Increlex®(mecasermin) 10 mg/ml solution for injection. EU/1/07/402/001
Interruption to supply

26th April 2013

Dear Healthcare Professional:

Ipsen Pharmaceuticals Ltd, in agreement with the Irish Medicines Board and the European Medicines Agency, would like to inform you of a market shortage of Increlex (mecasermin) in Ireland.

- The shortage is due to manufacturing difficulties. These issues are not related to the safety or efficacy of Increlex currently on the market.

- Based on current levels of demand, Increlex will be out of stock from early August 2013. Every effort is being made to return to normal supply; however at the moment the duration of this shortage is unknown. Re-supply before the end of 2013 is not currently anticipated.

- Any remaining product should only be used for patients who are already treated with Increlex for severe primary insulin-like growth factor-1 deficiency (Primary IGFD). For new patients, treatment should not be started until normal supplies are re-established.

- There are no alternative treatment options available in the absence of Increlex. Limited data suggest that Increlex treatment may be stopped and restarted in patients with severe primary IGF-1 deficiency without significant short-term concerns. Short-term interruption is not expected to have relevant long-term impact (e.g. on final height).

Recommendations
The treating physicians are advised to review patients as appropriate if their treatment is interrupted. Physicians should be aware that if patients (especially very young children) presented with hypoglycaemia before treatment, this hypoglycaemia could reoccur after stopping the treatment. There are no alternative treatment options for severe primary insulin-like growth factor-1 deficiency.

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

Severe primary IGFD is defined by:

- height standard deviation score ≤–3.0 and
- basal IGF-1 levels below the 2.5th percentile for age and gender and
- growth hormone (GH) sufficiency.
- exclusion of secondary forms of IGF-1 deficiency, such as malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids.

Severe primary IGFD includes patients with mutations in the GH receptor (GHR), post-GHR signalling pathway, and IGF-1 gene defects; these patients are not GH deficient, and therefore they cannot be expected to respond adequately to exogenous GH treatment. It is recommended that the diagnosis is confirmed by conducting an IGF-1 generation test.

Communication information
Additional information on Increlex can be found on the website of the European Medicines Agency at www.ema.europa.eu or at www.imb.ie.

Ipsen has established an Advisory Board of external clinicians, expert in the management of paediatric growth disorders, to answer any medical questions in an independent manner. Should you wish to access these experts or have any questions concerning the information in this letter, please contact medical information at Ipsen Pharmaceuticals Ltd on 01–809 8200 or email medinfo@ipsen.com.

Yours faithfully

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