



increlex[®]

(mecasermin [rDNA origin] injection)

PATIENT INFORMATION

INCRELEX[®] (EENK-ruh-lex)

(mecasermin [rDNA origin] injection)

Read the Patient Information that comes with INCRELEX[®] before your child starts taking INCRELEX[®] and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your child's doctor about your child's condition or treatment.

What is INCRELEX[®]?

INCRELEX[®] is a liquid that contains man-made insulin-like growth factor-1 (IGF-1), which is the same as the IGF-1 made by your body. INCRELEX[®] is used to treat children who are very short for their age because their bodies do not make enough IGF-1. This condition is called primary IGF-1 deficiency. IGF-1 should not be used instead of growth hormone.

INCRELEX[®] has not been studied in children under 2 years of age.

Who Should Not Use INCRELEX[®]?

Your child should not take INCRELEX[®] if your child:

- Has finished growing (the bone growth plates are closed)
- Has cancer
- Has other causes of growth failure
- Is allergic to mecasermin or any of the inactive ingredients in INCRELEX[®]. Check with your child's doctor if you are not sure.

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 health conditions, including if your child:

- Has diabetes
- Has kidney problems
- Has liver problems
- Has a curved spine (scoliosis)
- Is pregnant or breast-feeding.

Tell your child's doctor about all the medicines your child takes, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Especially tell your child's doctor if your child takes insulin or other anti-diabetes medicines. A dose adjustment may be needed for these medicines.

How Should My Child Use INCRELEX[®]?

- Use INCRELEX[®] exactly as prescribed for your child. Your doctor or nurse should teach you how to inject INCRELEX[®]. Do not give your child INCRELEX[®] unless you understand all of the instructions. See the "Instructions for Use" at the end of this leaflet.
- Inject INCRELEX[®] under your child's skin shortly (20 minutes) before or after a meal or snack. **Skip your child's dose of INCRELEX[®] if your child cannot eat for any reason.** Do not make up the missed dose by giving two doses the next time.
- Inject INCRELEX[®] just below the skin in your child's upper arm, upper leg (thigh), stomach area (abdomen), or buttocks. **Never inject it into a vein or muscle.** Change the injection site for each injection ("rotate the injection site").
- Only use INCRELEX[®] that is clear and colorless. If your child's INCRELEX[®] is cloudy or slightly colored, return it for a replacement.

What are the Possible Side Effects of INCRELEX[®]?

INCRELEX[®] may cause the following side effects, which can be serious:

- **Low blood sugar (hypoglycemia).** INCRELEX[®] may lower blood sugar levels like insulin. It is important to only give your child INCRELEX[®] right before or right after (20 minutes on either side of) a snack or meal to reduce the chances of low blood sugar. Do not give your child INCRELEX[®] if your child is sick or cannot eat. Signs of low blood sugar are:
 - Dizziness
 - Tiredness
 - Restlessness
 - Hunger
 - Irritability
 - Trouble concentrating
 - Sweating
 - Nausea
 - Fast or irregular heartbeat

Severe hypoglycemia may cause unconsciousness, seizures, or death. If you take INCRELEX[®], you should avoid participating in high risk activities (such as driving) within 2 to 3 hours after INCRELEX[®] injection, especially at the beginning of INCRELEX[®] treatment.

Before beginning treatment with INCRELEX[®] your doctor or nurse will explain to you how to treat hypoglycemia. You/your child should always have a source of sugar such as orange juice, glucose gel, candy, or milk available in case symptoms of hypoglycemia occur. For severe hypoglycemia, if your child is not responsive and cannot drink sugar-containing fluids, you should give an injection of glucagon. Your doctor or nurse will instruct you how to give the injection.

Glucagon raises the blood sugar when it is injected. It is important that your child have a well-balanced diet including protein and fat such as meat and cheese in addition to sugar-containing foods.

