

What to Expect When Taking 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.

Increlex is given twice daily by injection under your child's skin (subcutaneously). Visit Increlex.com for more information and Full Instructions for Use.



Below is some helpful information on the possible side effects of Increlex and ways to help manage them.

WHAT IS INCRELEX?

INCRELEX® (mecasermin) is a prescription medicine used to treat children who are very short for their age because their bodies do not make enough insulin-like growth factor-1 (IGF-1). This condition is called severe primary IGF-1 deficiency. INCRELEX should not be used instead of growth hormone. It is not known if INCRELEX is safe and effective in children under 2 years of age.

IMPORTANT SAFETY INFORMATION

Who should not receive INCRELEX?

Your child should not receive INCRELEX if your child: is allergic to mecasermin or any of the ingredients in INCRELEX; has finished growing; has any cancerous tumors or growths; or has a history of cancer. **Your child should never receive INCRELEX through a vein.**

What should I tell my child's doctor before my child starts INCRELEX?

Tell your child's doctor about all of your child's medical conditions, including if your child has diabetes; a curved spine (scoliosis); or is pregnant or breast-feeding.

Tell your child's doctor about all the medicines (prescription and over-the-counter), vitamins, and herbal supplements your child takes. Especially tell your child's doctor if your child takes insulin or other anti-diabetes medicines; a change in dose may be needed.

What are the possible side effects of INCRELEX?

INCRELEX may cause serious side effects, including:

- **Low blood sugar (hypoglycemia).** INCRELEX may lower blood sugar levels. 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. Signs of low blood sugar include: dizziness; tiredness; restlessness; hunger; irritability; trouble concentrating; sweating; nausea; and fast or irregular heartbeat. **Severe low blood sugar may cause unconsciousness, seizures, or death.** Your child should avoid participating in high risk activities (e.g. driving, exercise, etc.) within 2 to 3 hours after an INCRELEX injection, especially at the beginning of treatment. Your child should always have a source of sugar such as orange juice, glucose gel, candy, or milk available in case symptoms of low blood sugar happen. For severe low blood sugar, if your child is not responsive and cannot drink sugar-containing fluids, you should get emergency medical help for your child right away.



Olive, actual Increlex patient, and her mother, Renee

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information and Patient Information.


increlex®
(mecasermin) injection 10 mg

Tips for Managing Some Potential Side Effects of Increlex®

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



Make sure to 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, you should get emergency medical help for your child right away.

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 can cause reactions at the injection site such as 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).

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



IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of INCRELEX? (continued)

INCRELEX may cause serious side effects, including:

- **Allergic reactions** are a serious but common side effect of INCRELEX. Call your child's doctor right away if your child gets a rash or hives, which generally appear minutes to hours after the injection and may sometimes occur at many places on the skin. Stop taking INCRELEX and get medical help right away if your child has trouble breathing or goes into shock, with symptoms like dizziness, pale, clammy skin or passing out. INCRELEX can also cause reactions at the injection site including: loss of fat (lipoatrophy); increase of fat (lipohypertrophy); pain; redness; or bruising.
- **Increased pressure in the brain (intracranial hypertension).** INCRELEX, like growth hormone, can sometimes cause a temporary increase in pressure within the brain. Symptoms include persistent headache and nausea with vomiting.
- **Enlarged tonsils.** Signs include: snoring, difficulty breathing, sleep apnea (a condition where breathing stops briefly during sleep), or fluid in the middle ear.
- **A bone problem called slipped capital femoral epiphysis**, when the top of the upper leg bone (femur) slips apart. Get medical help right away if your child develops a limp or has hip or knee pain.
- **Worsened scoliosis** (caused by rapid growth).
- **Tumor Growths.** Several cases of cancerous tumors have been observed in children who received INCRELEX. Tell your doctor immediately if your child develops any new growths or symptoms of cancer.
- **Benzyl alcohol toxicity.** Benzyl alcohol, a preservative in INCRELEX, can cause serious side effects, including death in infants.

The most common side effects of INCRELEX include: low blood sugar (hypoglycemia), injection site reactions, allergic reactions and enlarged tonsils.

These are not all the side effects of INCRELEX. Call your child's doctor if your child has side effects that are bothersome or that do not go away. You may report side effects to FDA at 1-800-FDA-1088.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information and Patient Information.