



IPSEN CARES Enrollment Form

To be completed by patient and healthcare provider's office.

Please fill out form completely and
FAX BACK TO 1-888-525-2416

- Benefits Investigation and Drug Coverage
- Injection Training - Patient/Caregiver
- Adherence Calls
- Financial Assistance Assessment
- Injection Training - HCP Office

(Please complete requirements for each section below.)

PATIENT

Patient Name (First & Last) _____
 Date of Birth (MM/DD/YYYY) ____ / ____ / ____ Male Female
 Patient Address _____
 City _____ State _____ Zip _____
 Home Phone # (____) _____ Other Phone # (____) _____

PARENT/GUARDIAN

Parent/Guardian Name _____
 Email Address _____
 Home Phone # (____) _____ Other Phone # (____) _____
 May we leave a phone or email message referring to INCRELEX? Yes No
 Parent/Guardian Language Preference English Spanish Other _____

PHARMACY INSURANCE

Is patient insured? Yes No Does patient have secondary insurance? Yes No
 Primary Insurance Co. _____
 Insurance Co. Phone # (____) _____
 Subscriber _____ Policy ID # _____
 Policy/Employer/Group # _____

Secondary Insurance Co. _____
 Insurance Co. Phone # (____) _____
 Subscriber _____ Policy ID # _____
 Policy/Employer/Group # _____

Important: Please send a copy of insurance cards - front and back. Include both medical and pharmacy cards, if available.

PRESCRIBER

Prescriber Name _____
 Office/Institution _____
 DEA # _____ State License # _____
 Tax ID # _____ NPI # _____
 Medicaid Provider # _____
 Medicare PTAN # _____
 Specialty Pediatrician Endocrinologist Other _____

Street Address _____
 City _____ State _____ Zip _____
 Office Contact and Title _____
 Phone # (____) _____ Fax # (____) _____
 Preferred Method of Contact Phone Fax
 Email Address _____

DIAGNOSIS

Date of Diagnosis ____ / ____ / ____ Height ____ Weight ____ kg
 E34.3 Short Stature Due to Endocrine Disorder R62.52 Short Stature (Child) E23.0 Hypopituitarism Other _____

Important: Please remember to check ICD-10-CM Code for the Diagnosis or provide a description if necessary.

INCRELEX (mecasermin) injection 40 mg/4 mL vial

PRESCRIPTION

Has the patient previously been on INCRELEX therapy? Yes No If yes, last administered dose _____ mg/kg on ____ / ____ / ____ (MM/DD/YYYY)

Select a weight-based initial dosage	<input type="checkbox"/> 0.04 mg/kg <input type="checkbox"/> 0.05 mg/kg <input type="checkbox"/> 0.06 mg/kg <input type="checkbox"/> 0.07 mg/kg <input type="checkbox"/> 0.08 mg/kg	$\frac{\text{mg}}{\text{kg weight}} \times \text{mg/kg} = \text{mg X 10}$ $= \text{Inject}^{\dagger} \text{ Dose BID}$ <p style="text-align: right; margin: 0;">Units</p>
<input type="checkbox"/> Step up	↓ ↓ ↓ ↓ ↓	
If well tolerated after 7 days	<input type="checkbox"/> 0.08 mg/kg <input type="checkbox"/> 0.09 mg/kg <input type="checkbox"/> 0.10 mg/kg <input type="checkbox"/> 0.11 mg/kg <input type="checkbox"/> 0.12 mg/kg	$\frac{\text{mg}}{\text{kg weight}} \times \text{mg/kg} = \text{mg X 10}$ $= \text{Inject}^{\dagger} \text{ Dose BID}$ <p style="text-align: right; margin: 0;">Units</p>
<input type="checkbox"/> Step up	↓	
If well tolerated after an additional 7 days	<input type="checkbox"/> Maximum recommended dose of 0.12 mg/kg BID* 0.12 mg/kg BID*	$\frac{\text{mg}}{\text{kg weight}} \times 0.12 \text{ mg/kg} = \text{mg X 10}$ $= \text{Inject}^{\dagger} \text{ Dose BID}$ <p style="text-align: right; margin: 0;">Units</p>

You may include a different dosing schedule using your office prescription form.

