Part VI: Summary of the risk management plan for Calrecia, 100 mmol/l, solution for infusion (calcium chloride dihydrate)

This is a summary of the risk management plan (RMP) for Calrecia, 100 mmol/l, solution for infusion. The RMP details important risks of this medicinal product, how these risks can be minimised, and how more information will be obtained about its risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of the RMP.

I. The medicine and what it is used for

The medicinal product is authorised for calcium substitution during continuous renal replacement therapies (CRRT), sustained low efficiency (daily) dialysis (SLEDD) and therapeutic plasma exchange (TPE) using citrate for anticoagulation (see SmPC for the full indication). It contains calcium chloride dihydrate as the active substance and it is given by infusion into the extracorporeal circuit or central venous infusion.

CALRECIA is indicated in adults and children.

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

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

II.A List of important risks and missing information

No risks were included as important identified or potential risks to this risk minimisation plan as risk minimisation measures have become fully integrated into standard clinical practice, such as inclusion into SmPC and patient information leaflet.

II.B Summary of important risks

Not applicable.

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 this medicinal product.

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

There are no studies required for this medicinal product.