

PATIENT INFORMATION
INCRELEX® (EENK-RUH-LEX)
(mecasermin) injection
for subcutaneous use

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

What is INCRELEX?

- INCRELEX is a liquid that contains man-made insulin-like growth factor-1 (IGF-1). 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.
- It is not known if INCRELEX is safe and effective in children under 2 years of age.

Who should not receive INCRELEX?

Your child should not receive INCRELEX if your child:

- has cancer.
- is allergic to mecasermin or any of the ingredients in INCRELEX. See the end of this Patient Information leaflet for a complete list of ingredients in INCRELEX. Check with your child's doctor if you are not sure.
- has finished growing (the bone growth plates are closed).

Your child should never receive INCRELEX through a vein.

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

Tell your child's doctor about all of your child's medical conditions, including if your child:

- has diabetes.
- has a curved spine (scoliosis).
- is pregnant or you think your child might be pregnant. It is not known if INCRELEX can harm an unborn baby.
- is breastfeeding or plans to breastfeed. Talk to your child's doctor about the best way for your child to feed her baby if she receives INCRELEX.

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

How should my child receive INCRELEX?

- Use INCRELEX exactly as prescribed for your child. Your child's 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 Patient Information leaflet.
- Inject INCRELEX under your child's skin 20 minutes before or 20 minutes after a meal or snack.
- **Skip your child's dose of INCRELEX if your child cannot eat 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.

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
 - fast or irregular heartbeat

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.

Before beginning treatment with INCRELEX your child's doctor or nurse will explain to you how to treat hypoglycemia. Your child should always have a source of sugar such as orange juice, glucose gel, candy, or milk available in case symptoms of hypoglycemia happen. 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. Your doctor or nurse will show you how to give the injection.

- **Allergic reactions.** See "Who should not receive INCRELEX?" Allergic reactions are a serious but common side effect of INCRELEX. 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 many places on the skin. **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

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

- **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, nausea and vomiting. Tell your doctor if your child has a headache with vomiting. Your doctor can then check to see if intracranial hypertension is present. If it is present, your child's doctor may decide to temporarily reduce or stop INCRELEX therapy.
- **Enlarged tonsils.** Some signs of enlarged tonsils include: snoring, difficulty breathing, 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 child's doctor if these symptoms bother your child. Your child's doctor should do regular exams to check your child's tonsils.
- **A bone problem called slipped capital femoral epiphysis.** This happens when the top of the upper leg (femur) slips apart. Get medical help 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.
- **Benzyl alcohol toxicity.** Benzyl alcohol is a preservative in INCRELEX. Benzyl alcohol can cause serious side effects, including death in infants who have received medicines that contain the benzyl alcohol preservative.

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

Call your child's doctor if your child has any side effects that bothers them or that does not go away.

These are not all the possible side effects of INCRELEX. For more information, ask your child's doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store INCRELEX?

- **Before Opening:** Store new, unopened vials of INCRELEX in the refrigerator between 35°F to 46°F (2°C to 8°C).
- **After Opening:** Store opened vials of INCRELEX in the refrigerator between 35°F to 46°F (2°C to 8°C) for 30 days after you start using the vial. Throw away any unused INCRELEX after 30 days.
- **Do not** freeze INCRELEX. If a vial freezes, throw it away.
- Keep INCRELEX out of direct light.
- **Do not** use INCRELEX after the expiration date printed on the label.

Keep INCRELEX and all medicines out of the reach of children.

General information about the safe and effective use of INCRELEX.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. 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 harm them.

This Patient Information 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 about INCRELEX that is written for health professionals.

What are the ingredients in INCRELEX?

Active ingredient: mecasermin

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

Manufactured for: Ipsen Biopharmaceuticals, Inc.

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For more information, go to www.Increlex.com or call 855-463-5127.

**INSTRUCTIONS FOR USE
INCRELEX® (EENK-RUH-LEX)
(mecasermin) injection
for subcutaneous use**

Read this Instructions for Use before you start using INCRELEX and each time you get a refill. There may be new information. This information does not take the place of talking to your child's doctor about your child's medical condition or treatment.

Do not share your child's needles and syringes with another person. Your child may give another person an infection or your child could get an infection from them.

Important:

- Inject INCRELEX exactly as your child's doctor or nurse has shown you.
- **Follow your doctor's instructions for the type of syringe and needle to use to prepare and inject your child's dose of INCRELEX.**
- Always use a new, unopened needle and syringe for each injection.
- Only use single-use, disposable needles and syringes. Never reuse disposable needles and syringes.
- Throw away used needles and syringes in a puncture-resistant, disposable sharps container as soon as you finish giving the injection. See step 5 "**How should I throw away (dispose of) used needles and syringes?**" at the end of these instructions.

Supplies needed to give the injection:

- 1 vial of INCRELEX
- 1 alcohol swab
- 1 gauze or cotton ball
- alcohol (to clean the skin at the injection site)
- 1 sharps container for throwing away (disposing of) used needles and syringes. See step 5 "**How should I throw away (dispose of) used needles and syringes?**" at the end of these instructions.

Preparing the Dose:

1. Wash your hands before getting INCRELEX ready for your child's injection.
2. Check the liquid to make sure it is clear and colorless. **Do not** use if it is cloudy or if you see particles.
3. Check the expiration date printed on the label of the vial. **Do not** use INCRELEX if the expiration date has passed.
4. If you are using a new vial, remove the protective cap. Do not remove the rubber top (see Figure 1).

