Part VI: Summary of the risk management plan

Summary of risk management plan for Mesalazine 500 mg suppositories and Mesalazine 1000 mg suppositories

This is a summary of the risk management plan (RMP) for Mesalazine 500 mg suppositories and Mesalazine 1000 mg suppositories. The RMP details important risks of Mesalazine, how these risks can be minimised and how more information will be obtained about risks and Mesalazine 500 mg Mesalazine 1000 mg suppositories uncertainties (missing information).

Mesalazine 500 mg and Mesalazine 1000 mg suppositories summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how this medicine should be used.

1.1. I. The medicine and what it is used for

Mesalazine 500 mg suppositories and Mesalazine 1000 mg suppositories are authorised for the treatment of acute episodes of mild to moderate ulcerative colitis and treatment in maintenance of remission in ulcerative colitis. It contains mesalazine as the active substance and it is given by rectal route as suppositories.

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

Important risks of Mesalazine 500 mg suppositories and Mesalazine 1000 mg suppositories, together with measures to minimise such risks and the proposed studies for learning more about mesalazine suppositories 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, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Mesalazine 500 mg suppositories and Mesalazine 1000 mg suppositories is not yet available, it is listed under 'missing information' below.

1.2.1. II. A List of important risks and missing information

Important risks of Mesalazine 500 mg suppositories and Mesalazine 1000 mg suppositories 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 Mesalazine 500 mg suppositories or Mesalazine 1000 mg suppositories. 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.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 Mesalazine 500 and 1000 mg suppositories.

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

There are no studies required for Mesalazine 500 and 1000 mg suppositories.