Part VI: Summary of the risk management plan

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

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

I. The medicine and what it is used for

Sevelamer carbonate is authorised for the control of hyperphosphataemia in: (i) adult patients receiving haemodialysis or peritoneal dialysis and in (ii) adult patients with chronic kidney disease not on dialysis with serum phosphorus ≥1.78 mmol/L (see SmPC for the full indication). It contains sevelamer carbonate as the active substance and it is given orally as tablet (800 mg) or as powder for oral suspension (2.4 g).

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

Important risks of sevelamer carbonate, together with measures to minimise such risks and the proposed studies for learning more about sevelamer carbonate'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, including 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 is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of sevelamer carbonate 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 sevelamer carbonate. 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	Intestinal perforation, obstruction and ileus
Important potential risks	Difficulty swallowing tablets*
	Drug interactions with levothyroxine, ciprofloxacin, immunosuppressants, antiarrhythmics, anticonvulsants, and antifungal drugs
	Hypersensitivity reactions, including angioedema and anaphylactic reactions
	Off-label use in patients <18 years old
	Serious gastrointestinal disorders associated with sevelamer crystals
	Vitamin deficiency
Missing information	Use in hepatic impairment and immunocompromised patients
	Use in pregnancy and lactation

* For tablet formulation only.

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to that of the reference medicinal product Renvela ® (Sanofi) (1, 2).

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.

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

There are no studies required for Sevelamer carbonate.