Part VI: Summary of the risk management plan

Summary of risk management plan for Esomeprazol Oresund Pharma
This is a summary of the risk management plan (RMP) for Esomeprazol Oresund Pharma. The RMP details important risks of esomeprazole, how these risks can be minimised, and how more information will be obtained about esomeprazole's risks and uncertainties (missing information).

Esomeprazol Oresund Pharma's summary of product characteristics (SmPC) and its leaflet provide essential information to healthcare professionals and patients on how Esomeprazol Oresund Pharma should be used.

VI.1. The medicine and what it is used for

Esomeprazol Oresund Pharma contains a medicine called esomeprazole. This belongs to a group of medicines called "proton pump inhibitors". They work by reducing the amount of acid that your stomach produces.

Esomeprazol Oresund Pharma is used for the short-term treatment of certain conditions when you are unable to have treatment by mouth. It is used to treat:

- "Gastro-esophageal reflux disease" (GERD, sometimes also referred to as "GORD", depending on how esophageal is spelled) in adults, adolescents, and children. This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation, and heartburn.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazol Oresund Pharma can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

VI.1.1 Overview of disease epidemiology

GERD or commonly known as acid reflux is a public health concern defined by troublesome and frequent symptoms of heartburn or regurgitation and affecting up to 20% of the adult population in the western world. It is estimated that acid reflux affects 18.6 million people in the United States. There appears to be a lower prevalence of acid reflux (defined by at least weekly heartburn and/or regurgitation) in Europe compared to North America. Nonsteroidal anti-inflammatory drugs (NSAIDs) are well recognized as causing peptic ulceration and ulcer complications. Based on a widely quoted population study, it can be estimated that there are 8528 hospitalizations for gastric and duodenal ulcer bleeding per annum in the UK. NSAIDs cause approximately 3500 hospitalizations for and 400 deaths from ulcer bleeding per annum in the UK in those aged 60 years and above.

VI.1.2 Summary of treatment benefits

Esomeprazol Oresund Pharma is recommended for the treatment of GERD (acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation, and heartburn.), healing of stomach ulcers caused by medicines called NSAID, prevention of rebleeding in adults following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers. GERD or acid reflux

In a study, patients with peptic ulcer bleeding received either esomeprazole (n=375) or placebo (n=389). After the initial 72-hour period, all the patients received 40 mg oral esomeprazole for 27 days for acid suppression. The occurrence of rebleeding within 3 days was 5.9% in the esomeprazole treated group compared to 10.3% for the placebo group. At 30 days post-treatment, the occurrence of rebleeding in the esomeprazole treated versus the placebo treated group was 7.7% vs 13.6%.

However, these studies were conducted for the reference product (Nexium, AstraZeneca UK) and no studies were performed for Esomeprazol Oresund Pharma to evaluate the expected benefit, considering its similarity to the reference product.

VI.1.3 Unknowns relating to treatment benefits

Not applicable

VI.2. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Esomeprazol Oresund Pharma powder for solution for injection/infusion, together with measures to minimise such risks and the proposed studies for learning more about Esomeprazol Oresund Pharma's risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- Specific information, such as warnings, precautions, and advice on correct use, in the SmPC addressed to 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 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.*

If information that may affect the safe use of Esomeprazol Oresund Pharma is not yet available, it is listed under 'missing information' below.

VI.2.1 List of important risks and missing information

Important risks of Esomeprazol Oresund Pharma 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 Esomeprazol Oresund Pharma. 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.

List of Important Risks and Missing Information

Important identified risks	None
Important potential risks	None
Missing information	None

Esomeprazol Oresund Pharma has neither any important identified nor important potential risk.

There is no missing information.

VI.2.2 Summary of important risks

Not applicable. The safety information in the proposed Product Information is aligned to the reference medicinal product.

VI.2.3 Post-authorisation development plan

VI.2.3.1 Studies which are conditions of the marketing authorisation

There are no studies being conditions of the marketing authorisation or specific obligation of Esomeprazol Oresund Pharma.

VI.2.3.2 Other studies in post-authorisation development plan

There are no studies required for Esomeprazol Oresund Pharma.