



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Questions and answers on the shortage of Increlex (mecasermin)

The European Medicines Agency has been notified of manufacturing problems with Increlex and stocks will run out in all EU Member States where it is marketed¹ from early August 2013. While existing stocks last the Agency's Committee for Medicinal Products for Use (CHMP) is recommending that Increlex should be reserved for patients already receiving treatment with Increlex and that no new patients should be started. Once stocks have run out, patients may have to be regularly reviewed by their treating physicians while they are not receiving Increlex. Every effort is being made to ensure that normal supply is resumed as soon as possible in the interest of patients.

What is Increlex?

Increlex is used as an injection under the skin for the long-term treatment of patients aged two to 18 years who are of short stature due to a condition known as 'severe primary insulin-like growth factor-1 deficiency'. Patients with this condition have low levels of the hormone insulin-like growth factor-1 or IGF-1, which is required for normal growth.

Increlex received a marketing authorisation valid throughout the European Union on 3 August 2007. It is available in the following Member States: Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxemburg, the Netherlands, Poland, Portugal, Slovakia, Sweden, Spain, the United Kingdom, as well as Norway.

¹ Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxemburg, the Netherlands, Poland, Portugal, Slovakia, Sweden, Spain, the United Kingdom, as well as Norway.



What is the cause of the supply problem and how long will it last?

The company that markets Increlex, Ipsen Pharma, informed the Agency that problems at the manufacturing site in the USA have led to an interruption in the manufacture of the active substance and will lead to a worldwide shortage in the supply of Increlex. Existing stocks are expected to run out by early August 2013 in all EU member states where Increlex is marketed. The problems are linked to equipment failures at the site which are currently being addressed by the company. Although the duration of this shortage is unknown, new supplies are not anticipated before the end of 2013.

What are the recommendations of the CHMP during the shortage period?

The CHMP has agreed that the company should provide a letter to healthcare professionals in the countries where Increlex is marketed, informing them of the shortage in their country and that there are no alternative treatment options available in the absence of Increlex. Treating physicians are advised to review patients as appropriate when their treatment has to be interrupted. Limited data suggest that it is possible to stop and restart treatment with Increlex without significant concerns. Treatment interruption of short duration is not expected to have relevant long-term consequences (such as an impact on the final height).

The Committee is working closely with the company to ensure that normal supply is resumed as soon as possible in the interest of patients.

What are the recommendations for patients?

- Patients are informed of an upcoming shortage of Increlex.
- There will be a period during which Increlex will be unavailable. During this period you may have to be regularly reviewed by your doctor. Available evidence suggests that it is possible to stop and restart treatment with Increlex without significant concerns. A treatment interruption of short duration is not expected to have relevant long-term consequences (such as an impact on the final height).
- Patients who have any questions should speak to their doctor or pharmacist.

What are the recommendations for prescribers?

- Healthcare professionals will receive detailed information on the shortage of Increlex in their country.
- No new patients should be started on Increlex until normal supplies are re-established. While existing stocks last Increlex should only be given to continue the treatment of patients already being treated with Increlex.
- There are no alternative treatment options for 'severe primary insulin-like growth factor-1 deficiency'. When stopping treatment hypoglycaemia could re-occur in patients (especially young children) who experienced hypoglycaemic episodes before starting treatment with Increlex. Patients may therefore have to be monitored as appropriate.
- EMA will be working closely with the company and will keep the supply situation under review. Any further advice will be communicated, as appropriate.

The current European public assessment report for Increlex can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20Public%20Assessment%20Reports).