

Direct Healthcare Professional Communication

▼ INCRELEX 10mg/ml Solution for Injection (mecasermin) MA Number EU/1/07/402/001: Risk of benign and malignant neoplasia

Dear Healthcare professional,

Ipsen Pharma, in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency would like to inform you of the following:

Summary

- **Cases of benign and malignant neoplasms have been observed among children and adolescents who received treatment with mecasermin in the post-marketing setting.**
- **Mecasermin should be permanently discontinued if benign or malignant neoplasia develops, and expert medical care should be sought.**
- **Mecasermin is contraindicated in children and adolescents with active or suspected neoplasia, or any condition or medical history which increases the risk of benign or malignant neoplasia.**
- **Mecasermin should only be used in the treatment of severe primary IGF-1 deficiency and the maximum dose of 0.12 mg/kg given twice daily should not be exceeded. Available data suggest that the risk of neoplasia may be higher in patients who were given mecasermin without IGF-1 deficiency, or who receive mecasermin at higher than recommended doses resulting in increase of IGF-1 levels above normal**

Background on the safety concern

INCRELEX contains mecasermin, a recombinant human insulin-like growth factor 1 (rh-IGF-1) and is indicated for the long-term treatment of growth failure in children and adolescents aged from 2 to 18 years with confirmed severe primary insulin-like growth factor 1 deficiency (primary IGFD).

The current safety concern is driven by the recent clinical observations of neoplasms plausibly related to mecasermin use. A higher number of cases of benign and malignant neoplasms have been identified in patients receiving mecasermin in the post-marketing setting with respect to the background incidence in this patient population. These cases represented a variety of different malignancies and included rare malignancies usually not seen in children. Current knowledge of IGF-1 biology suggests that IGF-1 plays a role in malignancies within all organs and tissues. The role of the IGF family in the genesis of human benign and malignant neoplasms has been observed in several epidemiological and pre-clinical studies. Physicians should therefore be vigilant for any potential malignancy and the prescribing information should be strictly adhered to.

The SmPC of Increlex and the educational materials for physician and patients are being updated to reflect this safety information.

Call for reporting (*local information*)

Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

▼ INCRELEX is subject to additional monitoring. This will allow quick identification of new safety information.

Company contact point (*local contact information*)

Please contact Ipsen Limited's Medical Information Department on medical.information.uk@ipsen.com, by telephone on 01753 627700 or at 190 Bath Road, Slough, Berkshire, SL1 3XE, UK.

Annexes (*if applicable*)

<Link/reference to other available relevant information, such as information on the website of a competent authority>

<Additional scientific information, if applicable>

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