

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

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Pantoprazole Bluefish. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Pantoprazole Bluefish outweigh its risks, and the marketing authorisation can be granted in Sweden and in the following Member States of the European Union, Austria, Denmark, Germany, Finland, France, Hungary, Ireland, Italy, the Netherlands, Poland, Portugal, Spain as well as in Norway.

The review was carried out under an 'Article 29' referral¹.

What is Pantoprazole Bluefish?

Pantoprazole Bluefish 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 Bluefish, 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 Bluefish 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.

Pantoprazole Bluefish is a generic medicine based on the reference medicine Pantecta.

Why was Pantoprazole Bluefish reviewed?

Bluefish Pharmaceuticals AB submitted Pantoprazole Bluefish to the Swedish medicines regulatory agency for a decentralised procedure. This is a procedure when one Member State (the 'reference Member State', in this instance Sweden) 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 Austria, Denmark, Germany, Finland, France, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Portugal and Spain).

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

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

The grounds for the referral were concerns expressed by the Dutch, German, Irish and Italian medicines regulatory agencies regarding the bioequivalence study comparing Pantoprazole Bluefish and Pantecta. Bioequivalence 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 Bluefish had been shown to be bioequivalent to the reference medicine, and therefore the marketing authorisation should be granted in Sweden 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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Company responses provided on:	21 September 2009, 26 October 2009
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