



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2020
EMA/43762/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Cinacalcet Accordpharma

cinacalcet

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cinacalcet Accordpharma, intended for the treatment of secondary hyperparathyroidism, parathyroid carcinoma and primary hyperparathyroidism. The applicant for this medicinal product is Accord Healthcare S.L.U.

Cinacalcet Accordpharma will be available as 30-mg, 60-mg and 90-mg film-coated tablets for oral use. The active substance of Cinacalcet Accordpharma is cinacalcet, a calcimimetic agent (ATC code: H05BX01), which lowers parathyroid hormone levels by increasing the sensitivity of the calcium-sensing receptor in the parathyroid gland to extracellular calcium.

Cinacalcet Accordpharma is a generic of Mimpara, which has been authorised in the EU since 22 October 2004. Studies have demonstrated the satisfactory quality of Cinacalcet, and its bioequivalence to the reference product Mimpara. A question and answer document on generic medicines can be found [here](#).

The full indication is:

"Secondary hyperparathyroidism

Adults

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

Paediatric population

Treatment of secondary hyperparathyroidism (HPT) in children aged 3 years and older with end-stage renal disease (ESRD) on maintenance dialysis therapy in whom secondary HPT is not adequately controlled with standard of care therapy (see section 4.4).

Cinacalcet Accordpharma may be used as part of a therapeutic regimen including phosphate binders and/or Vitamin D sterols, as appropriate (see section 5.1).

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



Parathyroid carcinoma and primary hyperparathyroidism in adults

Reduction of hypercalcaemia 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.”

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.