

Telex : KK BU 2421
Telegram : MINHEALTH BRUNEI
Telephone : 2381640
Fax : 2382032



كمنترين كصيحائن
KEMENTERIAN KESIHATAN
MINISTRY OF HEALTH
JALAN MENTERI BESAR
BANDAR SERI BEGAWAN BE3910
NEGARA BRUNEI DARUSSALAM

Ref: (20)DGMHS/5/2018/B Pt.6

25th June 2024

Dear Product Licence Holders and Importers,

**DIRECTIVE FOR BROMHEXINE CONTAINING PRODUCTS IN BRUNEI DARUSSALAM:
UPDATE ON PRODUCT LABELLING / PACKAGE INSERT ON ITS USE IN CHILDREN**

The Brunei Darussalam Medicines Control Authority in its 47th Meeting held on 22nd June 2024 has reviewed and updated the requirement for registration of all Bromhexine containing products including those that are currently registered and marketed in Brunei Darussalam. This update is due to public safety concerns, considering that these products are classified as General Sale List Medicines and can be purchased without a prescription from a doctor or supervision of a pharmacist.

2. All Product Licence Holders and importers are therefore required to update the product labelling / package insert of all Bromhexine containing products to include the following information:
 - Do not use in children under 6 years of age unless advised by the doctor / pharmacist
 - Use with caution upon the advice of the doctor / pharmacist in children 6 to 12 years of age
 - Do not use for more than 5 days
 - If cough persists, please consult your doctor.
3. The implementation date on the requirement is as follows:
 - i) New applications and applications which are still in process of registration: **immediate effect commencing 26 June 2024**
 - ii) Registered products: **26 December 2024.**
4. Update on product labelling / package insert for registered products is required to be submitted as variation application prior to the implementation date.

Thank you for your kind attention and cooperation in this matter.

Yours sincerely,

Chair

Brunei Darussalam Medicines Control Authority
Ministry of Health
Brunei Darussalam