

## **Part VI: Summary of the risk management plan (RMP) Cinacalcet hydrochloride, 30 mg, 60 mg and 90 mg, Film-coated tablets**

This is a summary of the Risk management plan (RMP) for cinacalcet hydrochloride, 30 mg, 60 mg and 90 mg, film-coated tablets. The RMP details important risks of Cinacalcet hydrochloride, film-coated tablets, how these risks can be minimized, and how more information will be obtained about cinacalcet hydrochloride, film-coated tablets' risks and uncertainties (missing information).

Cinacalcet hydrochloride, film-coated tablets' summaries of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to healthcare professionals (HCPs) and patients on how cinacalcet hydrochloride, film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of the cinacalcet hydrochloride, film-coated tablets' RMP.

### **Part VI: I. The medicine and what it is used for**

#### **Secondary hyperparathyroidism**

##### *Adults*

Treatment of secondary hyperparathyroidism (HPT) in adult patients with end-stage renal disease (ESRD) on maintenance dialysis therapy.

##### *Pediatric population*

Treatment of 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.

Cinacalcet hydrochloride may be used as part of a therapeutic regimen including phosphate binders and/or Vitamin D sterols, as appropriate.

#### **Parathyroid carcinoma and primary hyperparathyroidism in adults**

Reduction of hypercalcemia in adult patients with:

- Parathyroid carcinoma
- Primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated.

It contains cinacalcet hydrochloride as active substance and is taken orally as film-coated tablets (30 mg, 60 mg and 90 mg).

### **Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks**

Important risks of cinacalcet hydrochloride film-coated tablets together with measures to minimize such risks and the proposed studies for learning more about cinacalcet hydrochloride film-coated tablets' risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

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

- Important advice on the medicine’s packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including periodic safety update report (PSUR) assessment (if applicable) 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 hydrochloride, film-coated tablets is not yet available, it is listed under ‘missing information’ below.

### **Part VI – II.A: List of important risks and missing information**

Important risks of cinacalcet hydrochloride, film-coated tablets are risks that need special risk management activities to further investigate or minimize 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 cinacalcet hydrochloride, film-coated tablets. 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).

**Table 13-1 List of important risks and missing information**

<b>List of important risks and missing information</b>	
Important identified risks	Hypocalcemia
	Convulsions/seizures
	QT prolongation and ventricular arrhythmias secondary to hypocalcemia
Important potential risks	None
Missing Information	Use in pregnant or breastfeeding women

### **Part VI – II.B: Summary of important risks**

The safety information in the proposed product information is aligned to the originator product.

### **Part VI – II.C: Post-authorization development plan**

#### **II.C.1 Studies which are conditions of the marketing authorization**

There are no studies which are conditions of the marketing authorization or specific obligation of cinacalcet hydrochloride, film-coated tablets.

#### **II.C.2. Other studies in post-authorization development plan**

There are no studies required for cinacalcet hydrochloride, film-coated tablets.