European Medicines Agency starts review of domperidone containing medicinal products

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Information on Medicinal Product

- Domperidone-containing medicines are medicinal products used to relieve symptoms of nausea and vomiting, fullness, abdominal discomfort and heartburn.
- Domperidone works by blocking receptors for the neurotransmitter dopamine found in the gut and in the part of the brain linked to vomiting. This results in an increase in the action of the muscles in the stomach so that food moves more effectively through the stomach into the intestine, which helps prevent vomiting and reduces feelings of sickness, bloating and fullness.
- In Malta there are several authorised medicinal products containing the active substance domperidone see annex 1.

Information from European Medicines Agency about the safety concern

The European Medicines Agency (EMA) has started a review of domperidone-containing medicines because of a trigger by the Belgian medicines agency (FAMHP) over concerns about its adverse effects on the heart. Adverse heart effects, including QT prolongation (an alteration of the electrical activity in the heart) and arrhythmias (unstable heartbeats), have previously been evaluated by the EMA. In 2011, the product information for domperidone-containing medicines was updated to reflect the risk of these adverse effects and that domperidone should be used with caution in patients with certain heart conditions, including heart failure, a previous heart attack, angina (chest pains), and heart rhythm disorders.

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Since then new reports of heart effects have been received and the Belgian medicines agency has come to the view that domperidone should no longer be used in some patients, such as those with QT prolongation or other underlying heart problems.

The European Medicines Agency will now review all available data on the benefit-risk balance of domperidone-containing medicines, and issue an opinion on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

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In Malta

Advice for Patients

While the review is ongoing patients should speak to their doctor or pharmacist if they have any questions or concerns.

Always speak to your doctor or pharmacist prior to taking domperidone.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on domperidone containing medicinal products name. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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