SFDA

Safety Communication

[17/02/2025]

Reminder on Restrictions of the Use of Domperidone Containing Products in Pediatrics

The Saudi Food and Drug authority (SFDA) would like to remind healthcare professionals that domperidone-containing products are not approved for use in children under 12 years of age or those weighing less than 35 kg. The only approved indication for domperidone is the relief of symptoms of nausea and vomiting in adults and adolescents aged 12 years and older and weighing 35 kg or more.

Domperidone-containing products have been approved in Saudi Arabia since 1981 and are available in the form of tablets and oral suspension under various trade names. For a list of registered drugs in Saudi Arabia, please refer to the SFDA Drug List.

Domperidone works by blocking dopamine receptors in both the gut and the brain's vomiting center, helping to prevent nausea and vomiting.

In 2020, the SFDA reviewed all the available evidence regarding the efficacy and safety of domperidone for nausea and vomiting in children under 12 years of age. Based on this review , the SFDA requested a label update restricting domperidone use to adults and adolescents aged 12 years old and older and weighing 35 kg or more due to lack of efficacy evidence in children under 12 years and serious cardiovascular risks , including QT interval prolongation, serious ventricular arrhythmias and sudden cardiac death. At that time, a Direct healthcare professionals communication (DHPC) letter was issued to inform healthcare professionals about these risks.

Advice for Healthcare Professionals:

- currently, Domperidone is only approved for the relief of nausea and vomiting in adults and adolescents aged 12 years and older and weighing 35 kg or more.

- Use the lowest effective for the shortest possible duration. The maximum treatment duration should not exceed one week.
- Domperidone is contraindicated in :
    - Patients with moderate to severe hepatic impairment
    - Patients with known QT prolongation or other cardiac conduction disorders.
    - Patients with significant electrolyte disturbances or underlying cardiac diseases, such as congestive heart failure.
    - Patients concomitantly taking QT-prolonging drugs or potent CYP3A4 inhibitors.
- Healthcare professionals should remain vigilant regarding potential risk of serious cardiac adverse reactions associated with the use of domperidone.

For more details, please refer to **the Summary of Product Characteristics (SPC) of the product** available at: https://sdi.sfda.gov.sa/.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:
The National Pharmacovigilance Centre (NPC):
Fax: +966-11-205-7662
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

aRMM: