Part VI: Summary of the risk management plan

Summary of risk management plan for Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion

This is a summary of the risk management plan (RMP) for Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion. The RMP details important risks of Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion, how these risks can be minimised, and how more information will be obtained about the product's risks and uncertainties (missing information).

The summary of product characteristics (SmPC) for Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion and its package leaflet give essential information to healthcare professionals and patients on how amiodarone should be used.

I. The medicine and what it is used for

Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion is authorised for the treatment of serious cardiac arrhythmias, in cases where other therapies are not effective or contraindicated:

- atrial arrhythmias, including atrial fibrillation or flutter
- AV nodal arrhythmias and AV reentrant tachycardia, e.g. as a manifestation of Wolff-Parkinson-White syndrome
- life-threatening ventricular arrhythmias, including persistent or non-persistent ventricular tachycardia or episodes of ventricular fibrillation

Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion can be used where a rapid response is required or where oral administration is not possible (see SmPC for the full indication). It contains amiodarone as the active substance and it is given by the intravenous route of administration.

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

Important risks of Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion, together with measures to minimise such risks and the proposed studies for learning more about the risks associated with Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion, 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 (i.e. only supplied with a prescription in the case of Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

If important information that may affect the safe use of Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Amiodarone Hydrochloride 50 mg/ml Concentrate for 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 Amiodarone Hydrochloride 50 mg/ml Concentrate for 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 use of the medicine in childrena and adolescents);

Summary of safety concerns	
Important identified risks	• Thyroid disorders • Hepatotoxicity • Pulmonary toxicity • Conduction disturbances • Proarrhythmic disorder (including arrhythmia, torsade de pointes and cardiac arrest) • Muscular toxicity in combination with statins • Severe skin reactions (including SJS and TEN)
Important potential risks	• None
Missing information	• Use in the paediatric population

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 a specific obligation of Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion.

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

There are no studies required for Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion.