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DOMPERIDONE-CONTAINING PRODUCTS: REMINDER OF INDICATION AND CONTRAINDICATIONS RELATED TO SERIOUS CARDIAC SIDE EFEFCTS

Dear Healthcare Professional,

This letter is intended to remind you of the approved indication and the contraindications of domperidone-containing products, to minimise the risks of serious cardiac side effects. This letter is being sent in agreement with the European Medicines Agency (EMA) and «Scientific centre of drug and medical technology expertise after academician E. Gabrielyan» CJSC.

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.

Domperidone products are contraindicated:

- in patients with moderate to severe hepatic impairment;
- in patients who have known existing prolongation of cardiac conduction intervals (particularly QTc) and in 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).

The benefits remain to outweigh the risks in this indication.

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Further information

The safety of domperidone-containing products was reviewed in 2014 by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC).

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 minimisation measures are necessary in order to improve the benefit/risk balance including:

1- restricting the registered indication to the relief of symptoms of nausea and vomiting;
2- 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;
3- shorter treatment duration: use for the shortest possible duration. The maximum treatment duration should not usually exceed 1 week;
4- addition of the following contraindications: in 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; in patients with significant electrolyte disturbances; and/or when co administered with QT-prolonging drugs or potent CYP3A4 inhibitors
    - domperidone is contraindicated with QT-prolonging drugs 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.
5- addition of warnings and precautions regarding cardiovascular effects of domperidone

In addition, PRAC requested an efficacy study testing the dissemination of the DHPC.

Recent studies conducted in several European countries have shown that a proportion of physicians are not aware of domperidone's restricted indication and its contraindications. All healthcare professionals are thus reminded of the safe use of domperidone-containing products in accordance with the product information.

Contact details for adverse events reporting

Upon receipt of information regarding adverse events, please contact 'Johnson & Johnson' LLS in Russian Federation:

- via phone + 7 (495) 726 55 55
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