

Summary Public Assessment Report

Pantoprazol Orion (pantoprazole)

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(pantoprazole)

Gastro-resistant tablet 20 mg

This is a summary of the public assessment report (PAR) for Pantoprazol Orion. It explains how Pantoprazol Orion 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 Orion.

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

What is Pantoprazol Orion and what is it used for?

Pantoprazol Orion is a ‘generic medicine’. This means that Pantoprazol Orion is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Pantoloc.

Pantoprazol Orion is used to treat

- *adults and adolescents 12 years of age and above for*
 - symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease caused by reflux of acid from the stomach
 - long-term management of reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitation of stomach acid) and preventing its return
- *adults for*
 - preventing 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.

How does Pantoprazol Orion work?

Pantoprazol Orion contains the active substance pantoprazole. Pantoprazole is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

How is Pantoprazol Orion used?

The pharmaceutical form of Pantoprazol Orion is gastro-resistant tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Pantoprazol Orion have been shown in studies?

Because Pantoprazol Orion is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Pantoloc. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Pantoprazol Orion?

Because Pantoprazol Orion 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. For the full list of restrictions, see the package leaflet.

Why is Pantoprazol Orion approved?

It was concluded that, in accordance with EU requirements, Pantoprazol Orion has been shown to have comparable quality and to be bioequivalent to the reference medicine Pantoloc. Therefore, the Medical Products Agency in Sweden decided that, as for Pantoloc, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Pantoprazol Orion?

A risk management plan has been developed to ensure that Pantoprazol Orion 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 Orion, 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 Pantoprazol Orion

The marketing authorisation for Pantoprazol Orion was granted on 2018-01-24 in Sweden.

The full PAR for Pantoprazol Orion can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Pantoprazol Orion, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2018-01.