

DPS

DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BANDAR SERI BEGAWAN
BRUNEI DARUSSALAM



جابتن فر خدمتن فر ماسي

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Rujukan Kami : (06) PRS/ADMIN/2021
Our Reference

18 Rabiulawal 1443
25 October 2021

Dear Product Licence Holders and Importers,

**DIRECTIVE FOR PRODUCTS CONTAINING SALICYLIC ACID DERIVATIVES IN BRUNEI DARUSSALAM:
UPDATE ON PRODUCT LABELLING / PACKAGE INSERT ON ITS USE IN CHILDREN, PREGNANT &
BREASTFEEDING WOMEN**

The Brunei Darussalam Medicines Control Authority in its 38th Meeting held on 12th July 2021 has reviewed and determined for all products containing salicylic acid derivatives, including but not limited to methyl salicylate, glycol salicylate and wintergreen which are registered and marketed in Brunei Darussalam to be updated to include information on warnings and precautions on its use in children, pregnant and breastfeeding women. This is due to public safety concerns that may arise with the use of these products which are readily available off the shelf without medical supervision and advice.

2. This directive applies to medicinal products as well as traditional medicines and health supplements which contain salicylic acid derivatives.
3. This directive now supersedes the Directive for Methyl Salicylate & Methyl Salicylate / Menthol / Camphor containing Products in Brunei Darussalam: Update on Product Labelling / Package Insert on its Use in Children, Pregnant & Breastfeeding Women, ref: (245) DPS/ADMIN/2019/2020 dated 27th January 2020. A separate directive shall be issued specifically for camphor containing products.
4. All product licence holders and importers are therefore required to comply with the directive and update the package insert / product labelling on all products containing salicylic acid derivatives to include the following information:

i) Products containing Salicylic Acid Derivatives:

- This product should not be used in children under 2 years of age.
- Use with caution in older children, in pregnant women and breastfeeding women. Avoid excessive use on large areas of the skin. If symptoms persist, please consult your doctor. Breast-feeding women should avoid use around the chest area or any parts of the skin that may come into contact with the nursing child.
- If you are taking warfarin, please consult your doctor before using this product.

30/10/21

ii) Products containing Salicylic Acid Derivatives & Menthol:

- This product should not be used in children under 2 years of age.
 - Use with caution in older children.
 - Do not use during pregnancy or when breastfeeding.
 - If you are taking warfarin, please consult your doctor before using this product.
5. The requirement to update the above information on all products containing salicylic acid derivatives shall be implemented with **immediate effect** commencing **25th October 2021**.
6. Update on product labelling / package insert for registered products containing salicylate acid derivatives is required to be submitted as variation application.

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

Yours sincerely,



(Hjh Zanatul 'Aini Hj Zainin)

Acting Director of Pharmaceutical Services
For Chair of BDMCA