AMGEN Ireland Limited
21 Northwood Court
Santry
Dublin 9
Tel: 00353 1 8527400
Fax: 00353 1 8527499

Cinacalcet (Mimpara®) - Report of a fatal case with severe hypocalcaemia in a paediatric investigational study.

15 March 2013

Dear Healthcare Professional,

Amgen Europe B.V. in agreement with the European Medicines Agency and the Irish Medicines Board would like to inform you of the following:

Summary of the issue

- **A fatal case with severe hypocalcaemia has been reported in a paediatric investigational study involving a patient receiving cinacalcet (Mimpara®).**
- **Mimpara® is <u>not</u> approved for use in paediatric patients.**
- **Prescribers are reminded that since cinacalcet lowers serum calcium, patients should be monitored carefully for the occurrence of hypocalcaemia.**

Further information on the safety concern and the recommendations

A fatal case with severe hypocalcaemia has occurred in a paediatric cinacalcet investigational study. Amgen has therefore suspended dosing, screening and enrolment in all paediatric cinacalcet investigational studies and is investigating this case to determine if any additional actions are necessary.

Mimpara® is approved only in adults. The product information (i.e. Summary of Product Characteristics) warns of the risk of hypocalcaemia associated with cinacalcet therefore, patients should be carefully monitored for the occurrence of hypocalcaemia. Please see the enclosed full Summary of Product Characteristics for more information on the management of hypocalcaemia in patients treated with cinacalcet.

Registered Office: c/o International Financial Services Centre, North Wall Quay, Dublin 1, Ireland
Place of Registration: Ireland
Company Registration Number: 379345
Directors: Michael Byrne, Thomas Dittrich (German), Rolf Hoffman (German), John Kearney (British)

Further information

Mimpara® is indicated for the treatment of secondary hyperparathyroidism (HPT) in patients with end-stage renal disease (ESRD) on maintenance dialysis therapy. Mimpara® may be used as part of a therapeutic regimen including phosphate binders and/or Vitamin D sterols, as appropriate.

Mimpara® is also indicated for the 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.

For more information regarding Mimpara® refer to the product details available on the EMA website: http://www.ema.europa.eu.

Call for reporting

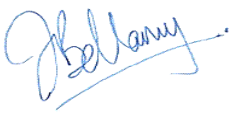
Please report any suspected adverse reactions to the Irish Medicines Board using a Yellow Card obtained from the Irish Medicines Board or electronically via the online reporting system at *www.imb.ie*. Adverse reactions can also be reported to the Irish Medicines Board by calling on (01) 676 4971.

Adverse reactions may also be reported to Amgen Europe B.V. by contacting Amgen UK/Ireland Drug Safety Department directly on 00 44 1223 436712.

Company contact point

Should you have any questions or require additional information regarding the use of Mimpara®, please contact Amgen UK/Ireland Medical Information on 00 44 1223 436441 or by email to gbinfoline@amgen.com.

Sincerely



Dr Steven Bellamy MBChB
Medical Director, UK & Ireland