Part VI: Summary of the risk management plan

Summary of risk management plan for <Product name> 10 mg/15 ml; 20 mg/15 ml Oral Solution (omeprazole)

This is a summary of the risk management plan (RMP) for Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution. The RMP details important risks of Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution, how these risks can be minimised, and how more information will be obtained about Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution risks and uncertainties (missing information).
Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution should be used.

I. The medicine and what it is used for

Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution is authorised in adults for treatment and prevention of relapse of duodenal and gastric ulcers, Helicobacter pylori (H. pylori) eradication in peptic ulcer disease, treatment and prevention of NSAID-associated gastric and duodenal ulcers, treatment of reflux esophagitis, long-term management of patients with healed reflux esophagitis as well as treatment of symptomatic gastro-esophageal reflux disease.

In children over 1 month of age, it is authorized for treatment of reflux esophagitis and symptomatic treatment of heartburn and acid regurgitation in gastro-esophageal reflux disease. Children over 4 years of age and adolescents should use Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution in combination with antibiotics in treatment of duodenal ulcer caused by H. pylori.

It contains omeprazole as the active substance and it is given orally.

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

Important risks of Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution together with measures to minimise such risks and the proposed studies for learning more about Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution '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.

II.A List of important risks and missing information

Important risks of Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution 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 Omeprazole 10 mg/15 ml and 20 mg/15 ml oral solution. 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);

List of important risks and missing information	
Important identified risks	None
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

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of invented name Omeprazole 10 mg/15 ml oral solution and 20 mg/15 ml oral solution.

II.C.2 Other studies in post-authorisation development plan

This RMP is submitted with the initial application for a marketing authorisation.