

DPS

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



جابتن فر خدمتن فر ماسي

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Our Reference

24 Rabiulakhir 1443
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Dear Product Licence Holders and Importers,

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

The Brunei Darussalam Medicines Control Authority in its 39th Meeting held on 24th November 2021 has issued a directive mandating all products containing camphor which are registered and marketed in Brunei Darussalam to be updated to include information on warnings and precautions on its use in children. This is due to public safety concerns of these products being sold in retail without medical supervision or appropriate medical advice.

2. This directive applies to medicinal products as well as traditional medicines and health supplements which contain camphor.
3. This directive 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 and Breastfeeding Women, ref: (245) DPS/ADMIN/2019/2020 dated 27th January 2020.
3. 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 camphor to include the following information:
 - This product is contraindicated in children below 2 years of age.
 - Use with caution in older children.
 - This product can cause convulsion.
 - It is dangerous to place any camphor containing product into the nostril of children. A small amount applied this way may cause immediate collapse.
4. The requirement to update the above information on all products containing camphor shall be implemented with **immediate effect** commencing **29th November 2021**.
5. Update on product labelling / package insert for registered products containing camphor 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