild to moderately severe, acute or chronic, musculoskeletal and soft tissue inflammation and acute gout.

BRU24123494P	Doxycillin Tablet 100mg	Doxycycline is indicated for treatment of the following infections: Rocky Mountain spotted fever, typhus fever and the typhus group; Q fever, rickettsial pox and tick fevers caused by *Rickettsiae* ; Respiratory infections caused by *Mycoplasma pneumoniae* ; Psittacosis caused by *Chlamydia psittaci* ; Lymphogranuloma venereum, caused by *Chlamydia trachomatis* ; Uncomplicated urethral, endocervical or rectal infections in adults caused by *Chlamydia trachomatis* ; Trachoma caused by *Chlamydia trachomatis* although the infectious agent is not always eliminated, as judged by immunofluorescence; Inclusion conjunctivitis caused by *Chlamydia trachomatis* may be treated with oral doxycycline alone or with a combination of topical agents; Granuloma inguinale (donovanosis) caused by *Calymmatobacterium granulomatis* ; Early (Stage 1) Lyme disease caused by *Borrelia burgdorferi* ; Louse-borne relapsing fever caused by *Borrelia recurrentis* ; Tick-borne relapsing fever caused by *Borrelia duttonii* ; Non-gonococcal urethritis (NGU) caused by *Ureaplasma urealyticum (T-Mycoplasma)* . Doxycycline is also indicated for the treatment of infections caused by the following gram-negative microorganisms: Acinetobacter species; *Bacteroides* species; *Fusobacterium* species; Brucellosis caused by *Brucella* species (in conjunction with streptomycin); Plague caused by *Yersinia pestis* ; Tularemia caused by *Francisella tularensis* ; Bartonellosis caused by *Bartonella bacilliformis* ; *Campylobacter fetus* . Because many strains of the following groups of microorganisms have been shown to be resistant to tetracyclines, culture and susceptibility testing are recommended. Doxycycline is indicated for treatment of infections caused by the following gram-negative microorganisms, when bacteriologic testing indicates appropriate susceptibility to the drug: *Shigella* species; Uncomplicated gonorrhea caused by *Neisseria gonorrhoeae* ; Respiratory infections caused by *Haemophilus influenzae* ; Respiratory and urinary infections caused by *Klebsiella species; Escherichia coli; Enterobacter aerogenes; Moraxella catarrhalis* . Doxycycline is indicated for treatment of infections caused by the following gram-positive microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug:

		Streptococcus species: A certain percentage of strains of *Streptococcus pyogenes* and *Streptococcus faecalis* have been found to be resistant to tetracycline drugs. Tetracyclines should not be used for streptococcal infections unless the organism has been demonstrated to be sensitive. For upper respiratory infections due to group A beta-hemolytic streptococci, penicillin is the usual drug of choice, including prophylaxis of rheumatic fever. This includes: Upper respiratory tract infections caused by *Streptococcus pneumoniae* ; Respiratory, skin and soft-tissue infections caused by *Staphylococcus aureus* . Tetracyclines are not the drug of choice in the treatment of staphylococcal infections. When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of: Actinomycosis caused by *Actinomyces* species; Infections caused by *Clostridium* species; Syphilis caused by *Treponema pallidum* and yaws caused by *Treponema pertenue* ; Listeriosis caused by *Listeria monocytogenes* ; Vincent's infection (acute necrotizing ulcerative gingivitis) caused by *Leptotrichia buccalis* (formerly, *Fusobacterium fusiform*). **Adjunctive treatment** In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides. In severe acne caused by *acne vulgaris* , doxycycline may be useful adjunctive therapy. **Treatment and Prophylaxis** Doxycycline is indicated for the prophylaxis and treatment of the following infections: Malaria caused by *Plasmodium falciparum* (in areas with chloroquine-resistant *P. falciparum*). Leptospirosis caused by genus *Leptospira* . Cholera caused by *Vibrio cholerae* . **Prophylaxis** Doxycycline is indicated as prophylaxis in the following conditions: Scrub typhus caused by Rickettsia *tsutsugamushi* ; Traveler's diarrhea caused by enterotoxigenic *Escherichia coli* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24123495P	Vocin 500 Tablet	Because of the risk of prolonged, disabling and potentially irreversible serious adverse drug reactions (see Precaution and Side effect). This product must only be prescribed when other antibiotics that are commonly recommended for the infection are inappropriate. This applies to all indications listed below. Situations where other antibiotics are considered to be inappropriate are where: • there is resistance to other first-line antibiotics recommended for the infection; • other first-line antibiotics are contraindicated in an individual patient; • other first-line antibiotics have caused side effects requiring treatment to be stopped; • treatment with other first-line antibiotics has failed. In adults, Levofloxacin tablets are indicated treatment of the following infections (see Precaution and Mechanism of Action): • Acute bacterial sinusitis • Acute bacterial exacerbations of chronic bronchitis • Community-acquired pneumonia • Complicated skin and soft tissue infections • Complicated urinary tract infections including pyelonephritis (see Precaution) • Chronic bacterial prostatitis • Uncomplicated cystitis (see Precaution) Inhalation Anthrax: post exposure prophylaxis and curative treatment (see Precaution) Levofloxacin may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous Levofloxacin. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU24123496P	Ticata 90 Tablet	**Acute Coronary Syndrome or a History of Myocardial Infarction** TICATA 90, co-administered with Acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with Acute Coronary Syndromes (unstable angina, non ST elevation Myocardial Infarction [NSTEMI] or ST elevation Myocardial Infarction [STEMI]), including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG). **Acute Ischemic Stroke or Transient Ischemic Attack (TIA)** TICATA 90 is indicated to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤ 5) or high-risk transient ischemic attack (TIA).
BRU24123497P	Strokan FC Tablet 250mg	Maintenance of patency of coronary artery by-pass grafts. Maintenance of patency of access sites in patients on chronic haemodialysis. Reducing risk of thrombotic stroke (fatal or nonfatal) in patients who have experienced stroke precursors and in patients who had completed stroke. Prevention of subacute occlusion following coronary STENT(s) implantation.
