衞生署藥物辦公室
藥物資訊及警戒科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

電話號碼 Tel. No.: 3974 4175
詢問處 Enquiries: (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND PHARMACOVIGILANCE DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

(來函請敍明此檔案號碼) DH DO PRIE/7-30/15
(IN REPLY PLEASE QUOTE THIS FILE REF.)

10 Sep 2021

Dear Healthcare Professionals,

Erenumab and hypertension

Your attention is drawn to the Therapeutic Goods Administration's (TGA) announcement that the Product Information (PI) for erenumab has been updated with a warning statement about a potential causal relationship between the drug and hypertension.

The 'Special Warnings and Precautions' section (Section 4.4) of the PI for erenumab has been updated to state that development of hypertension and worsening of pre-existing hypertension have been reported following use of the drug in the postmarketing setting internationally. Many of the affected patients had pre-existing hypertension or risk factors for hypertension. There were cases requiring pharmacological treatment and, in some cases, hospitalisation.

Hypertension can occur at any time during treatment, but it was most frequently reported within 7 days of dose administration. In the majority of cases, the onset or worsening of hypertension was reported after the first dose of erenumab. The drug was discontinued in many of the reported cases. There has been one report of hypertension associated with erenumab reported in Australia, to the TGA.

Additionally, hypertension has been added under 'Vascular disorders' in the 'Adverse Effects' section (Section 4.8) of the erenumab PI.

Health professionals are advised:

- If they are treating a patient with erenumab, they should monitor them for new-onset hypertension or worsening of pre-existing hypertension.
- If hypertension is observed and evaluation fails to establish an alternative etiology, consider whether discontinuation of erenumab is warranted.

Please refer to the following website in TGA for details:
https://www.tga.gov.au/publication/erenumab-and-hypertension

In Hong Kong, there are 2 registered pharmaceutical products containing erenumab, namely Aimovig Solution For Injection In Pre-filled Pen 70mg/ml (HK-66406) and Aimovig Solution For Injection In Pre-filled Pen 140mg/ml (HK-66847). Both products are registered by Novartis Pharmaceuticals (HK) Limited, and are prescription-only medicines. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction related to erenumab, of which one case is related to hypertension. In light of the above TGA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Ling PANG)
for Assistant Director (Drug)