Part VI: Summary of the risk management plan

Summary of risk management plan for Mesalazine ESPL 1600 mg modified-release tablets (Mesalazine)

This is a summary of the risk management plan (RMP) for Mesalazine ESPL 1600 mg modified-release tablets. The RMP details important risks of Mesalazine ESPL 1600 mg modified-release tablets, how these risks can be minimised, and how more information will be obtained about Mesalazine ESPL 1600 mg modified-release tablets' risks and uncertainties (missing information).

Mesalazine ESPL 1600 mg modified-release tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Mesalazine ESPL 1600 mg modified-release tablets should be used. This summary of the RMP for Mesalazine ESPL 1600 mg modified-release tablets should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary.

Important new concerns or changes to the current ones will be included in updates of Mesalazine ESPL 1600 mg modified-release tablets' RMP.

I. The medicine and what it is used for

Mesalazine ESPL 1600 mg modified-release tablets are proposed to be authorised for the treatment and maintenance of mild to moderate ulcerative colitis (see SmPC for the full indication). It contains mesalazine as the active substance and it is given by mouth.

Clinical studies have shown Mesalazine ESPL 1600 mg modified-release tablets to be effective for treating adults with ulcerative colitis.

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

Important risks of Mesalazine ESPL 1600 mg modified-release tablets, together with measures to minimise such risks and the proposed studies for learning more about Mesalazine ESPL 1600 mg modified-release tablets‘ 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, such as warnings, precautions, and advice on correct use;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine will be supplied to the public only with prescription to enable medical supervision.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, 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 1600 mg modified-release tablets is not yet available, it is listed under 'missing information' below

2.1 List of important risks and missing information

Important risks of Mesalazine ESPL 1600 mg modified-release tablets 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 1600 mg modified-release tablets. Potential risks are concerns for which an association with the use of this medicine is possible based on some preliminary data, but this association has not been fully proven and needs further evaluation.

List of important risks and missing information	
Important identified risks	Hypersensitivity including reactions in patients with a history of adverse drug reactions to sulphasalazine Drug induced blood dyscrasia including bone marrow failure Drug induced hepatic toxicity Drug induced renal toxicity Cardiac hypersensitivity reactions Aggravation of pulmonary disease, in particular asthma Aggravation of active gastric or duodenal ulcer
Important potential risks	None
Missing information	Effect on fertility, pregnancy and lactation Treatment benefits in paediatric patients 6-18 years of age Exposure in children younger than 6 years old

2.2 Summary of important risks

Hypersensitivity to the active ingredients or any of the ingredients including reactions in patients with a history of adverse drug reactions to sulphasalazine

Risk minimisation measures	SmPC section 4.3 and 4.8 SmPC section 4.4 where advice is given on monitoring of patients with a history of adverse drug reactions to sulphasalazine. PL sections 2 and 4 Prescription only medicine

Drug induced blood dyscrasia including bone marrow failure

Risk minimisation measures	SmPC section 4.8 SmPC section 4.4 where advice is given on need of conducting routine blood tests and to stop mesalazine treatment immediately and seek

	medical advice if there is a suspicion or evidence of blood dyscrasia PL sections 2 and 4 Prescription only medicine

Drug induced hepatic toxicity

Risk minimisation measures	SmPC sections 4.3 and 4.8 SmPC section 4.4 where advice is given on caution in patients with liver impairment and on the need to monitor the liver function PL sections 2 and 4 Prescription only medicine

Drug induced renal toxicity

Risk minimisation measures	SmPC sections 4.3 and 4.8 SmPC section 4.4 where advice is given on need to monitor the renal function, to not use in patients with renal impairment and to stop mesalazine treatment immediately if the renal function is impaired during treatment PL sections 2 and 4 Prescription only medicine

Cardiac hypersensitivity reactions

Risk minimisation measures	SmPC section 4.8 SmPC section 4.4 where advice is given on need of caution in patients with previous myo- or pericarditis of allergic background PL sections 2 and 4 Prescription only medicine

Aggravation of pulmonary disease, in particular asthma

Risk minimisation measures	SmPC section 4.8 SmPC section 4.4 where advice is given on need of very careful monitoring in patients with pulmonary disease, in particular asthma PL sections 2 and 4 Prescription only medicine

Aggravation of active gastric or duodenal ulcer

Risk minimisation measures	SmPC section 4.4 where advice is given on need of caution in patients with active gastric or duodenal ulcer PL section 2 Prescription only medicine

2.3 Summary of missing information

Effect on fertility, pregnancy and lactation

Risk minimisation measures	SmPC section 4.6 PL section 2 Prescription only medicine Pregnancy follow-up form

Treatment benefits in paediatric patients 6-18 years of age

Risk minimisation measures	SmPC sections 4.2 and 4.4 PL section 3 Prescription only medicine

Exposure in children younger than 6 years old

Risk minimisation measures	Prescription only medicine

2.4 Post-authorisation development plan

2.4.1 Studies which are conditions of the marketing authorisation

Not applicable.

2.4.2 Other studies in post-authorisation development plan

Not applicable.