BRU24123498P	Axcel Atenolol-50mg Tablet	i) Control of hypertension ii) Management of angina pectoris iii) Control of cardiac arrhythmias iv) Treatment of myocardial infarction. Early and late intervention.
BRU24123499P	Axcel Atenolol-100mg Tablet	i) Control of hypertension ii) Management of angina pectoris iii) Control of cardiac arrhythmias iv) Treatment of myocardial infarction. Early and late intervention.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25013500P	Axcel Erythromycin ES-400 Suspension	Indicated in the treatment of infections caused by susceptible strains of designated organisms in the diseases listed below: upper and lower respiratory tract infections that caused by *Streptococcus pyogenes* and *Streptococcus pneumoniae* . Pertussis (whooping cough) caused by *Bordetella pertussis* . Skin and soft tissue infections caused by *Streptococcus pyogenes* and *Streptococcus aureus* . Otitis media, erythrasma, listeriosis, diphetheria, primary syphilis in patients allergy to penicillin, prophylaxis of endocarditis.
BRU25013501P	Ezede'-D Oral Solution	Ezede'-D is indicated for the relief of symptoms associated with allergic rhinitis and the common cold including nasal congestion, sneezing, rhinorrhea, pruritus and lacrimation. Ezede'-D is recommended when both the antihistaminic properties of loratadine and the decongestant effect of pseudoephedrine sulfate are desired.
BRU25013502P	Edeline Injection 30mg/ml	Treatment of bronchial spasm in asthma, adjunct to correct haemodynamic imbalances and treat hypotension in epidural and spinal anaesthesia.
BRU25013503P	Thyrocord 25 Tablet 25mcg	Hypothyroidism.
BRU25013504P	Thyrocord 75 Tablet 75mcg	Hypothyroidism.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25013505P	Thyrocord 50 Tablet 50mcg	Hypothyroidism.
BRU25013506P	Thyrocord 100 Tablet 100mcg	Hypothyroidism.
BRU25013507P	Saphnelo 300mg Concentrate For Solution For Infusion	Saphnelo is indicated as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy.
BRU25013508P	Elipix 90mg Film Coated Tablets	Etoricoxib is indicated for: • Acute and chronic treatment of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA) • Treatment of ankylosing spondylitis (AS) • Treatment of acute gouty arthritis • Treatment of acute pain, including that related to primary dysmenorrhoea and minor dental procedures. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25013509P	Elipix 120mg Film Coated Tablets	Etoricoxib is indicated for: • Acute and chronic treatment of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA) • Treatment of ankylosing spondylitis (AS) • Treatment of acute gouty arthritis • Treatment of acute pain, including that related to primary dysmenorrhoea and minor dental procedures. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.
BRU25013510P	Bavencio 200mg/10ml Concentrate For Solution For Infusion	Bavencio is indicated as monotherapy for the treatment of patients with metastatic Merkel cell carcinoma (MCC). Bavencio is indicated for the first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) whose disease has not progressed with first-line platinum-based induction chemotherapy. Bavencio in combination with axitinib is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC) (see section 5.1).
BRU25033511P	Vaxigrip Influenza Vaccine (0.5ml Syringe)	Vaxigrip is indicated for the prevention of influenza disease caused by the two influenza A virus subtypes and the influenza B virus type contained in the vaccine for: - active immunisation of adults, including pregnant women, and children from 6 months of age and older, - passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women (see Sections 4.4, 4.6 and 5.1). The use of Vaxigrip should be based on official recommendations on vaccination against influenza.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25033512NP	Shine Joinflex Forte Film Coated Tablet	As adjuvant therapy for osteoarthritis.
BRU25033513P	Zinnia Tablet	Zinnia is indicated for the prevention of pregnancy.
BRU25033514NP	ConsiQare Oral Solution 667mg/ml	- ConsiQare helps in softening the stools and relieves constipation. - For hepatic encephalopathy (HE) treatment and prevention of hepatic coma or precoma.
BRU25033515P	Hydralat (Hydralazine Hydrochloride Injection 20mg/ml)	Treatment of hypertensive emergencies, particularly those associated with pre-eclampsia and toxaemia of pregnancy. Treatment of hypertension with renal complications.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25033516P	Cefuroxime Axetil-Zhijun Tablet 250mg	Cefuroxime axetil is indicated for the treatment of infections caused by sensitive bacteria. *Upper respiratory tract infections* eg, ear, nose and throat infections ie, otitis media, sinusitis, tonsillitis and pharyngitis. *Lower respiratory tract infections* eg, pneumonia, acute bronchitis and acute exacerbations of chronic bronchitis. *Genito-urinary tract infections* eg, pyelonephritis, cystitis and urethritis. *Skin and soft-tissue infections* eg, furunculosis, pyoderma and impetigo. Gonorrhoea, acute uncomplicated gonococcal urethritis and cervicitis. Cefuroxime is also available as the sodium salt (cefuroxime sodium) for parenteral administration. This permits the use of sequential therapy with the same antibiotic, when a change from parenteral to oral therapy is clinically indicated. Where appropriate, Cefuroxime Axetil Tablet is effective when used following initial parenteral administration of cefuroxime sodium in the treatment of pneumonia and acute exacerbations of chronic bronchitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25033517P	Rosudex Film-Coated Tablet 10mg	- Rosuvastatin is indicated as an adjunct to diet, for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol: HDL-cholesterol ratio and triglycerides and for increasing HDL-C, in hyperlipidemia and dyslipidemia conditions, when response to diet and exercise alone has been inadequate including: • Prevention of cardiovascular events. Rosuvastatin is indicated to reduce total mortality and the risk of major cardiovascular events (cardiovascular death, stroke, MI, unstable angina, or arterial revascularization). - Rosuvastatin is indicated as an adjunct to diet for the treatment of patients with: • Primary dysbetalipoproteinemia (type III hyperlipoproteinemia) • Primary hypercholesterolemia (type IIa including heterozygous familial hypercholesterolemia and severe nonfamilial hypercholesterolemia) • Combined (mixed) dyslipidemia (type IIb) • Homozygous familial hypercholesterolemia where rosuvastatin is used either alone or as an adjunct to diet and other lipid lowering treatment such as apheresis - Rosuvastatin is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower total-C and LDL-C to target levels. - Pediatric patients 10 to 17 years of age with heterozygous familial hypercholesterolemia (HeFH): adjunct to diet to reduce total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year postmenarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C >190 mg/dl or >160 mg/dl and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors.
