

INDICATION

INCRELEX® (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.

Please see Important Safety Information throughout and <u>click here</u> for Full Prescribing Information and Patient Information.



Understanding Severe Primary IGF-1 Deficiency (SPIGFD)

Insulin-like growth factor deficiency (IGFD) is a lack of IGF-1, a naturally occurring hormone that is vital in promoting growth. When your child is being evaluated for short-stature, your clinician may want to conduct more tests to determine if the potential cause is low levels of IGF-1.

If your child is:

- Shorter than almost all other children of the same age and sex
- Their growth hormone (GH) levels are normal or even high
- IGF-1 levels are very low



IMPORTANT SAFETY INFORMATION (continued)

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.

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.

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.

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Goal of Treatment

Working with your child's doctor to find the right treatment is very important in helping manage your child's SPIGFD. There's only a small window of time when your child is able to grow. Once your child enters the teen years, the potential to grow slows—and eventually stops—when the growth plates close. It's essential to act sooner rather than later.





The goal of treatment is to enhance your child's growth by replacing IGF-1 with INCRELEX.



INCRELEX Raises IGF-1 Levels, Which May Help Your Child Grow

INCRELEX is a prescription medication 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.

INCRELEX is given to your child twice daily as a subcutaneous (under the skin) injection.

INCRELEX is not a substitute for growth hormone for GH-approved indications.

Understanding Side Effects

It's important for you and your child to understand the possible side effects when being treated with INCRELEX. See Important Safety Information in this guide and also make sure to talk with your child's doctor if any side effects occur.



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.

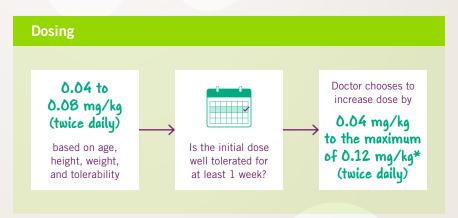
The most common adverse reactions include low blood sugar, reactions at the injection site or throughout your body, and enlarged tonsils.

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 or call 1-800-FDA-1088.

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What to Know About Dosing With INCRELEX

Your child's doctor will determine the correct dose of INCRELEX based on your child's age, weight, height, and other factors.



*Dosing over 0.12 mg/kg twice daily has not been evaluated and, due to hypoglycemic effects, should not be used.

The amount of INCRELEX your child will receive may seem very minimal, even if they are given the maximum dose. 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/her age, weight, or height.

Remember to give your child INCRELEX 20 minutes before or after eating a snack or meal to reduce the chance of hypoglycemia (low blood sugar). If your child is unable to eat shortly before or after a dose for any reason, that dose of INCRELEX should not be given. If your child misses a dose, do not double a dose to make up for it. If you're unsure about anything, check with the doctor's office.

Discuss with the doctor any changes to your child's height and weight, and whether the dose needs to be changed.





Eton Cares is here to help you and your child, every step of the journey

Eton Cares is a full-service patient support program designed to help you and your child access the medications and services you need.

Our reliable professionals are fully trained on INCRELEX and SPIGFD.



Insurance Specialists provide personalized assistance and ongoing support



Dedicated Pharmacists are available 24/7 to provide patient support by phone, worry-free refill reminders, and shipment alerts

Patients are automatically enrolled in Eton Cares when prescribed INCRELEX



INCRELEX patient, at age 10



Eton Cares provides copay and financial support

Copay support

Eton Cares can help eligible, commercially insured patients get their medication for as little as **\$0** per month*

Financial Support

Patients who do not have insurance and meet certain financial requirements may be eligible for additional financial support from a Patient Assistance Program*

*Restrictions, limitations, and/or eligibility requirements may apply. For patients who are not eligible for copay support or who need additional financial assistance, Eton Cares can help connect you with alternative forms of medication coverage or provide referrals to other possible sources of funding.



My Child's Growth Progress

It helps to record your child's growth progress to see how things are changing. Use the chart below to keep track of the date, your child's height and weight, and their dose. Ask your healthcare professional to provide the information during your visits.

Date	Dose	Height	Weight

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Doctor Discussion Guide

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Each Child Is Unique

Get Connected to a Community That Understands



The MAGIC Foundation

The MAGIC (Major Aspects of Growth In Children) Foundation is the global leader in endocrine health, advocacy, education, and support. From networking to physician referrals, the MAGIC Foundation provides a number of services to help you and your child during Severe Primary IGFD treatment.

Please visit MagicFoundation.org to learn more.



Become part of a support community. You are not alone.



Here every step of the way

Eton Cares is a full-service patient support program designed to help you and your child along the treatment journey.

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