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

increlex®
(mecasermin [rDNA origin] injection)

INCRELEX® IPSEN CARES™ Enrollment Form

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

☐ Benefits Investigation and Drug Coverage ☐ Prior Authorization Support (If Needed) ☐ Financial Assistance Assessment ☐ Injection Training ☐ Adherence Calls

(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 # (____) _____
Social Security Number _____

PARENT/GUARDIAN

Parent/Guardian Name _____
Social Security Number _____
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 _____
DEA # _____ State License # _____
Tax ID # _____ NPI # _____
Medicaid Provider # _____
Medicare PTAN # _____
Office/Institution _____
Specialty ☐ Pediatrician ☐ Endocrinologist ☐ Other: _____

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

DIAGNOSIS

Date of Diagnosis____ / ____/ _____
☐ R62.52 Short Stature (Child) ☐ E23.0 Hypopituitarism ☐ E34.3 Short Stature Due to Endocrine Disorder Other _____

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

PRESCRIPTION

INCRELEX® (mecasermin [rDNA origin] injection) 40 mg/4 mL vial

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

Select a weight-based initial dosage	☐ 0.04 mg/kg ☐ 0.05 mg/kg ☐ 0.06 mg/kg ☐ 0.07 mg/kg ☐ 0.08 mg/kg	_____ (Kg weight) **X** _____ **mg/kg** = _____ (Dose) **mg X 10** = **Inject†** _____ (Units) **BID**
☐ Step up		
If well tolerated after 7 days	☐ 0.08 mg/kg ☐ 0.09 mg/kg ☐ 0.10 mg/kg ☐ 0.11 mg/kg ☐ 0.12 mg/kg	_____ (Kg weight) **X** _____ **mg/kg** = _____ (Dose) **mg X 10** = **Inject†** _____ (Units) **BID**
☐ Step up		
If well tolerated after an additional 7 days	☐ Maximum recommended dose of 0.12 mg/kg BID* 0.12 mg/kg BID*	_____ (Kg weight) **X 0.12 mg/kg** = _____ (Dose) **mg X 10** = **Inject†** _____ (Units) **BID**

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 named patient. 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 patient named on this form. These medications will not be offered for sale, trade, or barter. Additionally, no claim for reimbursement will be submitted concerning these medications to Medicare, Medicaid, or any third party, nor will any medications be returned for credit. If named patient does not return for therapy, product will be returned to Ipsen. I acknowledge that I have assisted the 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.

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 _____

STATEMENT OF MEDICAL NECESSITY & PRIOR AUTHORIZATION INFORMATION

Have other products been used to treat IGFD for this patient? ☐ Yes ☐ No
Product _____
Date of Last Injection _____/ _____/_____
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 [rDNA origin] injection) 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. Severe Primary IGFD is defined by height standard deviation score < -3.0 and basal IGF-1 standard deviation score < -3.0 and normal or elevated growth hormone (GH).

INCRELEX® is not intended for use in subjects with secondary forms of IGFD, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids. Thyroid and nutritional deficiencies should be corrected before initiating INCRELEX® treatment.

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

INCRELEX® has not been studied in children< 2 years of age.

IMPORTANT SAFETY INFORMATION

Contraindications:

- Presence of active or suspected malignancy
- Hypersensitivity to mecasermin (rhIGF-1) or any of the active ingredients in INCRELEX®
- Intravenous administration
- Closed epiphyses

Warnings and Precautions:

- 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.
- Hypersensitivity: Allergic reactions have been reported, including anaphylaxis requiring hospitalization.
- Intracranial hypertension: Funduscopic examination is recommended at the initiation of and periodically during the course of therapy.
- Tonsillar/adenoidal hypertrophy: Patients should have periodic examinations to rule out potential complications.
- Slipped capital femoral epiphysis: Evaluate any child with onset of limp or hip/knee pain.
- Progression of scoliosis: Monitor any child with scoliosis.

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

Please See Accompanying Full Prescribing Information.

