Part VI: Summary of the risk management plan

Summary of risk management plan for Esomeprazole 40 mg powder for solution for injection/infusion (esomeprazole)

This is a summary of the risk management plan (RMP) for Esomeprazole 40 mg powder for solution for injection/infusion (hereinafter referred to as Esomeprazole DEMO). The RMP details important risks of Esomeprazole DEMO, how these risks can be minimised, and how more information will be obtained about Esomeprazole DEMO's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Esomeprazole DEMO for injection and infusion is indicated in adults for:

- Gastric antisecretory treatment when the oral route is not possible, such as:
    - gastroesophageal reflux disease (GERD) in patients with esophagitis and/or severe symptoms of reflux
    - healing of gastric ulcers associated with NSAID therapy
    - prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk.
- Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

Esomeprazole DEMO for injection and infusion is indicated in children and adolescents aged 1 – 18 years for:

- Gastric antisecretory treatment when the oral route is not possible, such as:

GERD in patients with erosive reflux esophagitis and/or severe symptoms of reflux (see SmPC for the full indication).

It contains esomeprazole as the active substance and it is given by intravenous injection or infusion.

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

Important risks of Esomeprazole DEMO, together with measures to minimise such risks and the proposed studies for learning more about Esomeprazole DEMO'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 Esomeprazole DEMO are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 DEMO. 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 DEMO.

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

There are no studies required for Esomeprazole DEMO.