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BANDAR SERI BEGAWAN BE3910
NEGARA BRUNEI DARUSSALAM

Ref: (22)DGMHS/5/2018/B Pt.6

25th June 2024

Dear Product Licence Holders and Importers,

DIRECTIVE FOR PRODUCTS CONTAINING ANGIOTENSIN-II RECEPTOR BLOCKERS (ARBs) IN BRUNEI DARUSSALAM: UPDATE ON PACKAGE INSERT WITH SAFETY INFORMATION RELATED TO CONCOMITANT USE WITH ALISKIREN-CONTAINING PRODUCTS AND ACE INHIBITORS

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 Angiotensin-II Receptor Blockers (ARBs) including those that are currently registered and marketed in Brunei Darussalam. This update is also in line with the current package insert for registered ARB containing products in other drug regulatory authorities such as UK, Singapore, Canada and Australia.

2. This directive now supersedes the Directive for losartan containing products in Brunei Darussalam: Update on Package Insert on Contraindications and Drug Interactions, ref: (09) DGMHS/5/2018/B PT.5 dated 2 December 2023.

3. All Product Licence Holders and importers are therefore required to update the package insert of all products containing ARBs to include the following information:
   a) Under 'Contraindications':
      Concomitant use of (active ingredient of ARB) with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m^2)

   b) Under 'Drug Interactions':
      ACE inhibitors: The use of (active ingredient of ARB) with an ACE inhibitor may increase the risk of hyperkalaemia, hypotension, and syncope, particularly in patients with atherosclerotic disease or heart failure, or in diabetics who have end-organ damage. Such combinations should be reserved for selected cases with close monitoring of renal function.

4. 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**.

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5. Update on 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