



**increlex<sup>®</sup>**  
(mecasermin) injection 10 mg

# What to Expect When Taking INCRELEX

## INDICATION

INCRELEX<sup>®</sup> (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 and into the muscle.** 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.**



*Olive, a former INCRELEX patient, at age 10, and her mother, Renee.*

Please see additional Important Safety Information throughout and [click here](#) for Full Prescribing Information and Patient Information.

## Important Things About Administering INCRELEX



Before preparing the dose, check the liquid in the INCRELEX vial to make sure it is clear and colorless. **Do not** use the vial if it is cloudy or if you see particles



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

## 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>.

### 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.

## 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 ask them to offer words of encouragement



Olive, a former INCRELEX patient, at age 10, and her mother, Renee.

**Follow the Instructions for Use included with this kit.**

### IMPORTANT SAFETY INFORMATION (Continued)

**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.

**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.

**Please see additional Important Safety Information throughout and [click here](#) for Full Prescribing Information and Patient Information.**



Medication is \$0 per month\*



\*Restrictions, limitations, and/or eligibility requirements apply.



To view the INCRELEX Dosing and Injection video, please scan the QR code or visit [INCRELEX.com](https://www.increlex.com).

## IMPORTANT SAFETY INFORMATION (Continued)

**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](https://www.fda.gov/safety/medwatch) or call 1-800-FDA-1088.

Please see additional Important Safety Information throughout and [click here](#) for Full Prescribing Information and Patient Information.



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