BRU25033518P	Renson 10mg Tablet	Adrenocortical insufficiency (Addison's disease), diminution of anterior pituitary function (hypopituitarism), congenital adrenal hyperplasia. Conditions where systemic glucocorticoid therapy is indicated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25033519NP	Poro Suspension 250mg/5ml (Orange Flavour)	For the relief of fever and mild to moderate pain.
BRU25033520P	Tezspire 210mg Solution For Injection In Pre-Filled Pen	TEZSPIRE is indicated as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.
BRU25033521P	Tezspire 210mg Solution For Injection In Pre-Filled Syringe	TEZSPIRE is indicated as an add-on maintenance treatment in adults and adolescents 12 years and older with severe asthma who are inadequately controlled despite high dose inhaled corticosteroids plus another medicinal product for maintenance treatment.
BRU25033522P	Dayvigo 5mg Film Coated Tablet	DAYVIGO is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.
BRU25033523P	Dayvigo 10mg Film Coated Tablet	DAYVIGO is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25043524P	Intasteride 0.5mg Soft Capsules	Monotherapy inTASTERIDE is indicated for the treatment and control of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for BPH-related surgery. Combination with Alpha-Blocker inTASTERIDE in combination with the alpha-blocker tamsulosin is indicated for the treatment of symptomatic BPH in men with an enlarged prostate.
BRU25043525P	Cardiamed Injection 1mg/1ml	For blood pressure control in certain acute hypotensive states (e.g. pheochromocytomectomy, sympathectomy, poliomyelitis, spinal anesthesia, myocardial infarction, septicemia, blood transfusion and drug interactions). As an adjunct in the treatment of cardiac arrest and profound hypotension.
BRU25053526NP	SOFT FLOW SC Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution With Dextrose 1.5% w/v	SOFT FLOW SC in polypropylene (PP) bags for CAPD (1 bag of Peritoneal Dialysis Solution & 1 Drain Bag) is indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate. SOFT FLOW SC in polypropylene (PP) bags for APD (1 bag of Peritoneal Dialysis Solution) is indicated for use in chronic renal failure patients being maintained on peritoneal dialysis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25053527NP	SOFT FLOW SC Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution With Dextrose 2.5% w/v	SOFT FLOW SC in polypropylene (PP) bags for CAPD (1 bag of Peritoneal Dialysis Solution & 1 Drain Bag) is indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate. SOFT FLOW SC in polypropylene (PP) bags for APD (1 bag of Peritoneal Dialysis Solution) is indicated for use in chronic renal failure patients being maintained on peritoneal dialysis.
BRU25053528NP	SOFT FLOW SC Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution With Dextrose 4.25% w/v	SOFT FLOW SC in polypropylene (PP) bags for CAPD (1 bag of Peritoneal Dialysis Solution & 1 Drain Bag) is indicated for use in chronic renal failure patients being maintained on continuous ambulatory peritoneal dialysis when nondialytic medical therapy is judged to be inadequate. SOFT FLOW SC in polypropylene (PP) bags for APD (1 bag of Peritoneal Dialysis Solution) is indicated for use in chronic renal failure patients being maintained on peritoneal dialysis.
BRU25053529P	Tecavir 0.5 (Entecavir Tablet 0.5mg)	Entecavir is a nucleoside analogue indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.
BRU25053530P	Bortero (Bortezomib For Injection 3.5mg)	Bortezomib for Injection is indicated for the treatment of patients with multiple myeloma. Bortezomib for Injection is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25053531NP	Progesic-250 Suspension	Progesic Suspension contains paracetamol - a modern analgesic that relieves pain and fever like aspirin but unlike aspirin may be used with confidence in children. Progesic Suspension is recommended for the relief of fever and pain such as toothache and headache in children.
BRU25053532P	Rocuronium-Hameln 10mg/ml Injection	Rocuronium-hameln 10 mg/ml injection is indicated as an adjunct to general anaesthesia to facilitate endotracheal intubation, to provide skeletal muscle relaxation and to facilitate mechanical ventilation in adults, children and infants from one month of age. Rocuronium-hameln 10 mg/ml injection is also indicated as an adjunct in the intensive care unit (ICU) to facilitate mechanical ventilation as part of Rapid Sequence Induction.
BRU25053533P	Duocoxib Film Coated Tablet 120mg	Duocoxib is indicated for: • Symptomatic relief of osteoarthritis (OA) • Rheumatoid arthritis (RA) • Symptomatic relief of ankylosing spondylitis (AS) • Pain and signs of inflammation associated with acute gouty arthritis • Treatment of acute pain, including that related to primary dysmenorrhea and minor dental procedures. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks, taking into consideration other available therapeutic options.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25053534P	Irbetas 150 Film-Coated Tablet 150mg	Irbesartan is indicated in adults for the treatment of essential hypertension. It is also indicated for the treatment of renal disease in adults patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen. Irbesartan can be used alone or in combination with other antihypertensive agents.
BRU25053535P	Irbetas 300 Film-Coated Tablet 300mg	Irbesartan is indicated in adults for the treatment of essential hypertension. It is also indicated for the treatment of renal disease in adults patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen. Irbesartan can be used alone or in combination with other antihypertensive agents.
