

DPS

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



جايتن فر خدمتن فر ماسي

JABATAN PERKHIDMATAN FARMASI
SIMPANG 433,
KAMPONG MADARAS,
MUKIM GADONG A,
NEGARA BRUNEI DARUSSALAM

Rujukan Kami :
Our Reference : (230)DPS/ADMIN/2018

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14 Rabiulakhir 1441
11 December 2019

Dear Product Licence Holders and Importers,

IMPORTATION AND SALE OF METFORMIN PRODUCTS IN BRUNEI DARUSSALAM

There have been recent reports that N-nitrosodimethylamine (NDMA), a probable human carcinogen, has been detected in amounts beyond accepted levels in several Metformin containing products, through our pharmacovigilance activities. The presence of internationally unacceptable levels of NDMA has resulted in recalls of several brands of Metformin containing products by the regulatory authority in Singapore. There is currently no regulatory action on Metformin containing products in Brunei Darussalam.

As a precautionary measure, the Department of Pharmaceutical Services has decided for all Metformin containing products in Brunei Darussalam to be placed under close vigilance. In our continuous effort to monitor the importation and sale of Metformin containing products, all product licence holders and importers are required to provide the following documents for every consignment coming into Brunei Darussalam:

- i) The batch numbers and quantity of the finished products that are planned to be imported into Brunei Darussalam including where it is to be supplied
- ii) Certificate of Analysis of Finished Product corresponding to the batch imported into Brunei Darussalam
- iii) Certificate of Analysis of the Active Pharmaceutical Ingredient used to manufacture the finished product corresponding to the batch imported into Brunei Darussalam
- iv) Information on impurity level of NDMA of the specific batch imported into Brunei Darussalam

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

Yours sincerely,

(WONG WAI SEE)

Acting Director of Pharmaceutical Services
For Chair of BDMCA