Summary Public Assessment Report

Generics

Pantoprazol Aurobindo 20 mg and 40 mg, gastro-resistant tablets

pantoprazole

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Active substance: pantoprazole

This is a summary of the public assessment report (PAR) for Pantoprazol Aurobindo gastro-resistant tablets. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Pantoprazol Aurobindo.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Pantoprazol Aurobindo and what is it used for?
Pantoprazol Aurobindo is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Pantoprazole Altana gastro-resistant tablets. The reference medicine is also marketed in Europe under several other trade names, such as Protium, Inipomp, Pantoloc and Pantozol.

This medicine is prescribed for treatment of acid-related disease of the stomach and intestine.

This includes:

- symptoms such as heartburn, acid reflux, pain on swallowing, caused by reflux of acid (rising up of stomach acid into the esophagus) from the stomach in case of oesophageal disease
- (long-term) management of reflux oesophagits (inflammation of the oesophagus accompanied by the regurgitation of stomach acid) and preventing its return.
- Prevention or treatment of duodenal and stomach ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs for example, ibuprofen) in patients at risk who need to take NSAIDs continuously.
- Treatment of an infection with a bacterium called *Helicobacter pylori* in patients with *H. pylori* associated ulcers in combination with two antibiotics (Eradication therapy). The aim is to get rid of the bacteria and so reduce the likelihood of these ulcers returning.
- Zollinger-Ellison-Syndrome and other pathological conditions producing too much acid in the stomach.

Read the package leaflet for further details. The right dose, 20 mg or 40 mg, depends on the condition. This medicine should not be used by children below 12 years of age. For certain symptoms this medicine can be used from the age of 12. However, for some types of disease this medicine is only indicated in adults. Refer to the package leaflet and always follow the advice of the prescribing doctor.

How does this medicine work?
The active substance pantoprazole is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in the stomach. Herewith it relieves the symptoms of acid reflux.
The tablets are gastro-resistant. This means that the tablet passes through the stomach without being broken down until it reaches the intestine. This prevents the active substance being destroyed by the acid in the stomach.

How is this medicine used?
The medicine can only be obtained with a prescription. The tablets should be taken with some water 1 hour before a meal. They should be swallowed whole without chewing and breaking. The usual dose is one tablet a day. The duration of treatment depends on the patient's condition and the time it takes to recover. Further information can be found in the package leaflet.

How has this medicine been studied?
Because Pantoprazol Aurobindo is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Pantoprazole Altana gastro-resistant

tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Pantoprazol Aurobindo is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine, Pantoprazole Altana.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Pantoprazole Altana, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Pantoprazol Aurobindo, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about this medicine
In the Netherlands, the marketing authorisation for Pantoprazol Aurobindo 20 mg and 40 mg, gastro-resistant tablets was granted on 17 June 2011.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Pantoprazol Aurobindo, read the package leaflet (for the 20 mg strength – http://mri.medagencies.org/download/NL_H_2944_001_FinalPL.pdf and for the 40 mg strength – http://mri.medagencies.org/download/NL_H_2944_002_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in December 2014.