



IPSEN CARES® Enrollment Form

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
- All IPSEN CARES® Services

(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 _____
 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 # (____) _____
 Email Address _____
 Preferred Method of Contact Phone Fax

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.

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	<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	$\frac{\text{_____}}{\text{Kg weight}} \times \text{_____ mg/kg} = \text{_____ mg X 10}$ $= \text{Inject}^{\dagger} \text{_____ BID}$ <p style="text-align: center; font-size: small;">Dose 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	$\frac{\text{_____}}{\text{Kg weight}} \times \text{_____ mg/kg} = \text{_____ mg X 10}$ $= \text{Inject}^{\dagger} \text{_____ BID}$ <p style="text-align: center; font-size: small;">Dose 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*	$\frac{\text{_____}}{\text{Kg weight}} \times \text{0.12 mg/kg} = \text{_____ mg X 10}$ $= \text{Inject}^{\dagger} \text{_____ BID}$ <p style="text-align: center; font-size: small;">Dose 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 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 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 [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: Fundoscopic 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 and Patient Information.



increlex[®]

(mecasermin [rDNA origin] injection)

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 [rDNA origin] injection)

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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.

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 mecasepmin 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 Accompanying Full Prescribing Information and Patient Information.