Please Fill Out Form Completely and Fax Back to 1-888-525-2416

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(mecasermin [rDNA origin] injection)

Patient Authorization

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, treatment, 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 get in touch with 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. Similarly, I consent to a program representative contacting my/the patient's doctor or other healthcare professional for the same purpose.

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: _____

Additional Product and Support Information

In addition to participating in the IPSEN CARES™ program described above, I authorize the disclosure of personal health information (PHI) about me, including health information relating to my medical condition, treatment, and insurance coverage, to Ipsen, its affiliates, and its agents in order for Ipsen to:

☐ Evaluate the effectiveness of Ipsen's patient support programs and conduct market analysis, including aggregating my PHI with other data for such analysis and solicit my opinions about IPSEN CARES™ services.

☐ Provide information to me, which may include marketing and educational material about INCRELEX® and relevant disease state programs that support patients.

☐ Solicit my opinions regarding INCRELEX® and Ipsen's products and services and market research.

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 my 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 of the parent/caregiver) to provide these 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 after signature. I may revoke this authorization by calling 1-866-435-5677 or by sending a request in writing to IPSEN CARES™, 11800 Weston Parkway, Cary, NC 27513.

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

Relationship to Patient: _____

Signature: _____ Date: _____

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

Please See Next Page for Important Safety Information Regarding INCRELEX®.

Who is INCRELEX® for?

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 severe primary IGF-1 deficiency. INCRELEX® should not be used for other causes of growth failure and should not be used instead of growth hormone.

Important Safety Information

Who Should Not Use INCRELEX®

Your child should not take INCRELEX® if your child: has finished growing (the growth plates at the end of the bones are closed) has cancer, OR is allergic to mecasermin or any of the inactive ingredients in INCRELEX®. INCRELEX® has not been studied in children under 2 years of age and should never be used in newborns. **Your child should never receive INCRELEX® through a vein**.

Before your child takes INCRELEX®, you should tell your child's doctor about:

All of your child's health conditions, including: diabetes, kidney problems, liver problems, allergies, scoliosis (curved spine), pregnancy, or breast-feeding.

All the medicines (prescription and nonprescription), vitamins, and herbal supplements your child takes, especially insulin or other anti-diabetes medicines, which may require dose adjustments of these medicines.

What are possible side effects of INCRELEX® (some of which can be serious)?

Low blood sugar (hypoglycemia) Only give your child INCRELEX® right before or right after (20 minutes on either side of) a snack or meal to reduce the chances of hypoglycemia. Signs include dizziness, tiredness, restlessness, hunger, irritability, trouble concentrating, sweating, nausea, and fast or irregular heartbeat. Do not give your child INCRELEX® if your child is sick or cannot eat. Severe hypoglycemia may cause unconsciousness, seizures, or death. People taking INCRELEX® should avoid participating in high-risk activities (such as driving) within 2 to 3 hours after an INCRELEX® injection.

Allergic reactions 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. If hives do occur, they generally appear minutes to hours after the injection as an itchy, raised skin reaction, pale in the middle with a red rim around them, and may sometimes occur at numerous places on the skin. Get medical help immediately if your child has trouble breathing or goes into shock, with symptoms like dizziness, pale, clammy skin, and/or passing out.

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, blurred vision, and nausea with vomiting.

Enlarged tonsils Signs include: snoring, difficulty breathing or swallowing, sleep apnea (a condition where breathing stops briefly during sleep), or fluid in the middle ear.

A bone problem called slipped capital femoral epiphysis This happens when the top of the upper leg (femur) slips apart from the rest of the bone. Seek immediate medical attention if your child develops a limp or has hip or knee pain.

Worsened scoliosis (caused by rapid growth).

Injection site reactions including: swelling, loss of fat, increase of fat, pain, redness, or bruising. This can be avoided by changing/rotating the injection site with each injection.

Your child's doctor is your primary source of information about treatment. For more information, please talk to your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For more information, please talk to your doctor or visit **www.ipsencares.com**.

Please See the Accompanying Patient Information.

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