Part VI: Summary of the risk management plan

Summary of risk management plan for ProAsa (acetylsalicylic acid)

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

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

Important new concerns or changes to the current ones will be included in updates of ProAsa 's RMP.

I. The medicine and what it is used for

ProAsa is used to reduce the risk of blood clots forming and thereby prevent further heart attacks, strokes and cardiovascular problems in patients who suffer from stable or unstable angina. ProAsa is also used in the treatment of acute heart attack (see SmPC for the full indication). It contains acetylsalicylic acid as the active substance and it is given by mouth.

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

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

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

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

Safety concerns are adequately addressed in the product information.

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 ProAsa.

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

There are no studies required for ProAsa.