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Review of domperidone started

The European Medicines Agency has started a review of domperidone-containing medicines used to relieve symptoms of nausea and vomiting, fullness, abdominal discomfort and heartburn.

The review was triggered by the Belgian medicines agency, the Federal Agency for Medicines and Health Products (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 Pharmacovigilance Working Party (PhVWP). In 2011, the PhVWP recommended that the product information for domperidone-containing medicines be 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.

Since then new reports of heart effects have been received in Belgium 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medicines, and issue an opinion on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

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

More about the medicine

Domperidone-containing medicines have been authorised in several EU Member States via national procedures since the 1970s and are widely available as over-the-counter or prescription-only medicines. They are available as tablets, oral suspension and suppositories under various trade names (such as Motilium).

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

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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.

More about the procedure

The review of domperidone has been initiated at the request of Belgium, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As domperidone-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a regulatory body that represents national medicines regulatory authorities of the EU Member States.