- **Enlarged tonsils.** INCRELEX[®] may enlarge your child's tonsils. Some signs of enlarged tonsils include: snoring, difficulty breathing or swallowing, sleep apnea (a condition where breathing stops briefly during sleep), or fluid in the middle-ear. Sleep apnea can cause excessive daytime sleepiness. Call your doctor should these symptoms bother your child. Your doctor should do regular exams to check your child's tonsils.
- **Increased pressure in the brain (intracranial hypertension).** INCRELEX[®], like growth hormone, can sometimes cause a temporary increase in pressure within the brain. The symptoms of intracranial hypertension can include headache and nausea with vomiting. Tell your doctor if your child has headache with vomiting. Your doctor can then check to see if intracranial hypertension is present. If it is present, your doctor may decide to temporarily reduce or discontinue INCRELEX[®] therapy. INCRELEX[®] therapy may be started again after the episode is over.
- **A bone problem called slipped capital femoral epiphysis.** This happens when the top of the upper leg (femur) slips apart. Get medical attention for your child right away if your child develops a limp or has hip or knee pain.
- **Worsened scoliosis** (caused by rapid growth). If your child has scoliosis, your child will need to be checked often for an increase in the curve of the spine.
- **Allergic reactions.** Your child may have a mild or serious allergic reaction with INCRELEX[®]. Call your child's doctor right away if your child gets a rash or hives. Hives, also known as urticaria, appear as a raised, itchy skin reaction. Hives appear pale in the middle with a red rim around it. Hives generally appear minutes to hours after the injection and may sometimes occur at numerous places on the skin. 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.

INCRELEX[®] can cause reactions at the injection site including:

- Loss of fat (lipoatrophy)
- Increase of fat (lipohypertrophy)
- Pain, redness, or bruising

Injection site reactions can be avoided by changing the injection site at each injection ("injection site rotation").

Call your child's doctor if your child has side effects that are bothersome or that do not go away.

These are not all the side effects of INCRELEX[®]. Ask your child's doctor or pharmacist for more information.

How Should I Store INCRELEX[®]?

- **Before Opening** – Store new unopened vials of INCRELEX[®] in the refrigerator (not the freezer) between 35° to 46°F (2° to 8°C). Do not freeze INCRELEX[®]. Keep INCRELEX[®] out of direct heat and bright light. If a vial freezes, throw it away.
- **After Opening** – Once a vial of INCRELEX[®] is opened, you can keep it in the refrigerator between 35° to 46°F (2° to 8°C) for 30 days after you start using the vial. Do not freeze INCRELEX[®]. Keep INCRELEX[®] out of direct heat and bright light. If a vial freezes, throw it away.

Keep INCRELEX[®] and all medicines out of reach of children.

General Information About INCRELEX[®]

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not give INCRELEX[®] to your child for a condition for which it was not prescribed. Do not give INCRELEX[®] to a person other than your child. It may be harmful.

This leaflet summarizes the most important information about INCRELEX[®]. If you would like more information, talk to your child's doctor. You can also ask your child's doctor or pharmacist for information that is written for health professionals.

More information is available at 1-866-837-2422.

What are the Ingredients in INCRELEX[®]?

Active ingredient: mecasermin

Inactive ingredients: sodium chloride, polysorbate 20, benzyl alcohol, and acetate.

INSTRUCTIONS FOR USE

INCRELEX® should be administered using sterile disposable syringes and needles. The syringes should be of small enough volume that the prescribed dose can be withdrawn from the vial with reasonable accuracy.

Preparing the Dose:

1. Wash your hands before getting INCRELEX® ready for your child's injection.
2. Use a new disposable needle and syringe every time you give a dose. Use syringes and needles only once. Throw them away properly. **Never** share needles and syringes.
3. Check the liquid to make sure it is clear and colorless. Do not use after the expiration date or if it is cloudy or if you see particles.
4. If you are using a new vial, remove the protective cap. Do not remove the rubber stopper.
5. Wipe the rubber stopper of the vial with an alcohol swab to prevent contamination of the vial by germs that may be introduced by repeated needle insertions (see Figure 1).

