increlex®
(mecasermin) injection 10 mg

The ONLY FDA-approved treatment for Severe Primary IGF-1 Deficiency (SPIGFD)

Managing Treatment With INCRELEX

Olive, a former INCRELEX patient. Age 18, 4'10.5"

INDICATION

INCRELEX® (mecasermin) is a prescription medicine used in children 2 years and older with short stature that have severely low levels of the hormone, insulin-like growth factor-1 (IGF-1). IGF-1 is needed for normal growth.

INCRELEX is not a substitute for growth hormone. It cannot be used for children with short stature due to low levels of growth hormone, malnutrition, when their thyroid gland doesn't make enough thyroid hormone, or when taking anti-inflammatory steroids used to manage inflammation.

IMPORTANT SAFETY INFORMATION

Always give INCRELEX exactly as your doctor directed.

Do not take INCRELEX if you are allergic to IGF-1 or any of its other ingredients. Report any allergic reactions.

INCRELEX should be injected under the skin (subcutaneous injection). It should not be injected directly into a blood vessel.

INCRELEX should not be used after growth plates close which happens during puberty.

INCRELEX should not be used in children with cancerous tumors or a history of cancer.

Please see additional Important Safety Information throughout and refer to full Prescribing Information and Patient Information.

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Tips for Managing Some Potential Side Effects of INCRELEX

Inject INCRELEX exactly as your child's doctor or nurse has shown you. Do not give your child INCRELEX unless you understand all of the instructions.

Olive, a former INCRELEX patient, at age 18, and her mother, Renee.

Low blood sugar (hypoglycemia)

INCRELEX may lower blood sugar levels. Signs and symptoms include:

- dizziness
- hunger
- sweating
- tiredness
- irritability
- nausea
- restlessness
- trouble concentrating
- fast or irregular heartbeat

It is important to only give your child INCRELEX 20 minutes before or 20 minutes after a meal or snack to reduce the chances of low blood sugar. Do not give your child INCRELEX if your child cannot eat.

Severe hypoglycemia may cause unconsciousness, seizures, or death. If your child receives INCRELEX, they should avoid participating in high-risk activities within 2 to 3 hours after the INCRELEX injection, especially at the beginning of INCRELEX treatment.

TIP

Always have a source of sugar such as orange juice, glucose gel, candy, or milk available in case symptoms of low blood sugar occur. For severe hypoglycemia, if your child is not responsive and cannot drink sugar-containing fluids, get emergency medical help right away.

It is important to notify your child's doctor of any side effects that occur with INCRELEX.

IMPORTANT SAFETY INFORMATION (continued)

Hypoglycemia (low blood sugar): INCRELEX should be administered 20 minutes before or after a meal or snack and should not be administered when the meal or snack is skipped.

Checking blood glucose levels is recommended. The dose of INCRELEX may need to be adjusted until an appropriate dose is decided by your doctor.

Intracranial Hypertension: Increased pressure in your skull may occur because of cerebrospinal fluid buildup around your brain. Therefore, your doctor may require an eye examination at the start of INCRELEX treatment and periodically during the time you are taking INCRELEX.

Lymphoid Tissue Hypertrophy: Lymphoid tissue hypertrophy is a noncancerous increase in the number of immune cells called lymphocytes. Patients should have periodic examinations with your doctor to rule out potential complications.

Allergic reactions

INCRELEX may cause hives, rash, or itching after use. Hives generally appear pale in the middle with a red rim around them minutes to hours after the injection and may sometimes occur at many places on the skin.

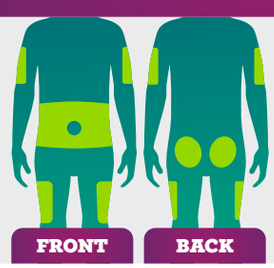
TIP

Call your child's doctor right away if your child gets a rash or hives. Get medical help immediately if your child has trouble breathing or goes into shock, with symptoms like dizziness, pale, clammy skin, and/or passing out.

Injection site reactions

INCRELEX is given twice daily by injection under your child's skin (subcutaneously). Injection site reactions may include pain, redness, or bruising. You may also notice an increase or loss of fat at the injection site.

TIP



These injection site reactions can potentially be reduced by changing (rotating) the injection site at each injection (either abdomen, thigh, upper arm, or buttock).

Icing the area prior to injection may help.

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Eton Cares Program®—Your rare disease journey is personal. So is our support.

When your doctor prescribes INCRELEX, you're automatically enrolled in the Eton Cares Program®—designed to support you and your family every step of the way.

$0 Copay for Eligible Patients*

*Restrictions, limitations, and/or eligibility requirements apply. Commercially eligible patients can pay $0 per month.

To learn more about what to expect with INCRELEX please scan the QR code or visit INCRELEX.com.

IMPORTANT SAFETY INFORMATION (continued)

Slipped Capital Femoral Epiphysis: Slipped capital femoral epiphysis is a bone problem where the top of the upper leg (femur) slips apart. This may lead to a serious condition where bone tissue dies due to a lack of blood supply (osteonecrosis). Get medical help for your child right away if your child develops a limp or has hip or knee pain.

Progression of Scoliosis: Your doctor will monitor you during treatment with INCRELEX if you have a history of scoliosis.

Malignant Neoplasia: There have been reports of cancerous tumors in children who received INCRELEX. It is unknown whether there is any relationship between INCRELEX therapy and new occurrence of tumors. Tumors were mostly reported in patients with rare genetic conditions of short stature associated with a higher risk of cancer, or in patients already at risk of cancer.

The tumors were seen more frequently in patients who received INCRELEX at higher than recommended doses or at doses that produced IGF-1 levels above normal for age and sex. Your doctor will carefully monitor you during your treatment with INCRELEX for development of tumors. If cancerous tumors develop, your doctor will stop your INCRELEX treatment.

Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preserved Solution: Serious and fatal adverse reactions can occur in neonates and infants treated with benzyl alcohol-preserved drugs. Use of INCRELEX in infants is not recommended.

The most common adverse reactions include low blood sugar, reactions at the injection site or throughout your body, and enlarged tonsils.

You are encouraged to report negative side effects of prescription drugs by contacting Eton Pharmaceuticals, Inc. at 1-855-224-0233 or the U.S. Food and Drug Administration (FDA) at www.fda.gov/safety/medwatch or call 1-800-FDA-1088.

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eton PHARMACEUTICALS

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