PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion:

This is a summary of the risk management plan (RMP) for Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion. The RMP details important risks of Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion, how these risks can be minimised, and how more information will be obtained about Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion's risks and uncertainties (missing information).

Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion's RMP.

I. The medicine and what it is used for

Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion is authorised to use in Short-term treatment of permanent bradycardia due to atrio-ventricular block while pending a pacemaker or when a pacemaker is contraindicated.

Short-term treatment of Adams-Stokes syndrome.

National and international recommendations and guidelines on the appropriate use of isoprenaline should be followed.

It contains isoprenaline hydrochloride as the active substance and it is given by intravenous route.

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

Important risks of Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion, together with measures to minimise such risks and the proposed studies for learning more about Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion'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 PL 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 Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/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 Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/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).

List of important risks and missing information	
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 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 Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion.

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

There are no studies required for Isoprenaline hydrochloride 0.2 mg/ml and 1mg/5ml solution for injection/Infusion.