Part VI: Summary of the risk management plan

Summary of risk management plan for Furosemide Kalceks 10 mg/ml solution for injection/infusion (Furosemide)

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

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

I. The medicine and what it is used for

Furosemide Kalceks 10 mg/ml solution for injection/infusion is indicated when no adequate diuresis is achieved with oral administration of furosemide or when oral use is not possible (see SPC for list of indications). It contains furosemide as the active substance and it is given by an intravenous or intramuscular injection in concentration of 10 mg/ml.

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

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

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

Important risks of Furosemide 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 Furosemide 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	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 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 Furosemide Kalceks.

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

There are no studies required for Furosemide Kalceks.