Part VI: Summary of the risk management plan

Summary of risk management plan for

Levosimendan Kalceks 2.5 mg/ml concentrate for solution for infusion

(levosimendan)

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

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

Important new concerns or changes to the current ones will be included in updates of Levosimendan Kalceks's RMP.

I. The medicine and what it is used for

Levosimendan Kalceks 2.5 mg/ml concentrate for solution for infusion is authorised for the 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. It contains levosimendan as the active substance and it is given by intravenous route of administration in concentration of 2.5 mg per millilitre.

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

Important risks of Levosimendan Kalceks, together with measures to minimise such risks and the proposed studies for learning more about risks of Levosimendan Kalceks, 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 SPC 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 Kalceks in not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Levosimendan Kalceks 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 Kalceks. 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	*Hypotension* *Supraventrikular tachyarrhythmias* *Ventricular tachyarrhythmias and use in patients with Torsade de Pointes* *Ischaemic heart disease* *Hypokalaemia*
Important potential risks	*Hepatic disorder* *Haemorrhage* *Overdose* *QT prolongation* *Erroneous handling during preparation of diluted solution for infusion*
Missing information	*Use in children and adulescents under 18 years of age* *Use in patients with impaired renal function* *Exposure 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 medical 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 Levosimendan Kalceks.

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

There are no studies required for Levosimendan Kalceks.