Part VI: Summary of the risk management plan

Summary of risk management plan for *Noradrenaline 0.2 mg/ml Solution for Infusion*

This is a summary of the risk management plan (RMP) for *Noradrenaline 0.2 mg/ml Solution for Infusion*. The RMP details important risks of *Noradrenaline 0.2 mg/ml Solution for Infusion*, how these risks can be minimised, and how more information will be obtained about the product's risks and uncertainties (missing information).

The summary of product characteristics (SmPC) for *Noradrenaline 0.2 mg/ml Solution for Infusion* and its package leaflet give essential information to healthcare professionals and patients on how noradrenaline (norepinephrine) should be used.

I. The medicine and what it is used for

Noradrenaline 0.2 mg/ml Solution for Infusion is authorised as an emergency measure in the restoration of blood pressure in cases of acute hypotension. It contains noradrenaline (norepinephrine) tartrate as the active substance and it is only given by the intravenous infusion via a central venous catheter or a cannula placed into a sufficiently large vein to minimise the risk of extravasation and subsequent tissue necrosis. It should be infused at a controlled rate using a syringe driver pump.

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

Important risks of *Noradrenaline 0.2 mg/ml Solution for Infusion*, together with measures to minimise such risks and the proposed studies for learning more about *Noradrenaline 0.2 mg/ml Solution for Infusion*, 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 product will be supplied as **Ready-To-Use** solution for infusion along with an **Integrated Syringe Label (ISL)®** to minimise the risk of medication errors;
- 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 a prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In the case of *Noradrenaline 0.2 mg/ml Solution for Infusion,* these measures are supplemented with additional risk minimization measures (when considered necessary by any CMS and agreed at national level) mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment 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 *Noradrenaline 0.2 mg/ml Solution for Infusion* is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of *Noradrenaline 0.2 mg/ml Solution for Infusion* 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 *Noradrenaline 0.2 mg/ml Solution for Infusion*. 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	• Risk of medication errors
Missing information	• None

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 *Noradrenaline 0.2 mg/ml Solution for Infusion*.

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

There are no studies required for *Noradrenaline 0.2 mg/ml Solution for Infusion*.