22 June 2017
EMA/CHMP/379833/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Mimpara

cinacalcet

On 22 June 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Mimpara. The marketing authorisation holder for this medicinal product is Amgen Europe B.V.

The CHMP adopted a change to the existing indication as follows[2]:

"**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).

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

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."

[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
[2] New text in bold

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