

## Part VI: Summary of the risk management plan

# Summary of risk management plan for Cinacalcet Orion (cinacalcet)

This is a summary of the risk management plan (RMP) for Cinacalcet Orion. The RMP details important risks of this product, how these risks can be minimised, and how more information will be obtained about product's risks and uncertainties (missing information).

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

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

## I. The medicine and what it is used for

Cinacalcet Orion is authorized for:

- treatment of secondary hyperparathyroidism in patients with serious kidney disease who need dialysis
- reduction of high levels of calcium in the blood (hypercalcaemia) in patients with parathyroid cancer
- reduction of high levels of calcium in the blood (hypercalcaemia) in patients with primary hyperparathyroidism when removal of the parathyroid gland is not possible.

(see SmPC for the full indication).

This product contains cinacalcet as the active substance and it is taken by mouth.

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

Important risks of Cinacalcet Orion, together with measures to minimise such risks and the proposed studies for learning more about Cinacalcet Orion'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.

If important information that may affect the safe use of Cinacalcet Orion is not yet available, it is listed under 'missing information' below.

## II.A List of important risks and missing information

Important risks of Cinacalcet Orion 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 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 (e.g. on the long-term use of the medicine);

<b>List of important risks and missing information</b>	
Important identified risks	Hypocalcaemia
	Convulsions/Seizures
	QT prolongation and ventricular arrhythmias secondary to hypocalcaemia
Important potential risks	None
Missing information	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

There are no studies required for Cinacalcet Orion.