Part VI: Summary of the risk management plan

Summary of risk management plan for Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials):

This is a summary of the risk management plan (RMP) for Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials).

The RMP details important risks of Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials), how these risks can be minimized and how more information will be obtained about Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials) risk and uncertainties (missing information).

Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials) summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials) should be used.

Important new safety concerns will be included in updates of Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials) RMP.

I. The medicine and what it is used for

Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials) contains Isoprenaline, a medicine used in certain heart rhythm disorders and some cardiac emergencies.

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

Important risks of Isoprenaline Hydrochloride, together with measures to minimise such risks and the proposed studies for learning more about Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials), are outlined below.

Measures to minimise the risks identified for these 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 authorized 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 (with 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*.

If important information that may affect the safe use of Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials) are not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials) 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 Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials). 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

Summary of safety concerns	
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 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 Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials).

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

There are no studies required for Isoprenaline hydrochloride 0.2 mg/mL Concentrate for Solution for Infusion (1mL and 5 mL vials).