

衛生署藥物辦公室  
藥物註冊及進出口管制部

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本署編號 OUR REF.:

DH DO PRIE/7-30/15

(來函請註明此檔案號碼)  
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Donald LI  
President  
Hong Kong Academy of Medicine  
(Fax Number: 2505 5577)

Dear Dr. LI,

**Ivabradine (Coralan): risk of cardiovascular events in patients with angina**

Your attention is drawn to the Therapeutic Goods Administration's (TGA) announcement regarding updated Product Information (PI) to reduce the risk of cardiovascular events in patients who take ivabradine for angina.

Ivabradine is a heart rate lowering agent that can be used to treat the symptoms of chronic stable angina or treatment of symptomatic chronic heart failure. The changes to the PI in Australia, which are based on a phase III clinical study, include updated indications and contraindications and other information to reduce the risk of cardiovascular events in patients with angina.

The TGA advises healthcare professionals that if they are treating a patient who is taking ivabradine for angina, they should review the updated indications, contraindications, precautions and interactions sections. In particular, ivabradine must not be used in patients who have a pre-treatment resting heart rate below 70 bpm. Ivabradine should not be taken concomitantly with potent cytochrome P450 3A4 [CYP3A4] inhibitors or moderate CYP3A4 inhibitors with heart rate reducing properties, including diltiazem and verapamil. Healthcare professionals should educate patients regarding the signs and symptoms of the cardiovascular events identified in the PI and instruct them to seek medical attention if any are suspected. An existing warning regarding a potential interaction with grapefruit juice has also been strengthened to advise that drinking grapefruit juice should be avoided (rather than 'restricted').

Please refer to the TGA's website for details:

<https://www.tga.gov.au/alert/ivabradine-coralan>

In Hong Kong, there are two registered pharmaceutical products containing ivabradine, namely Coralan Tab 7.5mg (HK-55438) and Coralan Tab 5mg (HK-55439). Both are prescription-only medicines registered by Servier Hong Kong Ltd (Servier). Related news has been released by the TGA and the EMA, and was posted on the Drug Office website on 9 May, 23 June, 8 November and 22 November 2014. Servier has applied to the Department of Health (DH) to include the relevant information in the package insert of the products, and the application is under evaluation. So far, the DH has not received any adverse drug reaction report on ivabradine. In view of the TGA's announcement on update of PI, the matter will be discussed in the meeting of 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.

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aspire to be an internationally renowned public health authority*



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BY FAX

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Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: [adr@dh.gov.hk](mailto: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 sincerely,



(Grant NG)

for Assistant Director (Drug)

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