Part VI: Summary of the risk management plan

Summary of risk management plan for Norepinephrine Kalceks 1 mg/ml concentrate for solution for infusion (Norepinephrine tartrate)

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

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

I. The medicine and what it is used for

Norepinephrine Kalceks is authorised for use as an emergency measure in the restoration of blood pressure in cases of acute hypotension. It contains norepinephrine tartrate as the active substance and it is given by an intravenous injection in concentration of 1 mg/ml.

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

Important risks of Norepinephrine Kalceks, together with measures to minimise such risks and the proposed studies for learning more about risks of Norepinephrine 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.

If important information that may affect the safe use of Norepinephrine Kalceks is not yet available, it is listed under "missing information" below.

II.A *List of important risks and missing information*

Important risks of Norepinephrine 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 Norepinephrine 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).

List of important risks and missing information	
Important identified risks	Overdose Bradycardia and cardiac arrhythmias Hypertension Dyspnoea Extravasation Necrosis and Peripheral ischaemia (including gangrene of the extremities)
Important potential risks	Use during pregnancy Drug-drug interaction Medication error / risk of medication error
Missing information	Use in patients with renal or hepatic insufficiency Use in paediatric population Use during breast-feeding

II.B Summary of important risks

The safety information in the proposed Product Information 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 Norepinephrine tartrate.

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

There are no studies required for Norepinephrine tartrate.