European Medicines Agency

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Questions and answers on the referral for Pantoprazole Olinka pantoprazole 20 and 40 mg tablets

The European Medicines Agency (EMEA) has completed an arbitration procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Pantoprazole Olinka. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Pantoprazole Olinka outweigh its risks, and the marketing authorisation can be granted in the United Kingdom and in the following Member States of the European Union, Germany and Poland.
The review was carried out under an 'Article 29' referral[1].

What is Pantoprazole Olinka?
Pantoprazole Olinka is a medicine used to treat diseases where the stomach produces too much acid. The 20 mg tablets can be used for reflux disease to treat symptoms such as heartburns and acid regurgitation (acid flowing up in the mouth), for the long-term management and prevention of relapse in reflux oesophagitis (inflammation of the gullet, due to acid), for the prevention of the stomach ulcers that can be caused by some medicines used to treat pain and inflammations called non-selective non-steroidal anti-inflammatory drugs (NSAIDs), when the patient needs continuous NSAID treatment.
The 40 mg tablets can be used for more severe acid diseases such as stomach ulcer, duodenal ulcer, Zollinger-Ellison syndrome (a condition caused by oversecretion of acid in the stomach) and to help rid the stomach of a bacterium called *Helicobacter pylori*, which is known to cause stomach ulcer.

The active substance in Pantoprazole Olinka, pantoprazole, is a proton pump inhibitor. It works by blocking 'proton pumps', proteins found in specialised cells in the stomach lining that pump acid into the stomach. By blocking the pumps, pantoprazole reduces acid production.

Pantoprazole Olinka is presented as gastro-resistant tablets. These are tablets that pass through the stomach without being broken down until they reach the intestine. This prevents the active substance from being destroyed by the acid in the stomach.

Pantoprozole Olinka is a generic medicine based on the reference medicine Pantecta.

Why was Pantoprazole Olinka reviewed?
Olinka UK Ltd. submitted Pantoprazole Olinka to the United Kingdom medicines regulatory agency for a decentralised procedure. This is a procedure when one Member State (the 'reference Member State', in this instance the UK) assesses a medicine with a view of granting a marketing authorisation that will be valid in this country as well as in other member states (the 'concerned Member States', in this instance Germany and Poland).

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

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However, the member states were not able to reach an agreement and the UK medicines regulatory agency referred the matter to the CHMP for arbitration on 30 April 2009.

The grounds for the referral were concerns expressed by the German medicines regulatory agency regarding the bioequivalence study comparing Pantoprazole Olinka and Pantecta. Bioequivalnce studies are used to compare how a generic medicine is absorbed by the body in comparison to the reference medicine.

What are the conclusions of the CHMP?
Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that Pantoprazole Olinka had been shown to be bioequivalent to the reference medicine, and therefore the marketing authorisation should be granted in the UK and all concerned member states.

The European Commission issued a decision on 30 March 2010.

Rapporteur:	Dr Robert James Hemmings (United Kingdom)
Co-rapporteur(s):	Dr Harald Enzmann (Germany)
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