

DOMPERIDONE-CONTAINING MEDICINES: NO LONGER APPROVED FOR USE IN CHILDREN DUE TO LACK OF EFFICACY

Results from a placebo-controlled study in children below the age of 12 years with acute nausea and vomiting using domperidone as an add-on to oral rehydration did not show any difference in efficacy compared with placebo.

Based on these study results, the authorised use of all domperidone-containing products* is restricted to adults and adolescents above the age of 12 years and weighing 35kg or more.

Lack of efficacy in the paediatric population

The safety of domperidone-containing products was reviewed in 2014 by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC). At the time there were limited data to support paediatric use in the relief of the symptoms of nausea and vomiting and studies to provide further data to support efficacy in the paediatric population were requested. Results from a placebo-controlled study in children below the age of 12 years with acute nausea and vomiting using domperidone as an add-on to oral rehydration did not show any difference in efficacy compared with placebo. The product information for domperidone-containing medicines will therefore be updated to remove the paediatric posology.

Reminder on the safe use of domperidone-containing products in accordance with the product information

Following finalisation of the safety review in 2014, it was concluded that risk minimisation measures were necessary in order to improve the benefit/risk balance and reduce the risk of serious cardiac adverse events. The HPRA previously communicated the outcome of the EU review in its Drug Safety Newsletter Edition 61 in 2014 and in a reminder article published in 2017 in Edition 81.

Reminder of indication

- Use of domperidone is restricted to the relief of symptoms of nausea and vomiting in adults and adolescents above the age of 12 years and weighing 35kg or more.

Reminder of contraindications

Domperidone is contraindicated in:

- patients with moderate to severe hepatic impairment,
- patients with known existing prolongation of cardiac conduction intervals (particularly QTc),
- patients with underlying cardiac diseases such as congestive heart failure,
- patients with significant electrolyte disturbances,
- during co-administration with QT-prolonging drugs[†] during co-administration with potent CYP3A4 inhibitors (regardless of their QT-prolonging effects).

[†]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.

Reminder of the restrictions on dose and treatment duration

- For adults and adolescents over 12 years of age and weighing 35kg or more, the recommended maximum dose in 24 hours is 30mg (dose interval: 10mg up to three times a day).
- Domperidone should be used at the lowest effective dose for the shortest possible duration.
- The maximum treatment duration should not usually exceed one week.

Key Message

Results from a placebo-controlled study in children below the age of 12 years with acute nausea and vomiting using domperidone as an add-on to oral rehydration did not show any difference in efficacy compared with placebo.

The authorised use of all domperidone-containing products is therefore restricted to adults and adolescents above the age of 12 years and weighing 35kg or more.

Furthermore, domperidone is associated with an increased risk of serious cardiac adverse reactions. Healthcare professionals are reminded of the following:

Therapeutic indications - Use of domperidone is restricted to the relief of symptoms of nausea and vomiting in adults and adolescents above the age of 12 years and weighing 35kg or more.

Contraindications - Domperidone is contraindicated in patients who have known existing prolongation of cardiac conduction intervals, in patients with significant electrolyte disturbances or underlying cardiac diseases, in patients who are concomitantly taking QT-prolonging drugs or potent CYP3A4 inhibitors and in patients who have moderate or severe hepatic impairment.

Dose and duration of use - For adults and adolescents over 12 years of age and weighing 35kg or more, the recommended maximum dose in 24 hours is 30mg (dose interval: 10mg up to three times a day). Domperidone should be taken at the lowest effective dose for the shortest duration possible. Maximum treatment period should not usually exceed one week.

A Direct Healthcare Professional Communication (DHPC) was circulated by the MAH (following approval by the HPRA) in May 2019 and is available from the HPRA website.

All reports of suspected adverse reactions should be reported to the HPRA via the usual methods.

*Products currently authorised in Ireland include Motilium and Domerid. Further details are available at www.hpra.ie