Summary of risk management plan for Pantoprazol SUN 40 mg - Powder for Solution for Injection

(pantoprazole as sodium sesquihydrate)

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

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

I. The medicine and what it is used for

Pantoprazol SUN is authorised for:

- Reflux oesophagitis.
- Gastric and duodenal ulcer.
- Zollinger Ellison Syndrome and other pathological hypersecretory conditions.

It contains pantoprazole (as sodium sesquihydrate) as the active substance and it is given by injection/infusion.

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

Important risks of Pantoprazol SUN, together with measures to minimise such risks and the proposed studies for learning more about Pantoprazol SUN'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.

II.A List of important risks and missing information

Important risks of Pantoprazol SUN 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 Pantoprazol SUN. 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 informatio	n
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 of Pantoprazol SUN 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 Pantoprazol SUN.

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

There are no studies required for Pantoprazol SUN.