*Dosing over 0.12 mg/kg BID has not been evaluated, and due to potential hypoglycemic effects, patients should not be dosed over 0.12 mg/kg BID.

Quantity ____ Number of Refills ____ Syringes for Injection 0.5 cc Qty ____ 1 cc Qty ____ Dispense as Written

Directions for Use _____

***Route of Administration:** INCRELEX is administered by subcutaneous injection. INCRELEX injections should be rotated to a different site (upper arm, thigh, buttock or abdomen) with each injection to help prevent lipohypertrophy.

PRESCRIBER ATTESTATION:

By signing below, I certify that the above therapy is medically necessary and that I have received the necessary authorization to release the above referenced information and medical and/or patient information relating to INCRELEX therapy to Ipsen and its agents or contractors for the purpose of seeking reimbursement for INCRELEX therapy, assisting in initiating or continuing INCRELEX therapy, and/or evaluating the patient's eligibility for Ipsen's patient support programs administered by IPSEN CARES. I authorize Ipsen to be my agent and to forward the above prescription, by fax or other mode of delivery, to the pharmacy chosen on behalf of the patient named on this form. For the state of New York, copies of all prescriptions should be on official New York state prescription forms. I certify that any medications received from Ipsen in connection with any IPSEN CARES program will be used only for the named patient. These medications will not be offered for sale, trade, or barter. Additionally, no claim for reimbursement will be submitted concerning these medications to any payor, including Medicare, Medicaid, or any other federal or state health insurance program, nor will any medications be returned for credit. If the named patient does not return for therapy, product will be returned to Ipsen. I acknowledge that I have assisted the named patient in enrolling in IPSEN CARES exclusively for purposes of patient care and not in consideration for, expectation of, or actual receipt of remuneration of any sort.

Prescriber Signature _____ Date _____

Please See Reverse Side for Indication and Important Safety Information and the Accompanying Full Prescribing Information and Patient Information.

Prescription is valid only if received by fax or mail. Special note: New York prescribers, please submit prescription on an original New York State prescription blank.

PHARMACY & SHIPMENT

Has a current prescription been submitted directly to the Specialty Pharmacy? Yes No

If yes, which Pharmacy? _____

Preferred Delivery Location Patient's Home Prescriber's Office Other _____

Special Shipping Instructions _____

MEDICAL NECESSITY & PRIOR AUTHORIZATION INFORMATION

Have other products been used to treat severe IGFD for this patient? Yes No

Product _____

Initial IGF-1 level prior to treatment with growth promoting agents _____

Date ____/____/____

List Allergies _____ NKDA

Patient Height _____ Weight _____ kg

Most Recent IGF-1 Test Results _____

Date of Most Recent IGF-1 Test ____ / ____ / ____

Other information supporting medical necessity _____

List Medications _____

Other Relevant Medical History _____

Indication

INCRELEX® (mecasermin) is indicated for the treatment of growth failure in children with severe primary IGF-1 deficiency* (IGFD), or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

INCRELEX is not intended for use in patients with secondary forms of IGFD, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids.

Limitations of use: INCRELEX is not a substitute to GH for approved GH indications.

*Severe primary IGFD is defined by height standard deviation score \leq -3.0 and basal IGF-1 standard deviation score \leq -3.0 and normal or elevated growth hormone (GH).

IMPORTANT SAFETY INFORMATION

Contraindications:

- **Benign or Malignant Neoplasia** in children with active or suspected neoplasia; history of malignancy; and any condition or family history that increases the risk of malignancy.
- **Hypersensitivity** to mecasermin (rhIGF-1), any of the inactive ingredients in INCRELEX or who have experienced a severe hypersensitivity to INCRELEX. Allergic reactions have been reported, including anaphylaxis requiring hospitalization.
- **Intravenous administration**
- **Closed epiphyses**

Warnings and Precautions:

