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EPAR summary for the public

Increlex

mecasermin

This is a summary of the European public assessment report (EPAR) for Increlex. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Increlex.

What is Increlex?

Increlex is a solution for injection that contains the active substance mecasermin.

What is Increlex used for?

Increlex is used for the long-term treatment of patients aged two to 18 years who are short for their age 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.

Because the number of patients with primary IGF-1 deficiency is low, the disease is considered 'rare', and Increlex was designated an 'orphan medicine' (a medicine used in rare diseases) on 22 May 2006.

The medicine can only be obtained with a prescription.

How is Increlex used?

Treatment with Increlex should be supervised by doctors who have experience in the diagnosis and treatment of patients with growth disorders.

The recommended starting dose is 0.04 mg per kilogram body weight twice a day. The dose should be tailored for each patient according to the speed of growth and side effects. The maximum dose is 0.12 mg per kilogram twice a day. Increlex is given by injection under the skin, and the injection site should be changed with each injection. It should never be injected into a vein. The injection should be carried

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out shortly before or after a meal or snack. Treatment should be interrupted if the patient cannot eat for any reason. For more information, see the summary of product characteristics.

How does Increlex work?

The active substance in Increlex, mecasermin, is a copy of the hormone IGF-1. IGF-1 is important in determining how tall a child grows. It does this by stimulating cells to divide and grow and to absorb nutrients, supporting the growth of body tissues. Increlex works in the same way as natural IGF-1, replacing the missing hormone and helping the child to grow taller.

How has Increlex been studied?

Increlex has been studied in five studies involving a total of 76 children aged between one and 15 years with severe primary IGF-1 deficiency, nine of whom had received another type of recombinant IGF-1 before joining these studies. Because the disease is rare, many of the children were included in more than one of the studies. One study compared Increlex with placebo (a dummy treatment) in eight patients, but the others did not compare Increlex with any other treatments. The studies lasted between 15 months and eight years, and the main measure of effectiveness was the speed of growth.

What benefit has Increlex shown during the studies?

Increlex caused the speed of growth to increase. When the results of the studies were looked at together, the average growth rate was 2.8 cm per year before treatment. This increased to 8.0 cm in the first year of treatment and 5.8 cm in the second. The growth rate stabilised at around 4.7 cm per year from the fourth year of treatment.

Some of the studies also included children who had defects in the gene for growth hormone (GH) and who had developed antibodies against GH. The company applied for an authorisation to use Increlex in these children, but withdrew its application after the end of the medicine's assessment, as this disease is not listed in the medicine's 'orphan' designation.

What is the risk associated with Increlex?

The most common side effects with Increlex (seen in more than 1 patient in 10) are headache, hypoglycaemia (low blood sugar levels), vomiting (being sick), injection site hypertrophy (lumps at the site of injection) and otitis media (infection of the middle ear).

Increlex must not be used in patients who have, or are thought to have active neoplasia (abnormal cell growth). Treatment with Increlex should be stopped if neoplasia develops. Increlex must not be used in premature babies or newborns. For the full list of all side effects and restrictions with Increlex, see the package leaflet.

Why has Increlex been approved?

The CHMP decided that Increlex's benefits are greater than its risks and recommended that it be given marketing authorisation.

Increlex has been authorised under 'Exceptional Circumstances'. This means that because the disease is rare, it has not been possible to obtain complete information about Increlex. Every year, the

European Medicines Agency will review any new information that may become available and this summary will be updated as necessary.

What information is still awaited for Increlex?

The company that makes Increlex will carry out a long-term study looking at the safety of the medicine, when treatment is started in young children and continued into adulthood.

What measures are being taken to ensure the safe and effective use of Increlex?

A risk management plan has been developed to ensure that Increlex is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Increlex, including the appropriate precautions to be followed by healthcare professionals and patients.

Additionally, the company that markets Increlex will supply information packs to doctors and patients explaining how the medicine is used and its side effects. The company will also supply dose calculators to help doctors and patients (or their carers) to work out the appropriate dose.

Other information about Increlex

The European Commission granted a marketing authorisation valid throughout the European Union for Increlex on 3 August 2007.

The full EPAR for Increlex can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Increlex, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Increlex can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 05-2015.