BRU25053536NP	Uphamol Menstrual Tablet 500/25mg	Uphamol Menstrual Tablet 500/25mg provides symptomatic relief of water-weight gain, bloating, swelling, headache, backache, muscular aches, pains and cramps associated with premenstrual and menstrual periods.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25053537P	Duocoxib Film Coated Tablet 90mg	Duocoxib is indicated for: • Symptomatic relief of osteoarthritis (OA) • Rheumatoid arthritis (RA) • Symptomatic relief of ankylosing spondylitis (AS) • Pain and signs of inflammation associated with acute gouty arthritis • Treatment of acute pain, including that related to primary dysmenorrhea and minor dental procedures. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks, taking into consideration other available therapeutic options.
BRU25053538P	Mucostop Granules For Oral Solution 600mg Sachet	All respiratory tract diseases leading to the formation of thick secretions difficult to be expectorated, such as acute and chronic bronchitis, laryngitis, sinusitis, tracheitis, influenza, bronchial asthma and (as complementary treatment) mucoviscidosis.
BRU25053539P	Mucokids Oral Solution 125mg/5ml	MucoKids is used for the adjunctive therapy of respiratory tract disorders characterised by excessive, viscous mucus, including chronic obstructive airways disease.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25053540P	Emazole 40mg Powder For Solution For Injection/Infusion	Emazole Powder for injection/infusion is indicated for - Gastric antisecretory treatment when the oral route is not possible, such as: • gastroesophageal reflux disease in patients with esophagitis and/or severe symptoms of reflux. • healing of gastric ulcers associate with NSAID therapy. • prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk. - Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.
BRU25053541P	Infusol NAC (Acetylcysteine 200mg/ml Solution For Intravenous Infusion)	Antidote for paracetamol poisoning.
BRU25053542NP	Injecsol MgSO4 (Magnesium Sulfate 50% w/v Concentrated Injection)	• Parenteral administration of Magnesium is indicated in the treatment of acute hypomagnesaemia. • Magnesium salts are also indicated to prevent hypomagnesaemia in patients receiving total parenteral nutrition. • Magnesium Sulfate is also indicated in the prevention and treatment of life threatening seizures in the treatment of toxemias of pregnancy (pre-eclampsia and eclampsia).

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25053543P	Osmivir Capsule 75mg	**Treatment of influenza:** OSMIVIR is indicated for the treatment of influenza in children 6 to 12 months of age during a pandemic influenza outbreak, OSMIVIR is indicated for the treatment of influenza in adults and children > 1 year of age. Treatment should commence as soon as possible but no later than forty-eight hours after the onset of the initial symptoms of infection. **Prevention of influenza:** OSMIVIR is indicated for post exposure prevention in adults and children > 1 year following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25063544P	Axcel Ciprofloxacin-500mg Tablet	Consideration should be given to official guidance on the appropriate use of antibacterial agents. Uncomplicated and complicated infections caused by ciprofloxacin sensitive pathogens: - *Infections of the respiratory tract: Ciprofloxacin can be regarded as an advisable treatment for pneumonias caused by *Klebsiella, Enterobacter, Proteus, E.coli, Pseudomonas, Haemophilus, Moraxella catarrhalis, Legionella* and *Staphylococcus* . - *Infections of the middle ear (otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by gram negative organisms including *Pseudomonas aeruginosa* or by staphylococci. - Infections of the eyes - *Infections of the kidneys and/or the efferent urinary tract - Infections of the genital organs, including adnexitis, gonorrhea, prostatitis and excluding vaginal infections - Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or of the biliary tract, peritonitis) - Infections of the skin and soft tissue - Infections of the bones and joints - *Sepsis - Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g. patients on immunosuppressants or have neutropenia) - Prophylaxis of invasive infections due to *Neisseria meningitidis* . *Axcel Ciprofloxacin Tablet should be only used: - When Pseudomonas is considered AND patient is allergic to antipseudomonal penicillins / cephalosporins; - For resistant organisms with no other alternative antibiotics available *Children and adolescents* : Ciprofloxacin may be used in children for the second- and third-line treatment of complicated urinary tract infections and pyelonephritis due to Escherichia coli (age range applied in clinical studies: 1–17 years) and for the treatment of bronchopulmonary infections of cystic fibrosis associated with *Pseudomonas aeruginosa* (age range applied in clinical studies: 5–17 years). Treatment should only be initiated after careful benefit / risk evaluation, due to possible adverse events related to joints and/or surrounding tissues. The clinical trials in children were performed in the indications listed above. For other indications clinical experience is limited. *Inhalation anthrax (post-exposure) in adults and in children* : To reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis* .

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25063545P	Gabapin 100-Gabapentin Capsules USP 100mg	**Epilepsy** Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 3 years and older. Safety and effectiveness for adjunctive therapy in pediatric patients younger than 3 years have not been established (*see Section 4.2 – Posology and method of administration: Pediatric patients aged 3 to 12 years*). **Neuropathic pain** Gabapentin is indicated for the treatment of neuropathic pain which include diabetic pain, post-herpetic neuralgia and trigeminal neuralgia. Safety and effectiveness in patients younger than 18 years have not been established.
BRU25063546P	Gabapin 300-Gabapentin Capsules USP 300mg	**Epilepsy** Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 3 years and older. Safety and effectiveness for adjunctive therapy in pediatric patients younger than 3 years have not been established (*see Section 4.2 – Posology and method of administration: Pediatric patients aged 3 to 12 years*). **Neuropathic pain** Gabapentin is indicated for the treatment of neuropathic pain which include diabetic pain, post-herpetic neuralgia and trigeminal neuralgia. Safety and effectiveness in patients younger than 18 years have not been established.
BRU25063547NP	Kordel's Glucosamine 550 Capsule	As an adjuvant therapy for osteoarthritis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25063548P	Ristor Oral Solution 1mg/ml	RISTOR is indicated for the treatment of a broad range of patients with schizophrenia, including first episode psychoses, acute schizophrenic exacerbations, chronic schizophrenia, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness), and/or negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISTOR alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. RISTOR is also effective in maintaining the 2 clinical improvement during continuation therapy in patients who have shown an initial treatment response. RISTOR is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders. It is also indicated for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents.
BRU25063549P	Lonfilis FC Tablets 20mg (Tadalafil)	Treatment of erectile dysfunction in adult males. In order for tadalafil to be effective, sexual stimulation is required. Tadalafil is not indicated for use by women.
