



increlex[®]▼
mecasermin

Information for parents, caregivers and patients about hypoglycemia and what to do if it develops.

This leaflet contains important information. Please read the entire leaflet carefully before starting to use the product.

This medication is subject to additional monitoring in order to allow the rapid identification of new safety information. You can help by reporting any side effects that your child may experience. See the information regarding how to report side effects at the end of this leaflet.

Before using the product, read the package leaflet, which includes detailed injection instructions.

What is hypoglycemia and why do I need to know about it?

The word "hypoglycemia" is the medical term for a low blood sugar level. If your child has been prescribed with Increlex, you must be familiar with the phenomenon of hypoglycemia and how to deal with it if it occurs.

Increlex is similar to insulin, a naturally occurring hormone in the body that controls blood sugar levels, and therefore, Increlex can affect blood sugar levels and has a growth-promoting effects. As a result, hypoglycemia is a possible side effect of treatment with Increlex.

If hypoglycemia develops, it usually occurs in the first month of treatment, and the problem lessens as the treatment continues.






It is important that you read the following information because the chances of hypoglycemia developing, and any problems that it may cause can easily be minimized by taking some very simple precautions.

How to prevent hypoglycemia

Two of the most important risk factors for hypoglycemia are:

- 1. Insufficient food consumption; for example, postponing or missing meals**
- 2. Physical activity without eating enough**

The following advice should be followed closely throughout the treatment with Increlex:

-  Increlex injections should be administered shortly before or immediately after a meal (within 20 minutes)
-  If a dose of Increlex cannot be administered shortly before or just after a meal, that dose should not be administered. The regular dose must be administered at the next scheduled time, and the dose should not be doubled to make up for the missed dose.
-  Until your child's physician advises otherwise, vigorous physical activity should be avoided for 2 to 3 hours after the injection.
-  If physical activity is performed after breakfast, a snack should be eaten afterwards. If your child is physically active after their evening meal, he or she should have a snack before going to bed.
-  It is important to keep snacks available, especially for younger children, and to teach them to eat as soon as they feel hungry. If hypoglycemia develops despite adequate food intake, you should report this to your child's physician, who may reduce the dose of Increlex.

How to deal with hypoglycemia if it develops

- ✿ Your child must eat or drink something that contains sugar, such as honey, a sugary drink, or glucose tablets, which can be purchased at the pharmacy.
- ✿ Food or drinks containing fat (e.g., chocolate, chocolate bars, cookies or milk) are less preferred. Sweets are also not ideal but they can be used if nothing else is available.
- ✿ After 10 to 15 minutes your child should be feeling better. If not, more sugar should be given. A snack, such as fruit or bread with cheese or meat may then be given, depending on the time left until the next meal.
- ✿ When you visit your child's physician, you must report all of the hypoglycemia events that occurred since your last visit. Keeping a record may make the reporting easier.

Examples of what your child should be given to treat hypoglycemia:

✿ **Glucose gel**

✿ **Orange juice**

✿ **Sweets**










✿ **Milk**

In very rare cases, severe hypoglycemia may develop. If indeed this happens, your child may not be conscious enough to swallow. In such cases, do not try to give your child anything to eat or drink; instead, you should administer your child an injection of glucagon. Glucagon raises the level of sugar in the blood after it has been injected. The clinical team at your hospital may teach you how to use glucagon, in case you need to administer it to your child.

How to recognize hypoglycemia

If hypoglycemia develops, your child will experience 'warning signs', and the people around him or her should be aware of symptoms such as changes in behavior or physical reactions.

These are listed below:

 Dizziness	 Trouble concentrating
 Fatigue	 Sweating
 Restlessness	 Nausea
 Irritability	 Rapid or irregular heartbeats
 Hunger	

In younger children, the most important symptoms to be aware of are your child becoming pale, stopping playing and remaining seated, or becoming sleepy.

If the hypoglycemia is severe, your child may experience reduced consciousness and/or convulsions. Both of these can be alarming, but they are usually not dangerous for your child. In this situation, you should make sure that the airways are open and that your child is lying on his / her side.

Symptoms of hypoglycemia that occur at night may include restlessness, anxiety or excitability, nightmares, bed wetting, or fatigue in the morning.

Important things to remember

- ✿ **Increlex can cause hypoglycemia, the medical term for a low blood sugar level.**
- ✿ **There are changes in behavior and physical symptoms that can help you identify hypoglycemia if it develops.**
- ✿ **Hypoglycemia is most likely to occur if your child is not eating enough or is performing physical exercise without eating enough. Therefore, Increlex injections should be administered shortly before or just after a meal.**
- ✿ **If hypoglycemia occurs, your child must eat or drink something that contains sugar, such as orange juice, sweets, milk or glucose gel or tablets, which can be purchased at the pharmacy.**
- ✿ **In very rare cases of severe hypoglycemia, your child may not be conscious enough to swallow and should be administered with an injection of glucagon.**

If your child develops side effects, including any possible side effects not listed in the package leaflet, consult with your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information about the safety of this medication.

You can report side effects to the Ministry of Health at <https://sideeffects.health.gov.il>

You can also report side effects to the license holder, Medison Pharma, at pv@medison.co.il

For simplicity and ease of reading, this leaflet has been phrased in the masculine form. However, the product is designed for both sexes.

This guide was reviewed and approved by the Ministry of Health in November 2021.