Summary of risk management plan for Mesalazine ESPL 1 g Suppositories (mesalazine)

This is a summary of the risk management plan (RMP) for Mesalazine ESPL 1 g Suppositories. The RMP details important risks of Mesalazine ESPL 1 g Suppositories, how these risks can be minimised, and how more information will be obtained about Mesalazine ESPL 1 g Suppositories' risks and uncertainties (missing information).

Mesalazine ESPL 1 g Suppositories' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Mesalazine ESPL 1 g Suppositories should be used.

Important new concerns or changes to the current ones will be included in updates of Mesalazine ESPL 1 g Suppositories' RMP.

I. The medicine and what it is used for

Mesalazine ESPL 1 g Suppositories is authorised for treatment of acute mild to moderate ulcerative colitis that is limited to the rectum (ulcerative proctitis). It contains mesalazine as the active substance and it is given by rectal route, in the form of suppositories containing 1 g of mesalazine.

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

Important risks of Mesalazine ESPL 1 g Suppositories, together with measures to minimise such risks and the proposed studies for learning more about Mesalazine ESPL 1 g 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 ESPL 1 g Suppositories is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Mesalazine ESPL 1 g 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 ESPL 1 g 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	Safety in pregnancy and lactation

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Important identified risks

None

Important potential risks

None

Missing information

Safety in pregnancy and lactation	
Risk minimisation measures	<u>Routine risk minimisation measures</u> Relevant text is provided in the following sections of the product information: SmPC section 4.6 and PL section 2. Legal status: Prescription only medicine. <u>Additional risk minimisation measures</u> 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 ESPL 1 g Suppositories.

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

There are no studies required for Mesalazine ESPL 1 g Suppositories.