Direct Healthcare Professional Communication

October 18, 2020

Dear Healthcare Professional,

This letter is being sent in agreement with Johnson & Johnson Middle East Branch and Saudi Food and Drug Authority (SFDA).
This letter is to inform you that domperidone label will be updated soon in SFDA regarding the posology, indicating domperidone is for use in adults and adolescents only. It is also intended to remind you of the approved indication and the contraindications of domperidone-containing products, to minimize the risks of serious cardiac side effects.

Summary

- The only registered indication for domperidone is the relief of symptoms of nausea and vomiting in adults and adolescents 12 years of age and older and weighing 35 kg or more. The indication in younger children has been deleted and the product label will be updated accordingly.

- Domperidone products are contraindicated in the following patients;
    - Patients with moderate to severe hepatic impairment
    - Patients who have known existing prolongation of cardiac conduction intervals (particularly QTc)
    - Patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure
    - During co-administration with QT-prolonging drugs
    - During co-administration with potent CYP3A4 inhibitors (regardless of their QT-prolonging effects)

- Information on side effects predominantly in very young children was deleted because it was no longer relevant to the approved indication.

- The benefits remain to outweigh the risks in this indication.

Further information

A placebo-controlled study in children below the age of 12 with acute nausea and vomiting using the new lower dosage as an add-on to oral rehydration did not show any difference in efficacy and safety compared with placebo, and based on the study results, the posology of domperidone products was restricted to adults and adolescents above the age of 12 and weighing ≥35 kg.
All healthcare professionals are reminded of the safe use of domperidone-containing products in accordance with the product information.

This review confirmed the risk of serious cardiac adverse drug reactions related to domperidone use including QTc prolongation, torsade de pointes, serious ventricular arrhythmia and sudden cardiac death. It was concluded that risk minimization measures are necessary in order to improve the benefit/risk balance including:

- Restricting the registered indication to the relief of symptoms of nausea and vomiting.
- Use of lower doses: 10 mg up to 3 times daily with a maximum dose of 30 mg per day for adults and adolescents 12 years of age and older and weighing ≥35 kg.
- Shorter treatment duration: use for the shortest possible duration, and the maximum treatment duration should not usually exceed 1 week.
- Addition of the following contraindications:
    - Patients with moderate to severe hepatic impairment.
    - Conditions where the cardiac conduction intervals, particularly QTc, are impaired or could be affected and underlying cardiac diseases as congestive heart failure.
    - Patients with significant electrolyte disturbances.
    - And/or co-administered with QT-prolonging drugs or potent CYP3A4 inhibitors including apomorphine, unless the benefit of co-administration with apomorphine outweighs the risks, and only if the recommended precautions for co-administration mentioned in the apomorphine SmPC are strictly fulfilled.

- Addition of warnings and precautions regarding cardiovascular effects of domperidone.

The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Call for reporting
Healthcare professional should report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system:

SFDA (National Pharmacovigilance Center)
Email: npc.drug@sfda.gov.sa
Telephone: 19999
Fax: +966 11 2057662
Online: http://ade.sfda.gov.sa

Company Contact Points:
If you have further question or require additional information, please contact our local safety department at:
Email: GCC-PV2@its.ini.com
PV Hotline: +966540015811

Yours Truly,

Hesham Helwa

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Medical Director - GCC Countries