Part VI: Summary of the risk management plan

Summary of risk management plan for Protamine Sulphate LEO Pharma (Protamine Sulphate)

This is a summary of the RMP for Protamine Sulphate LEO Pharma. The RMP details that no important risks or missing information of Protamine Sulphate LEO Pharma were identified and hence no additional risk minimisation activities have been defined. This is in accordance with the GVP module V (Rev. 2) (1).

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

I. The medicine and what it is used for

Protamine Sulphate LEO Pharma authorised for; - the treatment of overdosage or haemorrhage during heparin or LMWH therapy, - to counteract the anticoagulant effects of heparin or LMWH before emergency surgery, - to reverse the anticoagulant effects of heparin in cardiopulmonary bypass procedures. It contains Protamine Sulphate as the active substance and it is given by intravenous administration, as either a slowly administered single dose (maximum single dose is 5 ml or 50 mg) or by a constant slow intravenous infusion.

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

Important risks of a medicinal product, together with measures to minimise such risks and the proposed studies for learning more about the medicinal product'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 is 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 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 the medicinal product.
- *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).

No important risks or missing information have been identified for Protamine Sulphate LEO Pharma, and therefore no further activities to minimise or characterise risks are defined.

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

No important risks have been found for Protamine Sulphate LEO Pharma.

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 Protamine Sulphate LEO Pharma.

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

No other studies in post-authorisation development plan are required for Protamine Sulphate LEO Pharma.