2013-03-07

Cinacalcet (Mimpara) - Report of a fatal case with severe hypocalcemia in a pediatric investigational study.

Dear Healthcare Professional,

Amgen Europe B.V. in agreement with the European medicines Agency and N*ational Medicines Regulatory authority* would like to inform you of the following:

Summary of the issue

- **A fatal case with severe hypocalcemia has been reported in a pediatric investigational study involving a patient receiving cinacalcet (Mimpara).**
- **Mimpara is <u>not</u> approved for use in pediatric 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 hypocalcemia has occurred in a pediatric cinacalcet investigational study. Amgen has therefore suspended dosing, screening and enrollment in all pediatric 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 hypocalcemia associated with cinacalcet therefore, patients should be carefully monitored for the occurrence of hypocalcemia. Please see the enclosed full Summary of Product Characteristics for more information on the management of hypocalcemia in patients treated with cinacalcet

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

Mimpara Adverse Reporting

RP Cherubino LTD

DELF Building

Sliema Road

Gzira

Alternatively, you may send an email to luisa@cherubino.com.mt

OR

Any suspected adverse reactions and medication errors can also be reported to the Medicines Authority via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Company contact point

Should you have any questions or require additional information regarding the use of Mimpara, please contact Amgen's local representative at luisa@cherubino.com.mt

Sincerely

Luisa de Piro O'Connell

RP Cherubino LTD