Part VI: Summary of the risk management plan

Summary of risk management plan for Mebeverine Aristo 200 mg modified-release capsules, hard (mebeverine)

This is a summary of the risk management plan (RMP) for Mebeverine Aristo 200 mg modified-release capsules, hard. The RMP details important risks of Mebeverine Aristo 200 mg modifies-release capsules, hard and how more information will be obtained about Mebeverine Aristo 200 mg modified-release capsules, hard's risks and uncertainties (missing information).

Mebeverine Aristo 200 mg modified-release capsules, hard's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Mebeverine Aristo 200 mg modified-release capsules, hard should be used.

Important new concerns or changes to the current ones will be included in updates of Mebeverine Aristo 200 mg modified-release capsules, hard's RMP.

I. The medicine and what it is used for

Mebeverine Aristo 200 mg prolonged-release capsules, hard is authorised for the symptomatic relief of irritable bowel syndrome in adult patients (see SmPC for the full indication). It contains mebeverine as the active substance and it is given orally.

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

Important risks of Mebeverine Aristo 200 mg modified-release capsules, hard, together with measures to minimise such risks and the proposed studies for learning more about Mebeverine Aristo 200 mg modified-release capsules, hard'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

Important risks of Mebeverine Aristo 200 mg modified-release capsules, hard are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Mebeverine Aristo 200 mg modified-release capsules, hard. 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

No safety concerns have been considered important for inclusion in the list of safety concerns in the RMP.

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 Mebeverine Aristo 200 mg modified-release capsules, hard.

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

There are no studies required for Mebeverine Aristo 200 mg modified-release capsules, hard.