BRU25063550P	Dirine Injection 20mg/2ml	Edema of renal origin, cardiac edema. Ascites due to cirrhosis of the liver, mechanical obstruction of cardiac failure, peripheral edema, edema, pregnancy edema, pulmonary edema, cerebral edema, mild or moderate hypertension.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25063551NP	WINSPIRIN Acetylsalicylic Acid Dispersible Tablet 75mg	Indicated for the secondary prevention of thrombotic cerebrovascular or cardiovascular disease and following by-pass surgery.
BRU25063552NP	WINSPIRIN Acetylsalicylic Acid Dispersible Tablet 150mg	Aspirin used for its antiplatelet activity in the initial treatment of cardiovascular disorders such as angina pectoris and myocardial infarction and for the prevention of cardiovascular events in patients at risk. Other such uses include the treatment and prevention of cerebrovascular disorders such as stroke.
BRU25063553P	Sybrava 284mg/1.5ml Solution For Injection In Pre-Filled Syringe	Sybrava is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: • in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or • alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25073554P	Hema-Plus 2000 (0.5mL In Prefilled Syringe)	**Treatment of anemia due to chronic renal disease** Hema-Plus is indicated for the treatment of anemia associated to chronic renal failure, including both, dialysis patients and predialysis patients. The product is indicated to elevate or maintain the red blood cell level as manifested by the hematocrit or hemoglobin determinations and to decrease the need for transfusions in these patients. Prior to initiation of therapy the patient's iron stores, including transferrin saturation and ferritin, which should be at least 20 % and 100 ng/mL, respectively, should be evaluated. Blood pressure has to be properly controlled and monitored very carefully during the treatment. The treatment should be considered in patients with a hematocrit less than 30 %. **Treatment of cancer patients on chemotherapy** Hema-Plus is indicated for anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy for at least two months, and its purpose is to increase or preserve the level of erythrocytes in blood, shown or expressed through the hematocrit or hemoglobin level, and therefore reduce the number of transfusions these patients need.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25073555P	Z Mox Oral Suspension 125mg/5ml	Z MOX is useful in the treatment of infections caused by amoxicillin susceptible organisms: Respiratory tract infections • Upper airways and ENT infections • Lower airways infections, e.g. acute and chronic bronchitis, pneumonia, lung abscess, pertussis (incubation period and early stages) Urogenital infections • Acute and chronic pyelonephritis, pyelitis, prostatitis, epididymitis • Cystitis, urethritis, asymptomatic bacteriuria during pregnancy • Gonorrhoea Gynaecologic infections (septic abortion, adnexitis, endometritis, etc.) Gastro-intestinal infections • Typhoid fever, paratyphoid, particularly if complicated by septicemia (in combination with an aminoglycoside antibiotic); control of salmonella carriers • Shigellosis Infections of the biliary system (cholangitis, cholecystitis) Skin and soft tissue infections Leptospirosis Acute and latent listeriosis Unless parenteral treatment (e.g. with ampicillin) is required, Z MOX is also active in the conditions below: • Short-term (24 to 48 hrs) prophylactic treatment of patients undergoing surgery (e.g. in the oral cavity) • Endocarditis, e.g. enterococcal endocarditis (alone or in combination with an aminoglycoside antibiotic) • Bacterial meningitis (pending the outcome of susceptibility test; particularly in children) • Septicemias caused by amoxicillin-susceptible pathogens. Infections caused by pathogens with established penicillin G susceptibility should preferentially be treated with penicillin G.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25073556P	Cytarine Injection 100mg/ml	Cytarabine is indicated primarily for: Induction and maintenance of remission in acute myelocytic leukaemia of both adults and children. It has also been found to be useful in the treatment of other leukaemias such as: - Acute lymphocytic leukaemia - Chronic myelocytic leukaemia (blast phase) Cytarabine may be used alone or in combination with other antineoplastic agents, the best results are often obtained with combination therapy. Children with non-Hodgkin's lymphoma have benefited from a combination drug program (LSA2L2) that includes cytarabine. Remissions induced by cytarabine not followed by maintenance treatment have been brief. Maintenance therapy has extended these and provided useful and comfortable remissions with relatively little toxicity.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25073557P	VEENAT 100 Tablet	Imatinib tablets are indicated for the • treatment of adult and pediatric patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML) (for pediatric use see section DOSAGE REGIMEN AND ADMINISTRATION). • treatment of adult and pediatric patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy (for pediatric use see section DOSAGE REGIMEN AND ADMINISTRATION). • treatment of pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy. • treatment of adult patients with relapsed or refractory Ph+ ALL as monotherapy. • treatment of adult patients with Kit+ (CD117) unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST). • adjuvant treatment of adult patients following complete gross resection of Kit+ GIST The effectiveness of Imatinib is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in relapsed or refractory adult Ph+ ALL, on objective response rates in unresectable and/or metastatic GIST and on recurrence free survival in adjuvant GIST (see PHARMACODYNAMICS). Except in newly diagnosed chronic phase CML there are no controlled trials demonstrating increased survival.
BRU25073558NP	Pegalate Oral Sachet	It is a laxative for the treatment of chronic constipation and faecal impaction in adults, adolescents and elderly. It Is not recommended for children below 12 years of age.
BRU25073559NP	Rowatinex Capsules	Rowatinex® is indicated for the treatment of urinary tract spasm and inflammation associated with urolithiasis. Rowatinex® also assists in the dissolution and expulsion of stones in the renal system.
BRU25073560NP	Cin Cao Gao Cap Tai Chi	To relieve muscular pain and joint pain associated with rheumatism.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25073561NP	Idaman Ferrous Fumarate Tablet 200mg	Idaman Ferrous Fumarate Tablet is indicated in the prophylaxis and treatment of iron deficiency resulting from inadequate diet, malabsorption, pregnancy, parasitic infection and/or blood loss. For prophylaxis during pregnancy, a combination of iron and folic acid is usually recommended.
