FDA ADVISORY
No. 20240196

31 JAN 2024

TO : **ALL HEALTHCARE PROFESSIONALS AND GENERAL PUBLIC**

SUBJECT : **Safety Information: Domperidone and increased risk of serious ventricular arrhythmia**

Domperidone is a dopamine antagonist with pro-kinetic, antiemetic properties. Studies have shown that oral domperidone increases lower esophageal pressure, improves antraduodenal motility and accelerates gastric emptying. There is no effect on gastric secretion.

In the Philippines, the approved indications for Domperidone include: dyspeptic symptom complex that is often associated with delayed gastric emptying, gastroesophageal reflux and esophagitis: epigastric sense of fullness, early satiety, feeling of abdominal distension, upper abdominal pain; bloating, eructation, flatulence; nausea and vomiting; heartburn with or without regurgitation of gastric contents in the mouth, nausea and vomiting of functional organic, infectious or dietetic origin or induced by radiotherapy or drug therapy, nausea and vomiting induced by dopamine agonist in the treatment of Parkinson's disease (e.g., Levodopa and Bromocriptine).

The Food and Drug Administration conducted literature review to assess the safety of Domperidone considering regulatory actions made by other countries in response to an epidemiological study showing that Domperidone is associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death. A higher risk was observed in patients older than 60 years, patients taking daily doses greater than 30 mg, and patients concurrently taking QT-prolonging drugs *(e.g. disopyramide, quinidine, amiodarone, dofetilide, dronedarone, ibutilide, sotalol, haloperidol, pimozide, sertindole, citalopram, escitalopram)* or CYP3A4 inhibitors *(e.g. clarithromycin, erythromycin, itraconazole, oral ketoconazole, posaconazole, ritonavir, saquinavir, telithromycin, telaprevir and voriconazole)*.

The Philippine data to date, showed that out of 97 reports of suspected adverse reaction to Domperidone, four (4) reports involve QT prolongation and irregular heartbeat. All cases have other co-morbidities and concomitant drugs taken during the administration of Domperidone, none of the cases resulted in death/fatal outcome.

Safety Information for Healthcare Professionals:

1. Doctors should prescribe Domperidone with the lowest effective dose for the shortest possible duration, having caution in older patients and with a history of cardiac disease.

2. Pharmacists are advised to dispense Domperidone considering the contraindications and special warnings and precautions on its use particularly on cardiovascular effects.
3. Prescribe or advise the patient to take the lowest dose for shortest time up to a maximum daily dose of 3 tablets (30 mg/day).
4. Healthcare professionals are also encouraged to report adverse reactions, including any cardiac events, related to the use of Domperidone.

Safety Information for the General Public:

1. Patients who have heart problems or are taking cardiac medicines should consult your doctor or pharmacist prior to taking Domperidone.
2. Domperidone should only be used for a short period of time.
3. Seek medical attention immediately if you experience heart-related symptoms such as irregular heartbeat.
4. Report to your healthcare professional any adverse reactions on the use of Domperidone.

For more information, visit us at https://www.fda.gov.ph/pharmacovigilance/ and you may report any adverse drug reaction to https://bit.ly/FDAPHReportSideEffect, or send us an email at pharmacovigilance@fda.gov.ph.

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