Part VI: Summary of the risk management plan

Summary of risk management plan for Asacor (acetylsalicylic acid).

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

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

I. The medicine and what it is used for

Asacor is authorised for Adults above 18 years: Emergency treatment for suspected acute myocardial infarction after contact with emergency medical services (see SmPC for the full indication). It contains ASA as the active substance, and it is given for oral use. The content is to be drunken following reconstitution. The powder is to be dissolved in the solvent and then shaken until it is dissolved.

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

Important risks of Asacor, together with measures to minimise such risks and the proposed studies for learning more about Asacor'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;

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 Asacor are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely 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 Asacor. 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.

List of important risks and missing information	
Important identified risks	None
Important potential risks	• Treatment failure due to product storage error, incorrect opening technique and/or patient unable to open the bottle
Missing information	None

II.B Summary of important risks

Important potential risk – Treatment failure due to product storage error, incorrect opening technique and/or patient unable to open the bottle	
Evidence for linking the risk to the medicine	Asacor is indicated in emergency treatment for suspected acute myocardial infarction after contact with emergency medical services. Hence, product storage error and incorrect opening technique could hinder adequate treatment and therefore may cause serious health issues.
Risk factors and risk groups	As it is likely that Asacor will be stored in a patient's pocket or purse, there may be a risk of the liquid freezing during the wintertimer or when ambient temperatures drop below the freezing point of Asacor. The risk of using the incorrect opening technique, may increase under stress or if the patient has reduced grip force in fingers.
Risk minimisation measures	Routine risk communication: SmPC section 6.4 and 6.6 PL section 3 and 5 Routine risk minimisation activities recommending specific clinical measures to address the risk: None Other routine risk minimisation measures beyond the Product Information: The foldable label on the bottle of Asacor contains pictograms of the right opening technique. The foldable label on the bottle further ensures that the instructions are always available on the bottle, even if the package leaflet is discarded. The package of Asacor contains recommendation of storage.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies with conditions of the marketing authorisation for Asacor 300 mg, powder and solvent for oral solution.

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

There are no studies required for Asacor 300 mg, powder and solvent for oral solution.