- **Benign or Malignant Neoplasia:** Several cases of benign and malignant neoplasia have occurred postmarketing among children and adolescents who received treatment with INCRELEX. Neoplasia was mostly observed in patients who received INCRELEX for unapproved uses or at higher than recommended doses. Physicians should have a high index of suspicion for any potential malignancy. If benign or malignant neoplasia develops, INCRELEX should be discontinued immediately and appropriate expert medical care sought.
- **Hypoglycemic Effects:** INCRELEX should be administered 20 minutes before or after a meal or snack and should not be administered when the meal or snack is omitted. Glucose monitoring and INCRELEX dose titration are recommended until a well-tolerated dose is established and as medically indicated.
- **Intracranial Hypertension:** Fundoscopic examination is recommended at the initiation of and periodically during the course of therapy.
- **Lymphoid Tissue Hypertrophy:** Patients should have periodic examinations to rule out potential complications.
- **Slipped Capital Femoral Epiphysis:** Carefully evaluate any child with the onset of a limp or hip/knee pain during INCRELEX therapy.
- **Progression of Scoliosis:** Patients with a history of scoliosis, treated with INCRELEX, should be monitored.
- **Benzyl Alcohol:** Has been associated with serious adverse events and death, particularly in pediatric patients. Consider the combined daily metabolic load of benzyl alcohol from all sources.

Adverse Reactions

Common adverse reactions include hypoglycemia, local and systemic hypersensitivity, and tonsillar hypertrophy.

Please See Accompanying Full Prescribing Information and Patient Information.



increlex[®]
(mecasermin) injection 10 mg

Please fax the signed form to IPSEN CARES at the number above or send the form to:
IPSEN CARES Program
Ipsen Biopharmaceuticals, Inc.
11800 Weston Parkway, Cary, NC 27513

Patient Authorization and Signature - IPSEN CARES[®] Program

I authorize my/the patient's healthcare providers (including those pharmacies that may receive my/the patient's prescription for INCRELEX) to disclose personal health information ("PHI") about me/the patient, including health information relating to my/the patient's medical condition, prescription, and insurance coverage, to Ipsen Biopharmaceuticals, Inc., its affiliates, and its agents that have been hired to administer the Ipsen Coverage, Access, Reimbursement & Education Support (IPSEN CARES) program on its behalf (collectively, "Ipsen") in order for Ipsen to: (1) enroll me/the patient in IPSEN CARES; (2) establish my/the patient's benefit eligibility and potential out-of-pocket costs for INCRELEX; (3) communicate with my/the patient's healthcare providers and health plans about my/the patient's treatment plan; (4) provide support services, including patient education and financial assistance for INCRELEX; (5) help get INCRELEX shipped to me/the patient; and (6) facilitate my/the patient's participation in INCRELEX patient programs as I have requested or may request. I agree that, using the contact information I provide, Ipsen may contact me for reasons related to the IPSEN CARES program and support services and may leave messages for me that may disclose that I am/the patient is on INCRELEX therapy. I consent to being contacted by an IPSEN CARES program representative in order for the program to obtain further information or clarification regarding any adverse event I/the patient may experience.

I understand that once my/the patient's PHI has been disclosed to Ipsen, it is no longer protected by federal privacy laws and Ipsen may re-disclose it; however, Ipsen has agreed to protect my/the patient's PHI by using and disclosing it only for the purposes described above or as required by law. I understand that my/the patient's healthcare providers may receive remuneration from Ipsen in exchange for my/the patient's PHI and/or for any therapy support services provided to me.

I can withdraw this authorization by calling IPSEN CARES at 1-866-435-5677 or mailing a letter requesting such revocation to IPSEN CARES, 11800 Weston Parkway, Cary, NC 27513, but it will not change any actions taken before I withdraw authorization. Withdrawal of authorization will end further uses and disclosures of PHI by the parties identified in this form except to the extent those uses and disclosures have been made in reliance upon my authorization. I understand that I may refuse to sign this form and, if I do so, I/the patient will not be able to participate in IPSEN CARES programs, but it will not affect my/the patient's eligibility to obtain medical treatment, my/the patient's ability to seek payment for this treatment or affect my/the patient's insurance enrollment or eligibility for insurance coverage. This authorization expires one year after the date I sign it below. I understand that I will receive a copy of the signed authorization.

