Part VI: Summary of the risk management plan for Salofalk® all dosage forms

This is a summary of the risk management plan (RMP) for all dosage forms of Salofalk®. The RMP details important risks of all dosage forms of Salofalk®, how these risks can be minimised and how more information will be obtained about risks and uncertainties (missing information) associated with the use of the product.

For different dosage forms of Salofalk®, in total 10 summary of product characteristics (SmPC) and its respective package leaflets give essential information to healthcare professionals and patients on how the different dosage forms of Salofalk® should be used.

I. The medicine and what it is used for

Salofalk® 500 mg / 1000 mg / 1.5 g / 3 g prolonged-release granules are authorised for the treatment of acute episodes and the maintenance of remission of mild to moderate ulcerative colitis.
It contains mesalazine as the active substance and it is given by oral route of administration.

Salofalk® 1000 mg gastro-resistant tablets are authorised for the treatment of acute episodes of mild to moderate ulcerative colitis. Salofalk® 250 mg / 500 mg gastro-resistant tablets are authorized for the treatment of acute episodes and the maintenance of remission of ulcerative colitis and for the treatment of acute episodes of Crohn's disease. It contains mesalazine as the active substance and it is given by oral route of administration.

Salofalk® 4g/60ml enema / rectal suspension are authorised for acute attacks of ulcerative colitis (a chronic inflammatory disease of the large bowel). Salofalk® 2g/30ml enema are authorised for acute attacks of mild to moderate ulcerative colitis (a chronic inflammatory disease of the large bowel) limited to the rectum and the sigmoid colon. Salofalk® 2g/60ml enema are authorised for therapy and prophylaxis of acute attacks of mild ulcerative colitis, especially in the rectum and sigmoid colon and also in the descending colon.
It contains mesalazine as the active substance and it is given by rectal route of administration.

Salofalk® 1000 mg suppositories are authorised for the treatment of acute mild to moderate ulcerative colitis that is limited to the rectum (ulcerative proctitis). Salofalk® 500 mg suppositories are authorised for the treatment of acute episodes of ulcerative colitis that is limited to the rectum. Salofalk® 250 mg suppositories are authorised for the treatment of acute episodes and maintenance of remission of ulcerative colitis that is limited to the rectum.
It contains mesalazine as the active substance and it is given by rectal route of administration.

Salofalk® 1g/actuation rectal foam is authorised for the treatment of active, mild ulcerative colitis of the sigmoid colon and rectum.
It contains mesalazine as the active substance and it is given by rectal route of administration.

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

Risks of all dosage forms of Salofalk®, together with measures to minimise such risks are outlined below.

Measures to minimise any risks identified for Salofalk® medicinal products are:

- 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 authorized 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 a patient (e.g. with or without prescription) can help to minimize 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.

II.A List of important risks and missing information

Important risks of Salofalk® 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 Salofalk®. 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).

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

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 any Salofalk® dosage form.

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

Not applicable