

Summary of risk management plan for Omeprazol Orion 10 mg, 20 mg and 40 mg gastro-resistant capsules, hard (omeprazole) Orion Corporation

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

Omeprazol Orion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Omeprazol Orion should be used.

Important new concerns or changes to the current ones will be included in updates of Omeprazol Orion's RMP.

I. The medicine and what it is used for

Omeprazol Orion is authorised for treatment and prevention of peptic ulcers (including NSAID- and Helicobacter pylori associated), reflux oesophagitis/disease, and Zollinger-Ellison syndrome (see SmPC for the full indication). It contains omeprazole 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 Omeprazol Orion, together with measures to minimise such risks and the proposed studies for learning more about Omeprazol 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 identified risks

- Drug interactions
- Hypomagnesemia
- Fracture of hip, wrist and spine
- Gastrointestinal infections
- Severe cutaneous reactions

Important potential risks

None

Missing information

None

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 Omeprazol Orion.