Part VI: Summary of the risk management plan

Summary of risk management plan for Pepelia (mentha x piperitae)

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

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

I. The medicine and what it is used for

Pepelia is authorised for the symptomatic relief of minor spasms of the gastrointestinal tract, flatulence and abdominal pain, including in patients with irritable bowel syndrome (see SmPC for the full indication). It contains mentha x piperitae as the active substance and it is given by mouth.

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

Important risks of Pepelia, together with measures to minimise such risks and the proposed studies for learning more about Pepelia'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 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 of the risks of Pepelia need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken.

II.B Summary of important risks

None of the risks of Pepelia need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken.

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 Pepelia.

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

There are no studies required for Pepelia.