



Patient Information Sheet

Mecasermin [rDNA origin] Injection (marketed as Increlex)

This is a summary of the most important information about Increlex. For more information, talk to your child's healthcare professional.

What Is Increlex?

Increlex is an injectable 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). IGF-1 should not be used instead of growth hormone.

Increlex has not been studied in children under 2 years of age.

Who Should Not Be Treated With Increlex?

Your child should not be treated with Increlex if your child:

- has finished growing (the bone growth plates are closed)
- has cancer
- has other causes of growth failure
- is allergic to mecaseimerin or any of the inactive ingredients in Increlex.

Your child should never receive Increlex through a vein.

What Are The Risks?

The following are the major potential risks and side effects of Increlex therapy. However, this list is not complete.

Increlex may cause the following side effects, which can be serious:

- **Low blood sugar (hypoglycemia).** Increlex may lower blood sugar levels like insulin. It is important to only give your child Increlex within 20 minutes right before or within 20 minutes right after a snack or meal to reduce the chances of low blood sugar. Do not give your child

Increlex if your child is sick or cannot eat. Signs of low blood sugar are:

- dizziness
- tiredness
- restlessness
- hunger
- irritability
- trouble concentrating
- sweating
- nausea
- fast or irregular heartbeat

Severe low blood sugar may cause unconsciousness, seizures or death. Your child should avoid participating in high risk activities (such as driving) within 2 to 3 hours after Increlex injection, especially at the beginning of Increlex treatment.

Before beginning treatment with Increlex, your child's healthcare professional should explain to you the symptoms of low blood sugar and how to treat it.

- **Enlarged Tonsils.** Increlex may enlarge your child's tonsils. Some signs of tonsils that have increased in size include: snoring, difficulty breathing or swallowing, sleep apnea (a condition where breathing stops briefly during sleep), or fluid in the middle-ear. Your child's healthcare professional should do regular exams to check your child's tonsils.
- **Increased pressure in the brain (intracranial hypertension).** Increlex, like growth hormone, can sometimes cause a temporary increase in pressure within the brain. The symptoms of intracranial hypertension can include headache and nausea with vomiting. Tell your child's healthcare provider if your child has a headache with vomiting.
- **A bone problem called slipped capital femoral epiphysis.** This happens when the top of the upper leg (femur) slips apart. Get medical attention for your child right away if your child develops a limp or has hip or knee pain.
- **Worsened scoliosis** (caused by rapid growth). If your child has scoliosis, your child will need to be checked often for an increase in the curve of the spine.





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- **Allergic reactions.** Your child may have a mild or serious allergic reaction with Increlex. Call your child's healthcare professional right away if your child gets a rash or hives. Get medical help immediately if your child has trouble breathing or goes into shock.

Increlex can cause reactions at the injection site including:

- loss of fat
- increase of fat
- pain, redness or bruising

What Should I Tell My Child's Healthcare Professional?

Before your child starts taking Increlex, tell your child's healthcare professional if your child:

- has diabetes
- has kidney problems
- has liver problems
- has a curved spine (scoliosis)
- is pregnant or breast-feeding

Can Other Medicines Or Food Affect Increlex?

Tell your child's healthcare professional about all the medicines your child takes including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your child's healthcare professional if your child takes insulin or other anti-diabetes medicines.

How Should My Child Use Increlex?

- Use Increlex exactly as prescribed for your child.
- Your child's healthcare professional should teach you how to inject Increlex. Do not give Increlex unless you understand all of the instructions.
- See the "**Instructions for Use**" that come with Increlex.

Date Approved: August 2005

