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Questions and answers on Kytril and associated names (granisetron, 1 and 2 mg tablets, 3 mg/ml, 3 mg/5 ml, 1 mg/ml, 3 mg/3 ml solution for injection)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

The European Medicines Agency has completed a review of Kytril. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that there is a need to harmonise the prescribing information for Kytril in the European Union (EU).

What is Kytril?

Kytril is an anti-emetic (a medicine that prevents nausea and vomiting). It is used to prevent nausea and vomiting following treatments for cancer such as chemotherapy and radiotherapy.

The active substance in Kytril, granisetron, is a '$5HT_3$ antagonist'. This means that it stops a chemical in the body called 5-hydroxytryptamine (5HT, also known as serotonin) from attaching to $5HT_3$ receptors in the in the brain and the gut. When 5HT attaches to these receptors, it normally causes nausea and vomiting. Granisetron prevents the nausea and vomiting by blocking these receptors.

Kytril is also available in the EU under the trade name Kevatril. The company that markets these medicines is Roche.

Why was Kytril reviewed?

Kytril is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Kytril was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)).

On 3 June 2010, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Kytril in the EU.

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What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

The CHMP recommended that Kytril tablets and solution for injection can be used in adults for the prevention and treatment of acute nausea and vomiting associated with chemotherapy and radiotherapy, and also for the prevention of delayed nausea and vomiting associated with chemotherapy and radiotherapy.

In addition, the solution for injection can be used in adults for the prevention and treatment of nausea and vomiting following surgery.

The solution for injection can also be used in children aged two years above for the prevention and treatment of acute nausea and vomiting associated with chemotherapy.

4.2 Posology and method of administration

Kytril tablets should be swallowed whole with water. For the prevention of nausea and vomiting, the recommended dose is 1 mg twice a day or 2 mg once a day for up to one week following radiotherapy or chemotherapy.

Kytril solution for injection is given into a vein at a dose of 1-3 mg (10-40 μg/kg) for the prevention and treatment of nausea and vomiting in adults. When used for treatment, further doses of the solution may be given at least 10 minutes apart, up to a maximum of 9 mg per 24 hours.

4.3 Contra-indications

Kytril must not be used in patients who are hypersensitive (allergic) to the active substance or to any of the excipients.

Other changes

Other sections harmonised by the CHMP include sections on special warnings, side effects and the medicines pharmacological properties.

The amended information to doctors and patients is available here.

A European Commission issued a decision on 20 July 2011.