Summary of risk management plan for Furosemide Noridem (furosemide) 10 mg/ml Solution for injection/infusion.

This is a summary of the risk management plan (RMP) for Furosemide Noridem (furosemide) 10 mg/ml Solution for injection/infusion (hereinafter referred to as FUROSEMIDE). The RMP details important risks of FUROSEMIDE, how these risks can be minimised, and how more information will be obtained about FUROSEMIDE's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

FUROSEMIDE is authorised for:

- Congestive heart failure.
- Liver cirrhosis or renal disease accompanied by fluid retention.
- Hypertension as monotherapy or in combination with an antihypertensive agent in patients with heart failure or chronic renal disease, or persistent hypertension or when first-line drugs are not sufficient or not tolerated.
- Intravenous administration is recommended, when immediate diuresis is required, such as in cases of pulmonary oedema.

(see SmPC for the full indication).

It contains furosemide as the active substance and it is given by intravenous or intramuscular injection.

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

Important risks of FUROSEMIDE, together with measures to minimise such risks and the proposed studies for learning more about FUROSEMIDE'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*.

II.A List of important risks and missing information

Important risks of FUROSEMIDE 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. 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 longterm use of the medicine).

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

As the active substance of this product (furosemide) has been used for decades and their safety concerns are well-known there were no safety concerns applicable for this EU RMP based on the requirement to present only the important identified or potential risks and missing information linked to further pharmacovigilance activities or additional risk minimization measures in the EU.

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 FUROSEMIDE.

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

There are no studies required for FUROSEMIDE.