Part VI: Summary of the risk management plan

Summary of risk management plan for Entolex (peppermint oil)

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

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

I. The medicine and what it is used for

Entolex is authorised for the symptomatic relief of minor spasms of the gastrointestinal tract, flatulence, and abdominal pain, especially in patients with irritable bowel syndrome (see SmPC for the full indication). It contains peppermint oil 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 Entolex, together with measures to minimise such risks and the proposed studies for learning more about Entolex’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 public (e.g. with or without prescription) can help to minimises its risks.

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***.

II.A List of important risks and missing information

Important risks of Entolex are risks that need special risk management activities to further investigate or minimise the risk, 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 Entolex. 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. Missing information refers to information on the safety of the medicinal product that is currently missing and need 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 with the European Union herbal monograph on Mentha x piperita L., aetheroleum (EMA/HMPC/522410/2013) and the HMPC Assessment Report on Mentha x piperita L., aetheroleum (EMA/HMPC/522409/2013).

II.C Post-authorisation development plan

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

There are no on-going or planned studies which are conditions of the marketing authorisation or specific obligation of Entolex.

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

There are no on-going or planned category 1-2-3 studies required for Entolex.