

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

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

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Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Card website - <https://yellowcard.mhra.gov.uk/> or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the Yellow Card website (see link above).

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

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

Please report ANY suspected adverse drug reactions (ADRs) to new drugs and vaccines identified by the black triangle ▼ to the MHRA through the Yellow Card Scheme.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card Scheme.

Company contact point

Please contact Ipsen Limited's Medical Information Department on medical.information.uk@ipsen.com, by telephone on 01753 627777 or at 190 Bath Road, Slough, Berkshire, SL1 3XE, UK.



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