

#### 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?

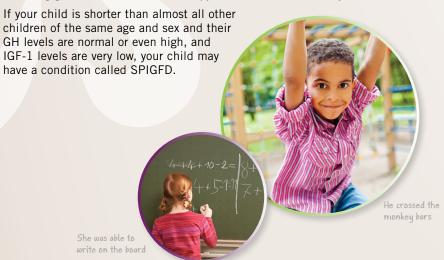
Your child should not receive INCRELEX if your child: is allergic to mecasermin or any of the ingredients in INCRELEX; has finished growing; has any cancerous tumors or growths; or has a history of cancer. Your child should never receive INCRELEX through a vein.

Please see Important Safety Information throughout and 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 diagnosed with idiopathic (unknown cause) short stature, or does not show improvement after receiving growth hormone (GH) therapy, low levels of IGF-1 may be the cause.



Actor portrayals are for illustrative purposes only.

#### **IMPORTANT SAFETY INFORMATION (continued)**

#### 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.

#### **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 promote growth in your child by introducing recombinant (man-made) IGF-1 into the body.



# 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.

# 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.



Increlex patient

#### **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.

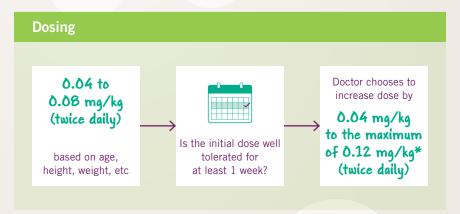
The most common side effects of INCRELEX include: low blood sugar (hypoglycemia), injection site reactions, allergic reactions and enlarged tonsils.

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 Important Safety Information throughout and Full Prescribing Information and Patient Information.

# 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.



<sup>\*</sup>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.



Actor portrayal is for illustrative purposes only.





# The IPSEN Coverage, Access, Reimbursement & Education Support Program

IPSEN CARES® helps streamline access to the Ipsen medications prescribed to you, as well as to related services, which lessens the burden and stress of finding resources on your own.

With IPSEN CARES®, you'll receive support from our Patient Access Specialists who can help:



Provide copay assistance if eligible\*



Navigate your insurance coverage process and determine your out-of-pocket costs for treatment



Provide free medication to eligible patients through the Patient Assistance Program (PAP)<sup>†</sup>



Help minimize delays or interruptions to treatment



Coordinate delivery through specialty pharmacies



Olive, actual Increlex patient



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### IPSEN CARES® provides services on your behalf when you enroll in the program.

\*Patient Eligibility & Terms and Conditions: Patients are not eligible for copay assistance through IPSEN CARES® if they are enrolled in any state or federally funded programs for which drug prescriptions or coverage could be paid in part or in full, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DD, or TRICARE (collectively, "Government Programs"), or where prohibited by law. Patients residing in Massachusetts, Minnesota, Michigan, or Rhode Island can only receive assistance with the cost of Ipsen products but not the cost of related medical services (injection). Patients receiving free starter therapy through the IPSEN CARES® program are not eligible for the copay assistance program while they are waiting for insurance prescription coverage to begin. Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, also are not eligible for the copay assistance program during the current enrollment year.

Cash-pay patients are eligible to participate. "Cash-pay" patients are defined for purposes of this program as patients without insurance coverage or who have commercial insurance that does not cover Increlex®. Medicare Part D enrollees who are in the prescription drug coverage gap ("donut hole") are not considered cash-pay patients and are not eligible for copay assistance through IPSEN CARES®. For patients with commercial insurance that are not considered to be cash-pay patients, the maximum copay benefit amount per prescription is an amount equal to the difference between the annual maximum copay benefit of \$12,000 and the total amount of copay benefit provided to the patient in the Increlex® Copay Program. For cash-pay patients, the maximum copay benefit amount per prescription is \$1,000, subject to the annual maximum of \$12,000 in total. Patient pays any amount greater than the maximum copay savings amount per prescription.

Patient or guardian is responsible for reporting receipt of copay savings benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled through the program, as may be required. Additionally, patients may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, or Health Reimbursement Account. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or RxCrossroads by McKesson are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Data related to patient participation may be collected, analyzed, and shared with Ipsen for market research and other purposes related to assessing the program. Data shared with Ipsen will be de-identified, meaning it will not identify the patient. Void outside of the United States and its territories or where prohibited by law, taxed, or restricted. This program is not health insurance. No other purchase is necessary.

\*Uninsured patients may be eligible for free medication through our Patient Assistance Program. To qualify, patients must: 1) be uninsured, 2) have an on-label diagnosis, 3) be US residents, and 4) meet income criteria. Parents/caregivers may enroll their child through IPSEN CARES®. If eligible, they may receive free medication from Ipsen.



#### 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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# **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.



# The Increlex Patient Support Network

Become part of a support

community.

You are not alone.

She got on the school bus

As a member of the Increlex Patient Support Network, you get more than just email updates, you become part of a community. From valuable support to educational and financial resources, we are with you every step of the way.

You can sign up by visiting increlex.com/join-patient-support-network/



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