BRU25073562P	Skyrizi Solution For Injection In Pre-Filled Cartridge With On-Body Injector 360mg/2.4ml	**Crohn's Disease** SKYRIZI is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy.
BRU25073563P	Skyrizi Concentrate For Solution For Infusion 600mg/10ml	**Crohn's Disease** SKYRIZI is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25073564P	Apalin 250mg Injection (2ml Amp)	1. Short term treatment of serious infections due to susceptible strains of gram negative bacteria (see below for susceptible strains). 2. Treatment of staphylococcal infections: The use of amikacin in the treatment of staphylococcal infection should be restricted to second line of defence rather than initial therapy and should be confined to patients suffering from severe infection caused by susceptible strains of staphylococcus who have failed to respond or are allergic to other available antibiotics. 3. Treatment of neonatal sepsis when sensitivity testing indicates that other aminoglycosides cannot be used. In certain severe infections such as neonatal sepsis, concomitant therapy with a penicillin-type drug may be indicated because of the possibility of infections due to gram-positive organisms such as streptococci or pneumococci. Clinical studies has shown amikacin to be effective in the following infections when due to susceptible organisms; bacteraemia, septicaemia, neonatal sepsis; serious infections of the respiratory tract, bones and joints, central nervous system, skin and soft tissues, intra-abdominal organs; burns, postoperative infections and recurrent urinary tract infections. **Antibacterial activity**: Amikacin is active, in vitro, against the following organisms. *(Refer to PI)*

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25073565P	METREX (Pemetrexed Lyophilised Powder For Injection 500mg/Vial)	Malignant Pleural Mesothelioma: METREX in combination with cisplatin for the treatment of chemotherapy-naive patients with unresectable malignant pleural mesothelioma. Non-small Cell Lung Cancer: METREX in combination with cisplatin for the 1st-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) other than predominantly squamous cell histology. METREX is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic NSCLC other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First-line treatment should be a platinum doublet with gemcitabine, paclitaxel or docetaxel. METREX is indicated as monotherapy for the 2nd-line treatment of patients with locally advanced or metastatic NSCLC other than predominantly squamous cell histology.
BRU25073566P	HEAMIC-T (Tranexamic Acid Injection 100mg/ml)	Bleeding tendencies in which systemic hyperfibrinolysis is considered to be involved. (Leukemia, aplastic anemia, purpura etc., abnormal bleeding during or after operation.) Abnormal bleeding in which local hyperfibrinolysis is considered to be involved. (pulmonary hemorrhage, nasal hemorrhage, vaginal hemorrhage, renal hemorrhage, abnormal bleeding during or after prostate surgery). Symptoms, such as erythema, swelling or pruritus in the following diseases: Eczema or similar conditions, urticaria, drug eruptions or toxicoderma. Symptoms, such as pharyngalgia, redness, hyperemia or swelling in the following diseases: Tonsillitis, pharyngolaryngitis. Pain in the oral cavity or mucosal aphtha in cases of stomatitis.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25073567P	Diaglycon MR 60mg Modified Release Tablets	Non insulin-dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose.
BRU25073568P	Avorix 0.5mg Film Coated Tablets	Indicated for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. The following points should be considered when initiating therapy with Entecavir: - This indication is based on histologic, virologic, biochemical, and serologic responses in nucleoside-treatment- naïve and lamivudine-resistant adult patients with HBeAg- positive or HBeAg-negative chronic HBV infection with compensated liver disease. - Virologic, biochemical, serologic, and safety data are available from a controlled study in adult subjects with chronic HBV infection and decompensated liver disease. - Virologic, biochemical, serologic, and safety data are available for a limited number of adult subjects with HIV/HBV co-infection who have received prior lamivudine therapy.
BRU25073569P	Xepagan-5 Elixir	Xepagan is indicated for symptomatic relief of allergy such as hay fever, urticaria, treatment of nausea and vomiting and motion sickness; and as sedative for mild insomnia.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25073570P	Xepagan Elixir	Xepagan is indicated for symptomatic relief of allergy such as hay fever, urticaria, treatment of nausea and vomiting and motion sickness; and as sedative for mild insomnia.
BRU25073571P	WINSPIRIN Acetylsalicylic Acid Dispersible Tablet 300mg	Aspirin has analgesic, antipyretic and anti-inflammatory actions. It is indicated for: 1) The relief of headache, toothache, migraine, neuralgia, sore throat, dysmenorrhoea. 2) The symptomatic relief of influenza, feverishness, rheumatic pains, sciatica, lumbago, fibrositis, muscular aches and pains. 3) It also has an antithrombotic action, mediated through inhibition of platelet activation, which has been shown to be useful in secondary prophylaxis following myocardial infarction, and in patients with unstable angina and cerebral transient ischaemic attacks.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25083572P	Dexasone Injection	• Acute lymphoid leukemia • Allergic condition • Asthma • Cerebral edema, Associated with primary or metastatic brain tumor, craniotomy, or head injury • Collagen disease • Disorder of endocrine system • Disorder of eye • Disorder of gastrointestinal tract • Disorder of hematopoietic structure • Disorder of respiratory system • Disorder of skin • Hypercalcemia of malignancy • Immune thrombocytopenia • Inflammatory disorder of musculoskeletal system • Mycosis fungoides • Neoplastic disease, Palliative management of leukemias and lymphomas • Nephrotic syndrome, Idiopathic or due to lupus erythematosus, without uremia • Trichinosis, With neurologic or myocardial involvement • Tuberculosis of meninges, With subarachnoid block or impending block when used concurrently with antituberculosis therapy; Adjunct

BRU25083573P	Moxifcin Eye Drops 0.5% w/v	a) Moxifcin Eye Drop is indicated for the treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of the following organisms: **Gram- positive bacteria**: *Corynebacterium species ** *Microbacterium species* *Micrococcus luteus* [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains]* *Staphylococcus aureus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]* *Staphylococcus epidermidis [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]* *Staphylococcus haemolyticus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]* *Staphylococcus hominis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]* *Staphylococcus warneri* [including erythromycin resistant strains]* *Streptococcus mitis* [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains]* *Streptococcus pneumoniae [including penicillin, erythromycin, gentamicin, tetracycline and/or trimethoprim resistant strains]* *Streptococcus viridians [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains]* **Gram-negative bacteria**: *Acinetobacter species* *Haemophilus "alconae"* [including ampicillin resistant strains] *Haemophilus influenza* [including ampicillin resistant strains] *Klebsiella pneumoniae** *Moraxella catarrhalis** *Pseudomonas aeruginosa**

		Other microorganisms: *Chlamydia trachomatis* **Efficacy for this organism was studied in fewer than 10 infections.* b) Moxifcin Eye Drop is indicated for preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required).
