

Part VI: Summary of the risk management plan

Summary of risk management plan for MESALAZINA DOC (mesalazine)

This is a summary of the Risk Management Plan (RMP) for MESALAZINA DOC. The RMP details important risks of mesalazine, how these risks can be minimised, and how more information will be obtained about mesalazine's risks and uncertainties (missing information).

MESALAZINA DOC 's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how mesalazine should be used.

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

I. The medicine and what it is used for

MESALAZINA DOC is authorised for ulcerative Colitis and Crohn's disease in adults and children over two years of age. It contains mesalazine as the active substance, and it is for oral and rectal use.

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

Important risks of mesalazine, together with measures to minimise such risks and the proposed studies for learning more about mesalazine's risks, are outlined below.

Measures to minimize 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. Mesalazine is subject to restricted medical prescription.

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 is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of mesalazine 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 mesalazine. 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	<ul style="list-style-type: none"> • Impairment of renal function including interstitial nephritis, renal insufficiency • Impairment of hepatic function including hepatitis, cholestatic hepatitis • Respiratory disorders including pneumonitis, viral/bacterial pneumonias • Blood dyscrasias including agranulocytosis, thrombocytopenia, aplastic anaemia
Important potential risks	<ul style="list-style-type: none"> • Neonatal gastrointestinal bleeding
Missing information	<ul style="list-style-type: none"> • None

II.B Summary of important risks

The safety profile in the proposed product information is aligned to the reference active substance .

II.C Post-authorisation development plan

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

Not applicable. There are no studies which are conditions of the marketing authorisation or specific obligation of mesalazine.

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

Not applicable. There are no studies required for mesalazine.