

Part VI: Summary of the risk management plan

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

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

I. The medicine and what it is used for

CORTIMENT is authorised for induction of remission in adult patients with mild to moderate active ulcerative colitis (UC) where 5-ASA treatment is not sufficient. Furthermore, CORTIMENT is also intended for induction of remission in adult patients with microscopic colitis (MC).

CORTIMENT contains budesonide (in a Multi-Matrix formulation (MMX)) as the active substance and it is given by prolonged-release tablet.

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

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

List of important risks and missing information	
Important identified risks	None.
Important potential risks	None.
Missing information	None.

II.B Summary of important risks

Not applicable (no important risks or missing information).

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 CORTIMENT.

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

There are no studies required for CORTIMENT.