Part VI: Summary of the risk management plan

Summary of risk management plan for <invented name>

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

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

I. The medicine and what it is used for

<Invented name> is authorised for Cardiopulmonary resuscitation in adults (see SmPC for the full indication). It contains adrenaline tartrate as the active substance and it is given by Solution for injection in pre-filled syringe. Each ml of solution for injection contains 1 mg of adrenaline “as adrenaline tartrate”. Each 5 ml pre-filled syringe contains 5 mg adrenaline as “adrenaline tartrate”.

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

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

II.A List of important risks and missing information

Important risks of <invented name> 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 <invented name>. 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);

Table 1: List of important risks and missing information

List of important risks and missing information	
Important identified risks	Administration error Lack of drug effect Tissue necrosis Peripheral ischemia
Important potential risks	None
Missing information	None

II.B Summary of important risks

Table 2: Summary of important risks

Important identified risks	**Administration error**
Evidence for linking the risk to the medicine	Information from the safety database
Risk factors and risk groups	Adrenaline toxicity depends on the sensitivity of the individual patient and on the dose involved
Risk minimisation measures	Routine risk minimisation measures: presentation (pre-filled syringe) should limit the risk of medication error Additional risk minimisation measures: none
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: none Additional pharmacovigilance activities: none

Important identified risks	**Lack of drug effect**
Evidence for linking the risk to the medicine	Information from the safety database
Risk factors and risk groups	Unknown
Risk minimisation measures	Routine risk minimisation measures: - SmPC section 4.4 - PL section 2 Additional risk minimisation measures: none
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: none Additional pharmacovigilance activities: none

Important identified risks	**Tissue necrosis**
Evidence for linking the risk to the medicine	Safety database and literature
Risk factors and risk groups	Unknown
Risk minimisation measures	Routine risk minimisation measures: - SmPC section 4.8 - PL section 4 Additional risk minimisation measures: none
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: none Additional pharmacovigilance activities: none

Important identified risks	**Peripheral ischemia**
Evidence for linking the risk to the medicine	Literature
Risk factors and risk groups	Unknown
Risk minimisation measures	Routine risk minimisation measures: - SmPC section 4.8 - PL section 4 Additional risk minimisation measures: none
Additional pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: none Additional pharmacovigilance activities: none

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.

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

There are no studies required.