Part VI: Summary of the risk management plan

This is a summary of the risk management plan (RMP) for Sevelamer hydrochloride 400 mg and 800 mg tablets. The RMP details important risks of Sevelamer hydrochloride 400 mg and 800 mg tablets, how these risks can be minimised, and how more information will be obtained about the risks and uncertainties (missing information) of Sevelamer hydrochloride 400 mg and 800 mg tablets.

Sevelamer hydrochloride 400 mg and 800 mg tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how they should be used.

I. The medicine and what it is used for

Sevelamer hydrochloride 400 mg and 800 mg tablets are indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. Sevelamer hydrochloride should be used within the context of a multiple therapeutic approach, which could include calcium supplements, 1,25-dihydroxy Vitamin D3 or one of its analogues to control the development of renal bone disease.

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

Important risks of Sevelamer hydrochloride 400 mg and 800 mg tablets, together with measures to minimise such 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.

If important information that may affect the safe use of Sevelamer hydrochloride 400 mg and 800 mg tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Summary of safety concerns	
Important identified risks	Intestinal perforation, obstruction and ileus. Diverticulitis. Acidosis, increased serum chloride levels.
Important potential risks	Serious gastrointestinal disorders associated with sevelamer crystals. Hypersensitivity reactions, including angioedema and anaphylactic reactions. Difficulty swallowing tablets. Vitamin deficiency. Drug interaction with levothyroxine, ciprofloxacin, immunosuppressants (e.g. ciclosporin, mycophenolate mofetil, tacrolimus), antiarrhythmics, anticonvulsants and antifungal drugs. Off-label use in patients below the age of 18 years.
Missing information	Use during pregnancy and breastfeeding. Use in hepatic impairment and in immunocompromised patients.

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 obligations of Sevelamer hydrochloride 400 mg and 800 mg tablets.

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

There are no studies required for Sevelamer hydrochloride 400 mg and 800 mg tablets.