

衛生署藥物辦公室
藥物註冊及進出口管制部

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Health Canada: Domperidone Maleate - Association with Serious Abnormal Heart Rhythms and Sudden Death (Cardiac Arrest)

Your attention is drawn to that Health Canada announced domperidone should be initiated at the lowest possible dose in adults due to an increased risk of abnormal heart rhythms and sudden death (cardiac arrest). Domperidone is indicated in adults for the symptomatic management of upper gastrointestinal (GI) motility disorders associated with gastritis and diabetic gastroparesis, it is also indicated to prevent GI symptoms associated with the use of dopamine agonist antiparkinsonian agents.

Recent epidemiological studies have shown that the use of domperidone may be associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death, particularly in patients taking daily doses greater than 30 mg, and in patients older than 60 years of age. It is recommended that domperidone should be initiated at the lowest possible dose, including in patients with Parkinson's disease. Caution should be exercised when using domperidone concomitantly with drugs that prolong the QT interval, in patients who have existing prolongation of cardiac conduction intervals, particularly QTc, and in patients with significant electrolyte disturbances or underlying cardiac disease such as congestive heart failure.


The manufacturers of all domperidone products are working with Health Canada to include this new drug dosage and usage recommendations, as well as information about the risk of serious ventricular arrhythmias and sudden cardiac death, in all Canadian Product Monographs for domperidone. For details, please refer to Health Canada's website:

http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2012/domperidone_hpc-cps-eng.php

In Hong Kong, there are 53 registered pharmaceutical products containing domperidone. The issue has been discussed in the meeting of The Registration Committee of the Pharmacy and Poisons Board on 28 February 2012. The Committee decided that the sales pack or package insert of domperidone-containing products should be updated to include the appropriate safety information. Department of Health will keep vigilant against any updated safety news related to the drug.

Please report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the following website at Drug Office under "Reporting an Adverse Drug Reaction": http://www.drugoffice.gov.hk/eps/root/en/healthcare_providers/adr_reporting/index.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,


(Ms Pamela LI)
for AD(D)

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