

DPS

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



جابتن فر خدمتن فر ماسي

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Rujukan Kami : (57) DPS/ADMIN/2020
Our Reference

24 Safar 1442
12 October 2020

Dear Product Licence Holders and Importers,

DIRECTIVE FOR DOMPERIDONE CONTAINING PRODUCTS IN BRUNEI DARUSSALAM: UPDATE ON PRODUCT LABELLING / PACKAGE INSERT ON ITS USE IN CHILDREN UNDER 12 YEARS OF AGE OR THOSE WEIGHING LESS THAN 35KG

The Brunei Darussalam Medicines Control Authority in its 35th Meeting held on 19 August 2020 has determined for all domperidone containing products marketed or registered in Brunei Darussalam to update information on its use in children under 12 years of age or those weighing less than 35kg. The decision was based on reviews by regulatory authorities in the United Kingdom and Europe on the effectiveness of domperidone containing products in children as there is lack of efficacy evidence to support the product use in paediatrics.

2. Therefore, you are required to update the product labelling/package insert to remove the indication in children under 12 years of age or those weighing less than 35kg on all products containing domperidone. The implementation date on the requirement is as follows:

- i) New applications and applications that are still in process of registration: **01 November 2020**
- ii) Registered products: **01 May 2021** (grace period of 6 months from the effective date). Update on product labelling / package insert for **registered** products is required to be submitted as variation application prior to the implementation date.

3. The effective date of implementation of this directive is **01 November 2020**.

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

Yours sincerely,

Handwritten signature of Wong Wai See in blue ink.
(WONG WAI SEE)

Director of Pharmaceutical Services
For Chair of BDMCA