Part VI: Summary of the risk management plan

Summary of risk management plan for Cinacalcet

This is a summary of the risk management plan (RMP) for cinacalcet. The RMP details important risks of cinacalcet, risk minimisation measures needed to minimise these risks and routine pharmacovigilance activities needed to obtain more information about cinacalcet risks and uncertainties (missing information).

Cinacalcet proposed Summary of Product Characteristics (SmPC) gives essential information to healthcare professionals and patients on how cinacalcet should be used.

I. The medicine and what it is used for

The proposed indications for cinacalcet are:

- Secondary hyperparathyroidism (HPT) in adult patients with end-stage renal disease (ESRD) on maintenance dialysis therapy.
- Secondary HPT in children aged 3 years and older with ESRD on maintenance dialysis therapy in whom secondary HPT is not adequately controlled with standard of care therapy.
- Reduction of hypercalcaemia in adult patients with parathyroid carcinoma and primary hyperparathyroidism.

It contains cinacalcet as the active substance and it is given by oral route.

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

Important risks of cinacalcet, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for cinacalcet can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflets and SmPCs 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, 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 cinacalcet is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of cinacalcet 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 cinacalcet. 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;

Important Identified Risks	• Hypocalcaemia • Convulsions/Seizures • Hypersensitivity reactions (including rash, urticaria and angioedema) • Hypotension and/or worsening heart failure • QT prolongation and ventricular arrhythmias secondary to hypocalcaemia
Important Potential Risks	• Fracture • Acute Pancreatitis • Possible drug-related hepatic disorders • Nervous system disorders (excluding seizures) • Neoplastic events
Missing information	• Use in pregnant or breastfeeding women

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

No post authorisation study is planned for this product.

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 cinacalcet.

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

There are no studies required for cinacalcet