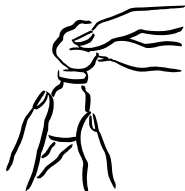


Figure 1: Wipe top with alcohol

6. Before putting the needle into the vial, pull back on plunger to draw air into the syringe equal to the INCRELEX® dose. Put the needle through the rubber top of the vial and push the plunger to inject air into the vial (see Figure 2).

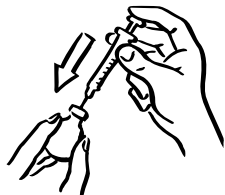


Figure 2: Inject air into vial

7. Leave the syringe in the vial and turn both upside down. Hold the syringe and vial firmly (see Figure 3).

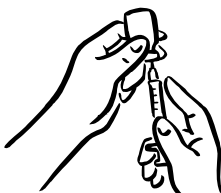


Figure 3: Prepare for extraction

8. Make sure the tip of the needle is in the liquid (see Figure 4). Pull the plunger to withdraw the correct dose into the syringe (see Figure 5).

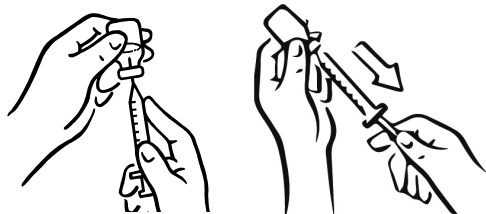


Figure 4: Tip in liquid



Figure 5: Extract Correct Dose

9. Before you take the needle out of the vial, check the syringe for air bubbles. If bubbles are in the syringe, hold the vial and syringe with needle straight up and tap the side of the syringe until the bubbles float to the top. Push the bubbles out with the plunger and draw liquid back in until you have the correct dose (see Figure 6).



Figure 6: Remove air bubbles and refill syringe

10. Remove the needle from the vial. Do not let the needle touch anything. You are now ready to inject (see figure 7).



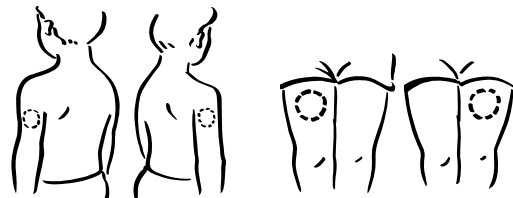
Figure 7: Ready to inject

Injecting the Dose:

Inject INCRELEX® as instructed by your child's doctor.

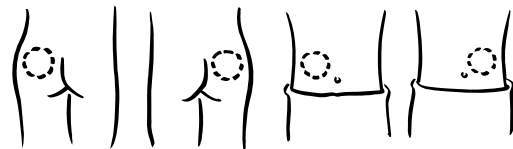
Do not give the INCRELEX® injection if your child is unable to eat within 20 minutes before or after the injection.

1. Decide on an injection area – upper arm, thigh, buttock, or abdomen (see below). The injection site should be changed for each injection (“rotate the injection site”).



Upper arm

Thigh



Buttock

Abdomen

2. Use alcohol or soap and water to clean the skin where you are going to inject your child. The injection site should be dry before you inject.
3. Lightly pinch the skin. Stick the needle in the way your child's doctor showed you. Release the skin (see figure A).



Figure A: Lightly pinch the skin and inject as instructed

4. Slowly push in the plunger of the syringe all the way, making sure you have injected all the liquid. Pull the needle straight out and gently press on the spot where you injected your child with gauze or a cotton ball for a few seconds. **Do not rub the area** (see figure B).



Figure B: Press (don't rub) with gauze or cotton

5. Follow your child's doctor's instructions for throwing away the needle and syringe. Do not recap the syringe. Used needle and syringe should be placed in a sharps container (such as a red biohazard container), hard plastic container (such as a detergent bottle), or metal container (such as an empty coffee can). Such containers should be sealed and disposed of properly.

For additional information, call 1-866-837-2422.

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