Part VI: Summary of the risk management plan

Summary of Risk Management Plan for [Sevelamer carbonate] 800 mg film-coated tablets

This is a summary of the risk management plan (RMP) for [Sevelamer carbonate] 800 mg film-coated tablets. The RMP details important risks of [Sevelamer carbonate] 800 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about [Sevelamer carbonate] 800 mg film-coated tablet's risks and uncertainties (missing information).
[Sevelamer carbonate] 800 mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Sevelamer carbonate] 800 mg film-coated tablets should be used.
Important new concerns or changes to the current ones will be included in updates of [Sevelamer carbonate] 800 mg film-coated tablet's RMP.

I. The medicine and what it is used for

[Sevelamer carbonate] 800 mg film-coated tablets is authorised for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis, for the control of hyperphosphataemia in adult patients with chronic kidney disease (CKD) not on dialysis with serum phosphorus ≥ 1.78 mmol/l, and it should be used within the context of a multiple therapeutic approach, which could include calcium supplement,1,25-dihydroxy Vitamin D3 or one of its analogues to control the development of renal bone disease. It contains sevelamer carbonate 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 [Sevelamer carbonate] 800 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about [Sevelamer carbonate] 800 mg film-coated tablets' risks, are outlined below.

Measures to minimise the known risks of this [Sevelamer carbonate] 800 mg film-coated tablets include:

- 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 periodic safety update report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of [[Sevelamer carbonate] 800 mg film-coated tablets is not yet available, it is listed under the 'missing information' below.

II.A List of important risks and missing information

Important risks of [Sevelamer carbonate] 800 mg film-coated tablets 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 [Sevelamer carbonate] 800 mg film-coated tablets. 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 authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of [Sevelamer carbonate] 800 mg film-coated tablets.

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

There are no studies required for [Sevelamer carbonate] 800 mg film-coated tablets.