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

The manufacturers of domperidone in collaboration with Health Canada announced an important additional safety information regarding a small increased risk of serious ventricular arrhythmias or sudden cardiac death in association with domperidone.

Domperidone is indicated in adults for the symptomatic management of upper gastrointestinal motility disorders associated with chronic and subacute gastritis and diabetic gastroparesis. Domperidone is also indicated to prevent gastrointestinal symptoms associated with the use of dopamine agonist antiparkinsonian agents.

A review of epidemiological studies and recent post-market safety data has demonstrated that domperidone exposure was associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. Based on this new evidence, the labelling of domperidone is being further strengthened to better reflect and address these cardiac risks.

- Domperidone may be associated with a small increased risk of serious ventricular arrhythmias or sudden cardiac death. A higher risk was observed in patients:
    - older than 60 years of age;
    - using daily doses greater than 30 mg;
    - having predisposing factors for QT prolongation including concomitant use of QT-prolonging drugs or CYP 3A4 inhibitors.
- Domperidone is now contraindicated in patients:
    - with prolongation of cardiac conduction intervals, particularly QT;
    - with significant electrolyte disturbances;
    - with cardiac disease (such as congestive heart failure);
    - with moderate or severe liver impairment;
    - receiving QT-prolonging drugs and potent CYP3A4 inhibitors.
- Domperidone should be used at the lowest effective dose to a maximum recommended daily dose of 30 mg and for the shortest possible duration.

Healthcare professionals should consider doing a cardiac assessment in patients at higher risk for QT interval prolongation and/or cardiac arrhythmia including an electrocardiogram (ECG) prior to initiation of domperidone and during treatment.

Patients should be advised to stop taking domperidone and seek immediate medical

attention if they experience signs or symptoms of an abnormal heart rate or rhythm while taking domperidone.

Please refer to the following website in Health Canada for details:
http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2015/43423a-eng.php

In Hong Kong, there are 47 registered pharmaceutical products containing domperidone. They can be sold without prescriptions at a registered pharmacy under the supervision of pharmacist. A number of related news regarding the risk of cardiac disorder has been released by various health authorities, and was posted on the Drug Office website since 2012. Letters to inform healthcare professionals were issued on 8 March 2012 and 10 March 2014. So far, the DH has not received any adverse drug reaction reports on the use of domperidone.

The matter was discussed in the meeting of the Registration Committee (The Committee) of the Pharmacy and Poisons Board on February 2012 and May 2014. The Committee came to the following decision:

- To update the sales pack or package insert of domperidone-containing products to include the appropriate safety information related to cardiovascular risk.
- To deregister all suppositories containing domperidone effective from 1 October 2014 as their benefits no longer outweigh the risks.
- To tighten control over the sale oral domperidone products so that they can only be sold with a prescription at pharmacies under the supervision of pharmacists.

The legislative amendments are undergoing. The DH will remain vigilant on the safety updates of the drug.

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