



Patient Information Sheet

Mecasermin rinfabate [rDNA origin] Injection (marketed as IPLEX)

This is a summary of the most important information about IPLEX. For more information, talk to your healthcare professional.

What Is IPLEX?

IPLEX is an injectable prescription medicine that contains man-made insulin-like growth factor-1 (IGF-1) and insulin-like growth factor binding protein-3 (IGFBP-3). IPLEX is used to treat children with severe primary IGF-1 deficiency. Children with severe primary IGF-1 deficiency are very short for their age because their bodies do not make enough IGF-1.

IPLEX should not be used in place of growth hormone. IPLEX is not for other causes of growth failure. IPLEX is not for children less than 3 years old or adults with primary IGF-1 deficiency.

Who Should Not Be Treated With IPLEX?

Your child should not take IPLEX if your child:

- has finished growing (bone growth plates are closed)
- has cancer
- is allergic to mecaseimerin rinfabate or any of the inactive ingredients in IPLEX.
- **Never inject IPLEX into a vein.**

What Are The Risks?

The following are the major potential risks and side effects of IPLEX therapy. However, this list is not complete. Call your child's healthcare professional if your child has side effects that bother them, or do not go away.

- **Low blood sugar** (hypoglycemia). IPLEX may lower your child's blood sugar levels the way insulin does. Do not give your child IPLEX if your child has signs of low blood sugar which include dizziness, headache, tiredness, restlessness, hunger, irritability, trouble concentrating, sweating, nausea, or fast or irregular heartbeat.

Severe low blood sugar may cause unconsciousness, convulsions, or death. Your child should not do risky activities until the healthcare professional has found the right dose for your child.

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

- **Enlarged tonsils.** IPLEX may enlarge your child's tonsils. Some signs of enlarged tonsils are snoring, problems breathing or swallowing, earaches, problems hearing, and breathing problems during sleep (sleep apnea, which can also cause excessive daytime sleepiness). Call your child's healthcare professional if your child gets any of these symptoms. Your healthcare professional should do regular exams to check your child's tonsils.
- **Increased pressure in the brain (intracranial hypertension).** Signs of increased pressure in the brain include headache, nausea, vomiting, and vision problems. Call your child's healthcare professional if your child has these symptoms.
- **A hip bone problem called slipped capital femoral epiphysis.** This happens when the upper end of the leg bone (femur) slips apart. Get medical attention for your child right away if your child develops a limp, or has hip or knee pain.
- **Worsened curve of the spine (scoliosis).** If your child has scoliosis, your child will need to be checked regularly for an increase in the curve of the spine.
- **Allergic reactions.** Your child may have a mild or serious allergic reaction to IPLEX. Call your child's healthcare professional right away if your child gets a rash or hives. Get medical help right away if your child has trouble breathing or goes into shock.
- **Reactions at the injection site including** redness, pain, increase of fat, lumps under the skin, or slight hair growth.





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What Should I Tell My Healthcare Professional?

Tell your child's healthcare professional about all of your child's health conditions, including if your child:

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

Can Other Medicines Or Food Affect IPLEX?

IPLEX and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines your child takes including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines your child takes. Keep a list of them with you to show your child's healthcare professional.

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It is especially important to tell your child's healthcare professional if your child takes insulin or other medicines for diabetes. A dose change may be needed for these medicines.

How Should My Child Use IPLEX?

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

