

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Cinacalcet HCl Sigillata 30mg, 60mg and 90mg Tablets

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

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

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

Cinacalcet HCl Sigillata is authorised for secondary hyperparathyroidism, parathyroid carcinoma and primary hyperparathyroidism in adults (see SmPC for the full indication). It contains cinacalcet as the active substance and it is given by oral route of administration.

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

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

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

Important risks of Cinacalcet HCl Sigillata 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 HCl Sigillata. 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                             | <ul style="list-style-type: none"><li>• Hypocalcaemia in the paediatric population</li></ul>                                |
| Important potential risks                              | <ul style="list-style-type: none"><li>• Medication errors with cinacalcet granules in capsules for paediatric use</li></ul> |
| Missing information                                    | <ul style="list-style-type: none"><li>• Pregnant or breast-feeding women</li></ul>  |

### ***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***

Not applicable