Part VI: Summary of the risk management plan

Summary of risk management plan for Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules (esomeprazole)

This is a summary of the risk management plan (RMP) for Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules. The RMP details important risks of Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules, and how more information will be obtained about Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules' risks and uncertainties (missing information).

Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules should be used.

Important new concerns or changes to the current ones will be included in updates of Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules' RMP.

I. The medicine and what it is used for

Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules is authorized for:

Adults

Gastroesophageal Reflux Disease (GERD):

- Treatment of erosive reflux esophagitis
- Long-term management of patients with healed esophagitis to prevent relapse
- Symptomatic treatment of gastroesophageal reflux disease (GERD)

In combination with appropriate antibacterial therapeutic regimens:

- Eradication of *Helicobacter pylori*
- Healing of *Helicobacter pylori* associated duodenal ulcer
- Prevention of relapse of peptic ulcers in patients with *Helicobacter pylori* associated ulcers

Patients requiring continued NSAID therapy:

- Healing of gastric ulcers associated with NSAID therapy
- Prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk

Prolonged treatment after i.v. induced prevention of rebleeding of peptic ulcers.

Treatment of Zollinger Ellison Syndrome.

Adolescents from the age of 12 years

Gastroesophageal Reflux Disease (GERD):

- Treatment of erosive reflux esophagitis
- Long-term management of patients with healed esophagitis to prevent relapse
- Symptomatic treatment of gastroesophageal reflux disease (GERD)

In combination with antibiotics in treatment of duodenal ulcer caused by *Helicobacter pylori.*

See SmPC for the full indication.

It contains esomeprazole as the active substance, and it's given by the oral route.

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

Important risks of Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules 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 of Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules 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 Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules. 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 Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules.

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

There are no studies required for Esomeprazole Xiromed 20 and 40 mg Maagsapresistente capsule and Esomeprazole Liconsa 20 and 40 mg gastro-resistant capsules.