**PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN**

**Summary of risk management plan for Noradrenalin Abcur 1 mg/ml concentrate for solution for infusion (herein after referred to as Noradrenaline).**

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

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

Important new concerns or changes to the current ones will be included in updates Noradrenaline RMP.

**I. The medicine and what it is used for**

Noradrenaline is used in short-term treatment of acute hypotension, such as in septic shock.

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

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

If important information that may affect the safe use of Noradrenaline is not yet available, it is listed under 'missing information' below

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

Important risks of Noradrenaline 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. 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<br>• Bradycardia and Cardiac arrhythmias<br>• Hypertension<br>• Dyspnoea<br>• Extravasation<br>• Necrosis and Peripheral ischaemia (including gangrene of the extremities) |
| **Important potential risks** | • Use during pregnancy<br>• Medication error / Risk of medication error<br>• Drug-drug interaction |
| **Missing information** | • Use in patients with renal or hepatic insufficiency<br>• Use in paediatric population<br>• 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 for Noradrenalin Abcur 1 mg/ml concentrate for solution for infusion.

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

There are no studies required for Noradrenalin Abcur 1 mg/ml concentrate for solution for infusion.