Part VI: Summary of the risk management plan

Summary of risk management plan for Isomacor

This is a summary of the risk management plan (RMP) for Isomacor 0.2 mg/mL concentrate solution for infusion. The RMP details important risks of Isomacor, how these risks can be minimised and how more information will be obtained about Isomacor risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Isomacor is authorised for

- Treatment of circulatory emergencies, especially when combined with a fall in cardiac output and an increase in central venous pressure when general measures are insufficient and more conventional treatments are not available or are contraindicated.
- Treatment of permanent bradycardia due to atrio-ventricular block pending or in the case of contraindication of a pacemaker
- Adams-Stokes syndrome treatment

It contains 0.2 mg/mL of isoprenaline hydrochloride as the active substance and it is given by concentrate for solution for infusion.

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

Important risks of Isomacor, together with measures to minimise such risks and the proposed studies for learning more about Isomacor'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 Isomacor is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Isomacor are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or taken. 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 Isomacor. 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 longterm use of the medicine).

Summary of safety concerns	
Important identified risk	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

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 Isomacor.

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

There are no studies required for Isomacor, concentrate for solution for infusion.