Part VI: Summary of the risk management plan for Budenofalk® 3mg gastro-resistant capsules

This is a summary of the risk management plan (RMP) for Budenofalk® 3mg gastro-resistant capsules. The RMP details important risks of Budenofalk® 3mg gastro-resistant capsules, 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.

Budenofalk® 3mg gastro-resistant capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Budenofalk® 3mg gastro-resistant capsules should be used.

I. The medicine and what it is used for

Budenofalk® 3mg gastro-resistant capsules are authorised for

- Induction of remission in patients with mild to moderate active Crohn's disease affecting the ileum and/or ascending colon
- the treatment of microscopic colitis
- the treatment of autoimmune hepatitis

It contains Budesonide as the active substance and it is given by oral route of administration.

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

Important risks of Budenofalk® 3mg capsules, together with measures to minimise such risks and the proposed study for learning more about Budenofalk®'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 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

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 Budenofalk® 3mg gastro-resistant capsules.

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

Not applicable