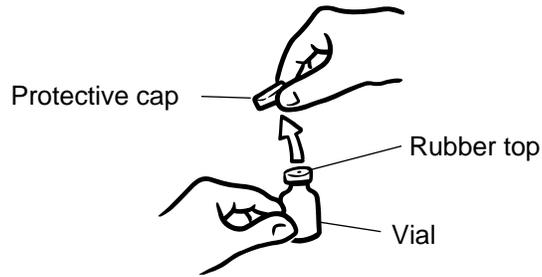


Figure 1: Remove the protective cap

5. Wipe the rubber top on the vial with an alcohol swab (see Figure 2).



Figure 2: Wipe rubber top with alcohol swab

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 3).

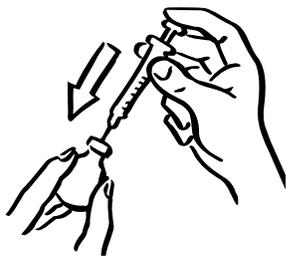


Figure 3: Inject air into vial

7. Leave the syringe in the vial and turn both upside down. Hold the syringe and vial firmly (see Figure 4).

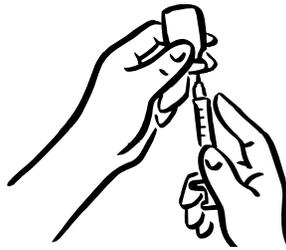


Figure 4: Prepare to withdraw liquid

8. Make sure the tip of the needle is in the liquid (see Figure 5). Pull the plunger to withdraw the correct dose into the syringe (see Figure 6).

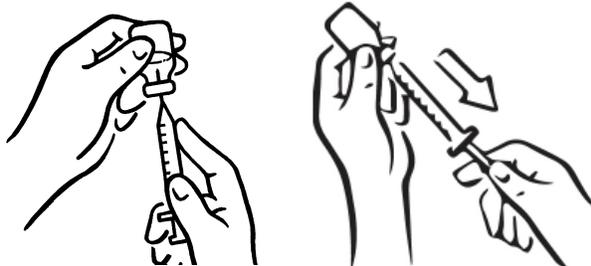


Figure 5: Tip in liquid

Figure 6: Withdraw 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 7).

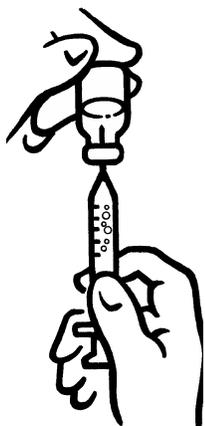


Figure 7: Remove air bubbles and refill syringe

10. Remove the needle from the vial. **Do not** let the needle touch anything. You are now ready to inject (see Figure 8).



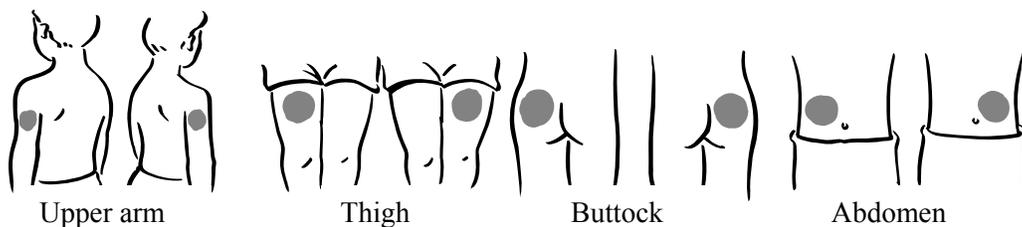
Figure 8: Ready to inject

Injecting the Dose:

Inject INCRELEX exactly as your child's doctor or nurse has shown you.

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

1. Choose an injection site – upper arm, upper leg (thigh), buttocks, or stomach area (abdomen) (see below). The injection site should be changed (rotated) for each injection.



2. Use alcohol to clean the skin where you are going to inject your child. The injection site should be dry before you inject.

Do not fan or blow on the cleaned skin.

Do not touch the injection site again before giving the injection.

3. Lightly pinch the skin. Insert the needle into the pinched skin as instructed by your child's doctor or nurse (see Figure A). Release the pinched skin.



Figure A: Lightly pinch the skin and inject as instructed

4. Slowly push the plunger of the syringe all the way in to make sure you have injected all of the liquid. Pull the needle straight out and gently press on the injection site with gauze or a cotton ball for a few seconds. **Do not rub the injection site** (see Figure B).

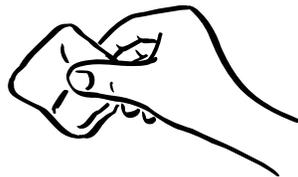


Figure B: Press (**do not** rub) with gauze or cotton ball

5. How should I throw away (dispose of) used needles and syringes?

- Put used needles and syringes in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and syringes in your household trash.**
- Do not try to touch the needle.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how to throw away needles and syringes. 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>.
- For the safety and health of you and others, needles and used syringes **must never** be re-used.
- The used alcohol swabs, cotton balls, and gauze may be placed in your household trash.
- **Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.**
- **Always keep the sharps disposal container out of the reach of children.**

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

For additional information, call 855-463-5127.

Manufactured for: Ipsen Biopharmaceuticals, Inc.
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