Dose Calculation Guide for Increlex®

increlex® (mecasermin) injection 10 mg

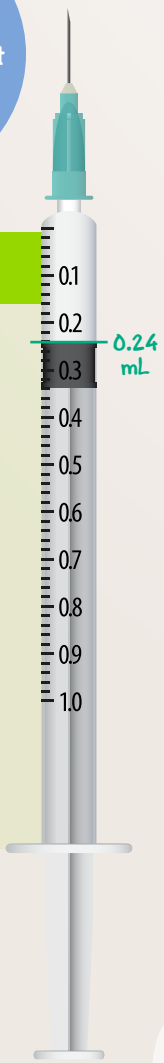
This guide may be used to determine the volume of medication to be administered to achieve the prescribed dose of Increlex.

The dosage of Increlex should be individualized for each patient.

- The recommended starting dose of Increlex is 0.04 to 0.08 mg/kg twice daily by subcutaneous injection
- 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 given twice daily*

*Doses greater than 0.12 mg/kg given twice daily have not been evaluated in children with primary IGFD and, due to potential hypoglycemic effects, should not be used.[1]

Each injection may be a small amount of medication



Number of Milliliters Per Dose 2 Times a Day[1]

Example—a child weighing 20 kg and prescribed a dose of 0.12 mg/kg (to be administered 2x per day)

20	x	0.12	=	2.40	x 10 =	24	÷ 100 =	0.24
Weight in **kg**		Dose in **mg/kg** set by prescriber		**mg** needed for each dose	Number of **mg** in each **mL**	**Units**	Number of units in each **mL**	**mL** per injection (2x daily)

Increlex Dosing Guide Formula

	x		=		x 10 =		÷ 100 =	
Weight in **kg**		Dose in **mg/kg** set by prescriber		**mg** needed for each dose	Number of **mg** in each **mL**	**Units**	Number of units in each **mL**	**mL** per injection (2x daily)

The following formula was used to calculate the dosage as units per injection: patient body weight (kg) x single dose of Increlex (mg/kg) x 1 mL/10 mg x 100 units/1 mL† = units/injection.
Two doses per day are recommended.

†1 mL=1 cc.

Increlex is a sterile solution available at a concentration of 10 mg per mL (40 mg in each 4 mL vial).[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® Administration

increlex® (mecasermin) injection 10 mg

Increlex should be administered shortly before or shortly after a meal or snack (ie, 20 minutes before or after). If the patient is unable to eat shortly before or after a dose for any reason, that dose of Increlex should be withheld.[1] Subsequent doses of Increlex should never be increased to make up for one or more omitted doses. Preprandial glucose monitoring is recommended until a well-tolerated dose is established and also if frequent symptoms of hypoglycemia occur.[1]

Injection sites should be rotated to a different site (upper arm, thigh, buttock, or abdomen) with each consecutive dose to help prevent lipohypertrophy.[1] Increlex is administered by subcutaneous injection.[1] See Instructions for Use in package insert for full details on how to administer Increlex.

To view the INCRELEX® Dosing and Administration video, please scan the QR code.

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.

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