Patient Name: _____ Parent/Legal Guardian Name:* _____

Relationship to Patient: _____

Signature: _____ Date: _____

Patient Date of Birth: _____ Patient Phone Number: _____

* Please provide name of parent or legal guardian, if patient is under 18 years of age.

Please See Important Safety Information on Last Page and Accompanying Full Prescribing Information and Patient Information.

Questions? Call IPSEN CARES at 1-866-435-5677

IPSEN CARES[®]
Coverage, Access, Reimbursement & Education Support



increlex®
(mecasermin) injection 10 mg

Please fax the signed form to IPSEN CARES at the number above or send the form to:
IPSEN CARES Program
Ipsen Biopharmaceuticals, Inc.
11800 Weston Parkway, Cary, NC 27513

Additional Product and Support Information

I agree to be contacted by autodialed text messages (“texts”) at the mobile phone number I have provided below for the purpose of helping the patient stay on therapy, which may promote or advertise the Ipsen products included in the therapy plan. I certify that the number I am providing belongs to me and not a family member or other third party. I understand that I may opt out of individual communications of the program entirely at any time by calling 866-435-5677 or replying “STOP” by text to any text from Ipsen. Ipsen will not sell or rent this information and will use it only in accordance with this authorization and consent. Consent to being contacted by text messages is not a condition of participation in the IPSEN CARES programs or the purchase of any products or services. I understand that my cellular service carrier’s data and text messaging rates may apply. Privacy policy at www.ipsencares.com. This authorization is valid for one year from the date the form is signed. If I am providing this consent on behalf of another person, I certify that I am authorized to agree to every element of this consent on behalf of such other person, and I agree that I will be liable and will hold Ipsen harmless in the event that such other person alleges that they did not give consent.

In addition to participating in the IPSEN CARES program above, I would also like to receive information from Ipsen via text message and voice call, all of which may include telemarketing, advertisements, and educational material about INCRELEX and programs that support patients. These text messages and voice calls may be made via the use of automatic telephone dialing systems. I certify that the number I am providing belongs to me and not to a family member or other third party. I understand that I do not have to sign this section of the form in order to participate in the IPSEN CARES program and that I may revoke this authorization to receive additional product information at any time. By signing below, I agree that Ipsen and its agents may use and disclose my personal information (including name, address, phone number, and/or email) to provide these services and Ipsen may also contact me to solicit my opinions regarding INCRELEX and Ipsen’s products and services. I understand that my cell phone carrier’s standard rates may apply for calls to my cell phone. This authorization is valid for one year from the date the form is signed. I may revoke this authorization, by calling 866-435-5677 or sending a request in writing to: IPSEN CARES, 11800 Weston Parkway, Cary, NC 27513. If I am providing this consent on behalf of another person, I certify that I am authorized to agree to every element of this consent on behalf of such other person, and I agree that I will be liable and will hold Ipsen harmless in the event that such other person alleges that they did not give consent.

Patient Name: _____ Parent/Legal Guardian Name:* _____

Relationship to Patient: _____

Signature: _____ Date: _____

Patient Date of Birth: _____ Patient Phone Number: _____

* Please provide name of parent or legal guardian, if patient is under 18 years of age.

Please See Important Safety Information on Last Page and Accompanying Full Prescribing Information and Patient Information.

Important Safety Information

Who should not receive INCRELEX?

Your child should not receive INCRELEX if your child: has any tumors or growths, noncancerous or cancerous; or has a history of cancer or a condition or family history that increases the risk of cancer; is allergic to mecaseimerin or any of the ingredients in INCRELEX; or has finished growing. **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 medical conditions, including if your child has any tumors or growths, noncancerous or cancerous; or has a history of cancer or a condition or family history that increases the risk of cancer, 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 possible side effects of INCRELEX?

INCRELEX may cause serious side effects, including:

- **Tumor Growths.** Several cases of tumors, both noncancerous and cancerous, have occurred in patients receiving INCRELEX. Tell your doctor immediately if your child develops any new growths or symptoms of cancer.
- **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 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.
- **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. 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).
- **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.

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.



Please See the Accompanying Full Prescribing Information and Patient Information.