PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung:

This is a summary of the risk management plan (RMP) for Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung. The RMP details important risks of Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung, how these risks can be minimised, and how more information will be obtained about Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung's risks and uncertainties (missing information).

Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung's summary of product characteristics (SmPC) and package leaflet (PL) give essential information to healthcare professionals and patients on how Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung should be used.

Important new concerns or changes to the current ones will be included in updates of Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung's RMP.

I. The medicine and what it is used for

Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung is a concentrated form of a medicine, which must be diluted before it is given to you as an infusion into your veins.

Levosimendan works by increasing the pumping force of the heart and allows blood vessels to relax. Levosimendan will lessen the congestion in your lungs and make it easier for blood and oxygen to go through your body. Levosimendan will help to relieve the shortness of breath from severe heart failure.

Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung is used for treatment of heart failure, in people who still find it hard to breathe, even though they are taking other medicines to get rid of extra water from the body.

Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung contains levosimendan as the active substance and it is given by intravenous route.

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

Important risks of Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung, together with measures to minimise such risks and the proposed studies for learning more about Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung'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 PL 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 Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung 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 Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung. 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 "Simdax 2,5 mg/ml - Konzentrat zur Herstellung einer Infusionslösung".

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 Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung fusion.

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

There are no studies required for Levosimendan Tillomed 2,5 mg / ml Konzentrat zur Herstellung einer Infusionslösung.