Part VI: Summary of the Risk Management Plan

Summary of risk management plan for [Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection.

This is a summary of the Risk Management Plan (RMP) for [Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection. The RMP details important risks of [Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection, how these risks can be minimised, and how more information will be obtained about [Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection and uncertainties (missing information).

[Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection should be used.

I. The medicine and what it is used for

[Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection is authorised for the prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure undergoing haemodialysis. It contains paricalcitol as the active substance and it is given via haemodialysis access.

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

Important risks for [Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection, together with measures to minimize such risks and the proposed studies for learning more about [Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection are outlined below.

Measures to minimise the risks identified for medicinal product can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and HCPs;
- 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

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 Zemplar® (Abbott Laboratories).

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 [Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection.

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

There are no studies required for [Paricalcitol] 2mcg/ml, 5mcg/ml, solution for injection.