EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 September 2015
EMA/CHMP/596066/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cinacalcet Mylan

cinacalcet

On 24 September 2015, 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 Mylan, intended for the treatment of hyperparathyroidism and parathyroid carcinoma. The applicant for this medicinal product is MYLAN S.A.S.

Cinacalcet Mylan will be available as 30 mg, 60 mg and 90 mg film-coated tablets. The active substance of Cinacalcet Mylan is cinacalcet, a calcimimetic agent (ATC code: H05BX01). It increases the sensitivity of the calcium-sensing receptors on the parathyroid glands and other tissues, leading to reduced secretion of parathyroid hormone by the parathyroid glands and a resultant decrease in blood calcium levels.

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

The full indication is:

"Treatment of secondary hyperparathyroidism (HPT) in patients with end-stage renal disease (ESRD) on maintenance dialysis therapy. Cinacalcet Mylan may be used as part of a therapeutic regimen including phosphate binders and/or vitamin D sterols, as appropriate (see section 5.1).

Reduction of hypercalcaemia in 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

[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

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