Part VI: Summary of the risk management plan

Summary of risk management plan for Levosimendan Kabi 2,5 mg/ml Konzentrat zur Herstellung einer Infusionslösung* (Levosimendan)

*(*Invented name in the RMS AT „Levosimendan Kabi 2,5 mg/ml Konzentrat zur Herstellung einer Infusionslösung“ will be used as „Levosimendan 2.5 mg/ml concentrate for solution for infusion“ for harmonisation)*

This is a summary of the risk management plan (RMP) for Levosimendan 2.5 mg/ml concentrate for solution for infusion. The RMP details important risks of Levosimendan 2.5 mg/ml concentrate for solution for infusion, how these risks can be minimised, and how more information will be obtained about Levosimendan 2.5 mg/ml concentrate for solution for infusion's risks and uncertainties (missing information).

Levosimendan 2.5 mg/ml concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Levosimendan 2.5 mg/ml concentrate for solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Levosimendan 2.5 mg/ml concentrate for solution for infusion's RMP.

I. The medicine and what it is used for

Levosimendan 2.5 mg/ml concentrate for solution for infusion is authorised for short-term treatment of acutely decompensated severe chronic heart failure (ADHF) in situations where conventional therapy is not sufficient, and in cases where inotropic support is considered appropriate (see SmPC for the full indication). It contains levosimendan as the active substance and it is given by intravenous infusion.

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

Important risks of Levosimendan 2.5 mg/ml concentrate for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Levosimendan 2.5 mg/ml concentrate for solution for infusion'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.

If important information that may affect the safe use of Levosimendan 2.5 mg/ml concentrate for solution for infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Levosimendan 2.5 mg/ml concentrate for solution for infusion 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 Levosimendan 2.5 mg/ml concentrate for solution for infusion. 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	- Hypotension - Supraventricular tachyarrhythmias - Ventricular tachyarrhythmia and use in patients with history of Torsades de Pointes - Ischaemic heart disease - Hypokalaemia
Important potential risks	- Hepatic disorder - Overdose - QT-prolongation
Missing information	- Use in children and adolescents under 18-years of age - Use in patients with impaired renal function - Use during pregnancy - Repeated administration of levosimendan - Use of levosimendan in the following disorders: restrictive cardiomyopathy, hypertrophic cardiomyopathy, severe mitral valve insufficiency, myocardial rupture, cardiac tamponade and right ventricular infarction

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal products.

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 Levosimendan 2.5 mg/ml concentrate for solution for infusion

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

There are no studies required for Levosimendan 2.5 mg/ml concentrate for solution for infusion