PART VI: Summary of the risk management plan

Summary of risk management plan for Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar (Omeprazole)

This is a summary of risk management plan (RMP) for Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar. The RMP details important risks of Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar and how more information will be obtained about Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar's risks and uncertainties (missing information).

Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar should be used.

Important new concerns or changes to the current ones will be included in updates of Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar's RMP.

I. The medicine and what it is used for

Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar is authorised for the treatment of:

Adults

• Treatment of duodenal ulcers

• Prevention of relapse of duodenal ulcers

• Treatment of gastric ulcers

• Prevention of relapse of gastric ulcers

• In combination with appropriate antibiotics, Helicobacter pylori (H. pylori) eradication in peptic ulcer disease

• Treatment of NSAID-associated gastric and duodenal ulcers

• Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk

• Treatment of reflux oesophagitis

• Long-term management of patients with healed reflux oesophagitis

• Treatment of symptomatic gastro-oesophageal reflux disease

• Treatment of Zollinger-Ellison syndrome

Children over 1 year of age and ≥ 10 kg

• Treatment of reflux oesophagitis

• Symptomatic treatment of heartburn and acid regurgitation in gastro-oesophageal reflux disease

Children and adolescents over 4 years of age

• In combination with antibiotics in treatment of duodenal ulcer caused by H. pylori

(see SmPC for the full indication).

It contains omeprazole as the active substance, and it is given by oral route.

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

Important risks of Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar, together with measures to minimise such 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, including PSUR assessment 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 Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar 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 Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar. 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 Risk	Nephrotoxicity
Important Potential Risk	None
Missing information	None

II.B Summary of important risks

The safety information in the 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 Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar.

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

There are no studies required for Omeprazol Medical Valley 10, 20 and 40 mg hårda enterokapslar.