Tips on How to Give an Increlex® Injection

Olive, actual Increlex patient

Important Things About Administering 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

It is important to only inject Increlex under your child's skin (subcutaneously) 20 minutes before or 20 minutes after a meal or snack. **Increlex should not be given if your child is unable to eat shortly before or after a dose for any reason**

Do not give your child an extra dose of Increlex or increase the amount of your child's dose to make up for a missed dose

Before preparing the dose, check the liquid in the Increlex vial to make sure it is clear and colorless. **Do no**t use the vial if it is cloudy or if you see particles

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.

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

increlex®
(mecasermin) injection 10 mg

Disposing of the Used Needles and Syringes Following the Injection

- Throw away (dispose of) used needles and syringes in a puncture-resistant, disposable sharps container as soon as you finish giving the injection. Do not throw away loose needles and syringes in your household trash*
- Do not try to touch the needle. For the safety and health of you and others, needles and used syringes **must never** be reused
- The used alcohol swabs, cotton balls, and gauze may be placed in your household trash

*For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.

Helpful Reminders

- The amount of Increlex your child will receive with each injection may seem very small. The doctor may adjust your child's dose based on a number of factors, such as how your child tolerated and responded to treatment, as well as his or her age, weight, or height
- Building a routine around injections is important for following your child's prescribed treatment regimen. You should discuss the importance of taking Increlex exactly as prescribed with your child
- Family involvement is also crucial as your child receives Increlex treatment. If your child has siblings, make sure to include them and allow them to help out in any capacity, such as offering words of encouragement

Visit Increlex.com for more information and full Instructions for Use and step-by-step instructions on how to administer the Increlex injection.

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.

IPSEN
Innovation for patient care

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increlex®
(mecasermin) injection 10 mg