Dilatrend (carvedilol) – Warning on risk of severe skin reactions

Your attention is drawn to the Singapore Health Sciences Authority’s (HSA) announcement regarding the risk of severe skin reactions associated with the use of Dilatrend (carvedilol).

From a review of the cumulative data from the manufacturer’s safety database, very rare cases of severe cutaneous adverse reactions such as toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) have been reported during treatment with carvedilol. The package insert for Dilatrend will be updated with this important new safety information in Singapore. Healthcare professionals are recommended to consider permanently discontinuing the use of Dilatrend in patients who experience severe cutaneous adverse reactions possibly attributable to carvedilol.

Please refer to HSA’s website for details:

In Hong Kong, there are a total of 27 carvedilol containing pharmaceutical products including Dilatrend Tab 25mg (HK-36984), Dilatrend Tab 12.5mg (HK-42821) and Dilatrend Tab 6.25mg (HK-42822) which are registered by Roche Hong Kong Limited (Roche). All of them are prescription only medicines indicated for the treatment of hypertension, angina pectoris and stable chronic heart failure. According to Roche, a letter to healthcare professionals has been issued on 1 April 2014 to draw their attention to the issue, and the company will submit an application to the Department of Health (DH) to update the package insert of the products to include the relevant warnings and precautions. In view of the HSA’s announcement, the matter will be brought up to the Product Registration Committee of the Pharmacy and Poisons Board for consideration of updating the product label/insert to include the relevant warning. So far, the DH has not received any adverse reaction report in connection with the drug. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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 sincerely,

[Signature]

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for Assistant Director (Drug)

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