Increlex Dose Should Be Individualized

increlex® (mecasermin) injection 10 mg

- Patients start Increlex on a weight-based dose in the recommended starting range of 0.04 to 0.08 mg/kg BID subcutaneously[1]
  - Preprandial glucose monitoring is recommended at treatment initiation and until a well-tolerated dose is established[1]*

Adjust dose based on the periodic assessment of patient's weight, tolerability, and laboratory parameters[1]

Initiate Your Patient's Dose With 3 Simple Steps[1]

Step 1 | **START**	Step 2 | **TITRATE**	Step 3 | **ADJUST**
Start on 0.04 to 0.08 mg/kg BID subcutaneously	If well tolerated for at least 1 week, the dose may be increased by 0.04 mg/kg per dose to the maximum dose of 0.12 mg/kg BID subcutaneously†	Adjust dose based on tolerability and weight‡

BID=twice daily.

Injection sites should be rotated to avoid lipohypertrophy.

*If frequent symptoms of hypoglycemia or severe hypoglycemia occur, preprandial glucose monitoring should continue.[1]

† Doses greater than 0.12 mg/kg BID have not been evaluated in children with primary IGF-1 deficiency (IGFD) and, due to the potential risk of neoplasia and hypoglycemic effects, should not be used. If hypoglycemia occurs with recommended doses despite adequate food intake, the dose should be reduced.[1]

‡ As the child's weight changes, and based on tolerability, the dose will need to be adjusted to stay within FDA-approved range. This means that if a child continues to grow, the unit dose will need to be increased.[1]

INDICATION

INCRELEX® (mecasermin) is indicated for the treatment of growth failure in pediatric patients aged 2 years and older with severe primary IGF-1 deficiency§ (IGFD), or with hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

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

§ Severe primary IGF-1 deficiency (IGFD) is defined by height standard deviation score ≤ -3.0 and basal IGF-1 standard deviation score ≤ -3.0 and normal or elevated GH.

IMPORTANT SAFETY INFORMATION

Contraindications

- **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**
- **Malignant Neoplasia** in pediatric patients with malignant neoplasia or a history of malignancy.

Please see additional Important Safety Information on next page and click here for Full Prescribing Information.

increlex®
(mecasermin) injection 10 mg

Appropriate dose adjustments of Increlex are necessary to avoid administering a dose that may be too high or too low for an individual patient. Patients should be weighed and measured frequently, as regular monitoring is critical for proper unit dosing.[1]

Olive, a former Increlex patient, at age 10, and her mother, Renee.

To learn more about Increlex dosing and administration, please scan the QR code or visit Increlex.com/hcp

IMPORTANT SAFETY INFORMATION (Continued)

Warnings and Precautions

- **Hypoglycemia:** 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:** Funduscopic 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 pediatric patient 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.
- **Malignant Neoplasia:** There have been postmarketing reports of malignant neoplasia in pediatric patients who received treatment with INCRELEX. The tumors were observed more frequently in patients who received INCRELEX at higher than recommended doses or at doses that produced serum IGF-1 levels above the normal reference ranges for age and sex. Monitor all patients receiving INCRELEX carefully for development of neoplasms. If malignant neoplasia develops, discontinue INCRELEX treatment.
- **Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preserved Solution:** Serious and fatal adverse reactions including "gasping syndrome" can occur in neonates and infants treated with benzyl alcohol-preserved drugs. Use of INCRELEX in infants is not recommended.

Adverse Reactions

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

To report a suspected adverse event related to INCRELEX, contact 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.

Please click here for Full Prescribing Information.

Reference: 1. INCRELEX. Package insert. Eton Pharmaceuticals, Inc; 2023.

eTon PHARMACEUTICALS