Summary of risk management plan for Budesonide 3 mg hard capsules

This is a summary of the risk management plan (RMP) for Budesonide 3 mg hard capsules. The RMP details important risks of Budesonide 3 mg hard capsules, how these risks can be minimised, and how more information will be obtained about Budesonide 3 mg hard capsules' risks and uncertainties (missing information).

Budesonide 3 mg hard capsules summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Budesonide 3 mg hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of Budesonide 3 mg hard capsules' RMP.

I. The medicine and what it is used for

Budesonide 3 mg hard capsules is authorised to reduce inflammation. Mild to moderate Crohn's disease of the ileum and ascending colon: budesonide is used to treat an inflammation of the small bowel and the first part of the large bowel. Active microscopic colitis and maintenance treatment of severe, recurrent microscopic colitis: budesonide is used to treat microscopic colitis (a disease with chronic inflammation of the large bowel which is typically with chronic watery diarrhoea) (see SmPC for the full indication). It contains budesonide as the active substance, and it is given by oral route.

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

Important risks of Budesonide 3 mg hard capsules together with measures to minimise such risks and the proposed studies for learning more about Budesonide 3 mg hard capsules' 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 Budesonide 3 mg hard capsules are risks that need special risk management activities to further investigate or minimise the risks, 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 Budesonide 3 mg hard capsules. 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	- None

II.B Summary of important risks

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

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Budesonide 3 mg hard capsules.

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

There are no studies required for Budesonide 3 mg hard capsules.