IPSEN
Innovation for patient care

7th January 2014

Increlex® (mecasermin; recombinant human IGF-1. 10mg/mL solution for injection) shortage resolved

Dear Healthcare Professional,

The European Medicines Agency, Irish Medicines Board and Ipsen Pharma wish to inform you that the shortage of Increlex® (mecasermin) has been resolved. The medicine is available again for prescription.

- Please limit initial prescriptions to one month to ensure an orderly return to normal supply levels. Assess patients one month after starting or re-starting mecasermin. If treatment has been well tolerated, prescriptions for longer periods may be issued.

  There are limited data on re-starting mecasermin in patients whose treatment has been interrupted. The dose should be titrated as if starting treatment for the first time (see below) while taking into account patients' clinical history with previous mecasermin treatment.

- Remind or re-train patients and carers in the safe use of mecasermin.

Additional information
Mecasermin is a recombinant human insulin like growth factor-1 (rhIGF-1). It is approved for long-term treatment of growth failure in children and adolescents from 2 to 18 years with severe primary insulin-like growth factor-1 deficiency (IGFD).

A diagnosis of severe primary IGFD can be made if patients meet all of the following criteria:

- height standard deviation score ≤−3.0
- basal IGF-1 levels below the 2.5th percentile for age and gender
- growth hormone sufficiency
- secondary forms of IGF-1 deficiency have been excluded (e.g. malnutrition, hypothyroidism, chronic treatment with anti-inflammatory steroids).

Patients with severe primary IGFD may have mutations in the growth hormone receptor (GHR), post-GHR signalling pathway or IGF-1 gene. These patients are not growth hormone deficient and therefore should not be treated with growth hormone. It is recommended that the diagnosis is confirmed by conducting an IGF-1 generation test.

The starting dose of mecasermin is 0.04mg/kg body weight twice daily by subcutaneous injection. This dose is titrated to 0.08mg/kg twice daily after the first week and to 0.12mg/kg twice daily after the second week, provided the patient tolerates the dose increase well. Adverse reactions to mecasermin treatment or a previous history of such reactions may require slower titration regimens.

Doses higher than 0.12mg/kg twice daily have not been evaluated in children with severe primary IGFD.

Please refer to the Summary of Product Characteristics for full prescribing advice, a copy is attached for your information.

Call for reporting

- Please report suspected side effects of any medicine to the Irish Medicines Board by using the IMB's online form (http://www.imb.ie/EN/Human-Medicines/New-EU-Pharmacovigilance-Legislation/Reporting-Suspected-Adverse-Reactions-.aspx). A downloadable version of the form is also available, which can be filled in manually and sent to the IMB by freepost at the following address:
  Freepost,
  Pharmacovigilance Section
  Irish Medicines Board
  Kevin O'Malley House
  Earlsfort Centre
  Earlsfort Terrace
  IRL-Dublin 2
  Tel: +353 1 6764971
  Fax: +353 1 6767836

- **Company contact point**

Ipsen has established an independent Advisory Board of experts in the management of paediatric growth disorders to answer any medical questions. Should you wish to contact these experts or have any questions concerning the information in this letter, please contact us directly by phone at 01 8098200 or by email at alan.bass@ipsen.com

Yours sincerely,

Alan Bass
Managing Director
Ipsen Pharmaceuticals Ltd