

Summary of risk management plan for Pantoprazol Orion (pantoprazole) Orion Corporation

Date: 15-06-2017, Version 1

This is a summary of the risk management plan (RMP) for Pantoprazol Orion. The RMP details important risks of Pantoprazol Orion, how these risks can be minimized, and how more information will be obtained about Pantoprazol Orion's risks and uncertainties (missing information).

I. The medicine and what it is used for

Pantoprazol Orion is authorised for treatment of gastro-oesophageal reflux disease (GERD); reflux oesophagitis; prevention of gastroduodenal ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs); eradication of *Helicobacter pylori* (*H. pylori*) in combination with appropriate antibiotic therapy in patients with *H. pylori* associated ulcers; gastric and duodenal ulcers; and Zollinger-Ellison-Syndrome (ZES) and other pathological hyper secretory conditions (see SmPC for the full indication). It contains pantoprazole as the active substance and it is given by mouth.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Pantoprazol Orion, together with measures to minimise such risks and the proposed studies for learning more about Pantoprazol Orion's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Pantoprazol Orion are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of

a link with the use of Pantoprazol Orion. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

Summary of safety concerns	
Important identified risks	<ul style="list-style-type: none"> • Masking the symptoms of malignant gastric tumour • Increased risk of gastrointestinal infections • Drug interaction of pantoprazole with drugs which have pH dependent absorption • Hypomagnesaemia
Important potential risks	<ul style="list-style-type: none"> • Increased risk of fractures • Use in patients with severe hepatic impairment • Subacute cutaneous lupus erythematosus (SCLE)
Missing information	<ul style="list-style-type: none"> • Use during pregnancy and breastfeeding • Use in children below 12 years of age • Long term use

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

There are no studies required for Pantoprazol Orion.