Apr 06, 2025

Direct Healthcare Professional Communication

Prokinin® (domperidone) is not indicated in pediatric patients under 12 years of age or weighing less than 35 kg

Dear Healthcare professional,

Tabuk Pharmaceutical Manufacturing Company, in agreement with Saudi Drug and Food Authority (SFDA), would like to remind you about the approved indications of Prokinin® (domperidone).

Summary:

- The only registered indication for Prokinin® (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 previously deleted.
- Domperidone should be used at the lowest effective dose for the shortest duration necessary to control nausea and vomiting. The maximum treatment duration should not usually exceed 1 week.
- For adults and adolescents (over 12 years and weighing 35 kg or more), the recommended dose is 10 mg up to three times daily with a maximum oral daily dose of 30 mg.

Reminder of contraindications:

- Known hypersensitivity to domperidone or any of the excipients.
- Prolactin-releasing pituitary tumour (prolactinoma).
- When stimulation of the gastric motility could be harmful. e.g., in patients with gastro-intestinal haemorrhage, mechanical obstruction or perforation.
- In patients with moderate or severe hepatic impairment.
- Patients with certain heart conditions including heart failure, previous heart attack, angina (chest pains), and heart arrhythmia disorders.
- In patients who have known existing prolongation of cardiac conduction intervals, particularly QTc patients with significant electrolyte disturbances.
- Co-administration with QT-prolonging drugs.
- Co-administration with potent CYP3A4 inhibitors (regardless of their QT prolonging effects).

Background:

This communication is sent to remind healthcare providers that the only registered indication for Prokinin® (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.

In 2020, the indication for its use in children younger than 12 years or those weighing less than 35 kg was removed following the results from a randomized-controlled study showing that the use of domperidone in children below 12 years of age with acute gastroenteritis (in combination with oral rehydration therapy) had no difference in efficacy when compared to placebo.[1]

Advice for Healthcare Providers:

- Healthcare providers should adhere to the locally approved indications and posology.
- Domperidone should not be used in infants and children less than 12 years of age who weighs less than 35 kg due to lack of efficacy in this population.
- Be aware of the contraindications associated with the use of Domperidone.
- Prescribe domperidone at the lowest effective dose and for the shortest duration possible.
- For adults and adolescents (over 12 years and weighing 35 kg or more), the recommended dose is 10 mg up to three times daily with a maximum oral daily dose of 30 mg.
- Use for the shortest possible duration which should not usually exceed 1 week

Call for reporting:

We encourage healthcare providers to report any side effect(s) to:

Pharmacovigilance department in Tabuk Pharmaceuticals:

Email: pv.info@tabukpharmacuticals.com

Tel: +966114774946

Saudi Food and Drug Authority

National Pharmacovigilance Center

Email: npc.drug@sfda.gov.sa

Call Center: 19999

Website: https://ade.sfda.gov.sa/

References:

1. Leitz, G., Hu, P., Appiani, C., Li, Q., Mitha, E., Garces-Sanchez, M., & Gupta, R. (2019). Safety and Efficacy of Low-dose Domperidone for Treating Nausea and Vomiting Due to Acute Gastroenteritis in Children. *Journal of pediatric gastroenterology and nutrition*, *69*(4), 425–430. https://doi.org/10.1097/MPG.0000000000002409

Yours sincerely,

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Qualified Person for Pharmacovigilance