BRU25083574P	Esocard Injection 10mg/ml	**Supraventricular Tachycardia** ESOCARD INJECTION is indicated for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter in perioperative, postoperative, or other emergent circumstances where short term control of ventricular rate with a short acting agent is desirable. ESOCARD INJECTION is also indicated in noncompensatory sinus tachycardia where, in the physician's judgement, the rapid heart rate requires specific intervention. **Intraoperative and Postoperative Tachycardia and/or Hypertension** ESOCARD INJECTION is indicated for the treatment of tachycardia and hypertension that occur during induction and tracheal intubation, during surgery, on emergence from anesthesia, and in the postoperative period, when in the physician's judgement such specific intervention is considered indicated. Use of ESOCARD INJECTION to prevent such events is not recommended.
BRU25083575P	Diaglycon MR 30mg Modified Release Tablets	Non insulin-dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25083576P	Trevive Tablets 100mg	Imatinib mesylate tablets are indicated for the treatment of: • adult and pediatric patients with newly diagnosed chronic myeloid leukaemia (CML) as well as for the treatment of adult and pediatric patients with CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon- alpha therapy. • adult patients with unresectable and / or metastatic malignant gastrointestinal stromal tumours (GIST). • adjuvant treatment of adult patients following resection of GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. • adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy. • adult patients with relapsed or refractory Ph+ ALL as monotherapy. • adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR)gene re-arrangements. • adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangement. • adult patients with unresectable, recurrent and / or metastatic dermatofibrosarcoma protuberans (DFSP). • adult patients with aggressive systemic mastocytosis (ASM) without the D816V c- Kit mutation or with c-Kit mutational status unknown The effectiveness of Imatinib mesylate tablet is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and ASM and on objective response rates in GIST and DFSP, and on recurrence-free survival in adjuvant GIST. The experience with Imatinib mesylate tablet in patients with MDS/MPD associated with PDGFR gene rearrangements is very limited. Except in newly diagnosed chronic phase CML, there are no controlled trials demonstrating a clinical benefit or increased survival in diseases.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25083577P	Trevive Tablets 400mg	Imatinib mesylate tablets are indicated for the treatment of: • adult and pediatric patients with newly diagnosed chronic myeloid leukaemia (CML) as well as for the treatment of adult and pediatric patients with CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon- alpha therapy. • adult patients with unresectable and / or metastatic malignant gastrointestinal stromal tumours (GIST). • adjuvant treatment of adult patients following resection of GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. • adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy. • adult patients with relapsed or refractory Ph+ ALL as monotherapy. • adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR)gene re-arrangements. • adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangement. • adult patients with unresectable, recurrent and / or metastatic dermatofibrosarcoma protuberans (DFSP). • adult patients with aggressive systemic mastocytosis (ASM) without the D816V c- Kit mutation or with c-Kit mutational status unknown The effectiveness of Imatinib mesylate tablet is based on overall haematological and cytogenetic response rates and progression-free survival in CML, on haematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on haematological response rates in HES/CEL and ASM and on objective response rates in GIST and DFSP, and on recurrence-free survival in adjuvant GIST. The experience with Imatinib mesylate tablet in patients with MDS/MPD associated with PDGFR gene rearrangements is very limited. Except in newly diagnosed chronic phase CML, there are no controlled trials demonstrating a clinical benefit or increased survival in diseases.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25083578P	Pergoveris (300 IU + 150 IU)/0.48mL Solution For Injection In Pre-Filled Pen	Pergoveris is indicated for the stimulation of follicular development in adult women with severe LH and FSH deficiency.
BRU25083579P	Pergoveris (900 IU + 450 IU)/1.44mL Solution For Injection In Pre-Filled Pen	Pergoveris is indicated for the stimulation of follicular development in adult women with severe LH and FSH deficiency.
BRU25083580P	CO-AMOXICLAV For Injection 1.2g	Co-Amoxiclav is for short-term treatment of bacterial infections at the following sites: • Upper respiratory tract infections [including eyes, ears, nose (EENT)] e.g., recurrent tonsillitis, sinusitis, otitis media. • Lower respiratory tract infections e.g., acute exacerbation of chronic bronchitis, lobar, and bronchopneumonia. • Skin and soft tissue infections e.g., boils, abscesses, cellulitis, wound infections. Bone and joint infections e.g., osteomyelitis. • Other infections e.g., dental infections, septic abortion, puerperal sepsis, intra-abdominal sepsis. Also septicemia, peritonitis, and postsurgical infections. Co-Amoxiclav is also indicated for prophylaxis against infection which may be associated with major surgical procedures e.g., gastrointestinal, pelvic, head and neck, cardiac, renal, joint replacement, and biliary tract.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25083581P	Sedilix-Rx Linctus	Sedilix-Rx is indicated for the relief of dry irritating coughs such as those associated with common cold or upper respiratory tract infections. Sedilix-Rx helps to relieve nasal congestion, sneezing and rhinorrhoea associated with allergy and the common cold.
BRU25083582PS1; BRU25083582PS2	Soliris 10mg/ml Concentrate For Solution For Infusion	Soliris is indicated in adults and children for the treatment of: - Paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history (see section 5.1). - Atypical haemolytic uremic syndrome (aHUS) (see section 5.1). - Refractory generalized myasthenia gravis (gMG) in patients aged 6 years and above who are anti-acetylcholine receptor (AChR) antibody-positive (see section 5.1). Soliris is indicated in adults for the treatment of: - Neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody-positive with a relapsing course of the disease (see section 5.1).
BRU25083583P	Clomazol Cream 1% w/w	For topical treatment of tinea pedis, tinea cruris, tinea corporis, candidiasis and tinea versicolor.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25083584NP	Three Legs Antiseptic Cream	As an antiseptic for skin lesions, cuts, abrasions, infected wounds and burns.
BRU25083585P	Orphenamol Tablet	Tension headache, occipital headaches associated with spasm of skeletal muscles in the region of the head and neck. Acute and traumatic conditions of the limbs and trunk: sprains, strains, whiplash injuries, acute torticollis, prolapsed intervertebral disc.
BRU25083586P	Vaxcel Azithromycin 500mg IV For Infusion	Azithromycin intravenous (IV) is indicated for the treatment of community acquired pneumonia (CAP) caused by susceptible organisms, including Legionella pneumophila, in patients who require initial intravenous therapy. Azithromycin intravenous (IV) is indicated for the treatment of pelvic inflammatory disease (PID) caused by susceptible organisms (Chlamydia trachomatis, Neisseria gonorrhoea, Mycoplasma hominis), in patients who require initial intravenous therapy.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25083587P	Pharmaniaga Fentanyl 50mcg/ml Injection	Fentanyl is a short acting opioid used • as an intravenous analgesic agent in surgical procedures. • as an adjunct in the maintenance of general anaesthesia. • in combination with a neuroleptic agent in the technique of neuroleptanalgesia. • as a respiratory depressant/analgesic in patients requiring prolonged assisted ventilation. • for induction of anaesthesia.
BRU25103588P	Oxaliplatin 5mg/ml Concentrate For Solution For Infusion	Oxaliplatin in combination with 5-fluorouracil (5-FU) and folinic acid (FA) is indicated for: • Adjuvant treatment of stage III (Dukes C) colon cancer after complete resection of primary tumour. • Treatment of metastatic colorectal cancer.
BRU25103589P	Linmycin Injection 300mg/ml	For the treatment of serious infections due to streptococci, pneumococci, staphylococci and other susceptible organisms. It may be administered concomitantly with other antimicrobial agents when indicated.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25103590P	Lycan Injection 2% w/v	Lidocaine is intended for the production of local or regional anaesthesia by nerve block, infiltration injection, caudal or other epidural blocks: Treatment or prophylaxis of life-threatening ventricular arrhythmias, including those associated with myocardial infarction, general anaesthesia in patients predisposed to ventricular arrhythmias, digitalis intoxication, or following resuscitation from cardiac arrest.
BRU25103591P	Hemlibra Solution For Injection 30mg/ml	Hemlibra is indicated for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes in adults and children with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors. Hemlibra can be used in all age groups.
BRU25103592P	Hemlibra Solution For Injection 150mg/ml	Hemlibra is indicated for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes in adults and children with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors. Hemlibra can be used in all age groups.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25103593NP	Infusol® D10	- Energy supply - Hypertonic dehydration - Vehicle solution for supplementary medication - Hypoglycaemia
BRU25103594P	Ondatron (Ondansetron Injection BP 2mg/ml)	Adults: Ondansetron injection is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy. Ondansetron injection is also indicated for the prevention and treatment of post-operative nausea and vomiting. Paediatric Population Injection and oral formulations: Ondansetron is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy. No studies have been conducted on the use of orally administered ondansetron in the prevention or treatment of post-operative nausea and vomiting; IV injection is recommended for this purpose.
BRU25103595P	Taminfate (Protamine Sulfate 10mg/ml Solution For Injection)	Protamine sulfate is used to counteract the anticoagulant effect of heparin: before surgery; after renal dialysis; after open-heart surgery; if excessive bleeding occurs and when an overdose has inadvertently been given.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25103596NP	HospiCare 4% Chlorhexidine Surgical Hand Wash	For antimicrobial hand washing, surgical hand washing and body washing.

LIST OF REGISTERED MEDICINAL PRODUCTS WITH INDICATION (UPDATED NOVEMBER 2025)

BRU25103597P	Lipostat 10mg FC Tablet	Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), and triglycerides (TG) and to increase high density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial hypercholesterolemia), combined (mixed) hyperlipidaemia (Fredrickson Types IIa and IIb), elevated serum TG levels (Fredrickson Type IV), and for patients with dysbetalipoproteinaemia (Fredrickson Type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total-C and LDL-C in patients with homozygous familial hypercholesterolemia. *Prevention of Cardiovascular Disease* In adult patients without clinically evident cardiovascular disease (CVD), but with multiple risk factors for coronary heart disease (CHD) such as age, smoking, hypertension, low HDL-C, or a family history of early CHD, Atorvastatin is indicated to: - Reduce the risk of myocardial infarction (MI) - Reduce the risk of stroke - Reduce the risk for revascularization procedures and angina In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for coronary heart disease such as retinopathy, albuminuria, smoking, or hypertension, atorvastatin is indicated to: - Reduce the risk of myocardial infarction - Reduce the risk of stroke

		In patients with clinically evident CHD, atorvastatin is indicated to: - Reduce the risk of non-fatal MI - Reduce the risk of fatal and non-fatal stroke - Reduce the risk for revascularization procedures - Reduce the risk of hospitalization for congestive heart failure (CHF) - Reduce the risk of angina *Paediatric Patients (10-17 years of age)* Atorvastatin is indicated as an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: - LDL-C remains ≥190 mg/dL or - LDL-C remains ≥160 mg/dL and • There is a positive family history of premature CVD or • Two or more other CVD risk factors are present in the paediatric patient
BRU25103598P	Zamir 15 Tablet	Mirtazapine is indicated in adults for the treatment of episodes of major depression.
BRU25103599P	Zamir 30 Tablet	Mirtazapine is indicated in adults for the treatment of episodes of major depression.
BRU25103600NP	Wina Oral Liquid Paraffin 100% w/w	For the temporary relief of constipation.