Part VI: Summary of the risk management plan for Esomeprazole Orifarm

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

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

I. The medicine and what it is used for

Esomeprazole Orifarm reduces the amount of acid that your stomach produces and is authorised for use in children 1-11 years of age for treatment of gastroesophageal reflux disease and for children over 4 years of age for treatment if duodenal ulcer caused by Helicobacter pylori. Esomeprazole can also be used in adults and adolescents with difficulties swallowing tablets.

It contains esomeprazole as the active substance and it is given as gastro-resistant granules for oral suspension.

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

Important risks of Esomeprazole Orifarm, together with measures to minimise such risks and the proposed studies for learning more about Esomeprazole Orifarm's risks, are outlined below.

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the Danish, Swedish, Norwegian and Finnish Medicines Agency.
- The medicine's is prescription only medicine and must be prescribed by a physician.

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 Orifarm 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 Orifarm. 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);

Summary of safety concerns	
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 Orifarm.

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

There are no studies required for Esomeprazole Orifarm.