increlex®▼
mecasermin

Important information for patients and the patients' parents regarding severe primary IGF-1 deficiency and how Increlex can help

Read the package leaflet before use.

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It is important to take special care if your child develops a systemic allergic reaction during the treatment with Increlex. You must stop the treatment and refer for immediate medical assistance if your child develops a generalized rash or hives on the body at a site remote from the injection site, develops respiratory difficulty, experiences a feeling of fainting, collapse or feels generally unwell.

Other side effects

You must consult the attending physician if your child is feeling unwell or displays any of the following symptoms:

- A worsening in snoring, respiratory problems during sleep, ear pain, hearing problems or a feeling of congestion in the ears (all of these may develop if the treatment with Increlex has caused enlargement of your child's tonsils and / or adenoids)
- Worsening of a curved spine (scoliosis)
- A limp, difficulty walking or complains of pain in the hips or knees

Side effects can be reported to the Ministry of Health via the portal for the report of side effects on the Ministry of Health homepage, at www.health.gov.il, or via the link:
https://sideeffects.health.gov.il/
Side effects can be reported to Medison Pharma Ltd. by email, at pv@medison.co.il,
or by fax at 03-9234218.

Additional information

In case of any other questions or concerns regarding your child's condition or treatment with Increlex, please consult your attending physician.

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under treatment with Increlex. Increased pressure in the brain may be caused by several factors other than treatment with Increlex. Therefore, if your child experiences the symptoms of increased pressure in the brain, which include severe headache, pain behind the eyes or changes in vision such as blurred vision with nausea and vomiting, it is important to determine the reason for these symptoms.
It is important to tell your doctor if your child is suffering from a severe, unexplained, persistent headache
or disturbance in vision.
By examining your child's eyes, the attending physician can confirm whether or not your child is suffering from increased pressure in their brain. The attending physician may then perform additional tests to determine the cause of these symptoms, and may adjust the dose of Increlex or stop the treatment if necessary. It may be possible to resume the treatment after the symptoms resolve.

Lipohypertrophy (small lump under the skin at the injection site)
The administration site must be changed for each administration of Increlex. The injection site will usually be in the stomach, thigh, buttocks or upper arm, to avoid an increase in fatty tissue (lipohypertrophy) around the area of injection. It is very important to make sure to rotate the sites, as lipohypertrophy may prevent the absorption of Increlex into the body, thereby preventing the medication from being effective.
Allergic (hypersensitivity) reactions
Do not administer Increlex if your child is allergic (hypersensitive) to mecasermin or to any of the other ingredients of Increlex.
Allergic reactions have been reported in several patients who receiving treatment with Increlex and can develop at the site of the injection (a local reaction) or affect the whole body (a systemic reaction). Allergic reactions at the injection site include itching (pruritus), redness and hives (urticaria); and these types of localized reactions usually do not require any further action. Systemic allergic reactions affect the whole body, with swelling of the face especially around the mouth and tongue (angioedema), hives over the whole body (generalized urticaria), or swelling of the throat causing difficulty in breathing (dyspnea). This medical condition may be life-threatening and may require hospitalization.

In addition, you will also receive instruction regarding how to recognize the signs and symptoms of cancer, so that it can be identified early if it does develop and start medical treatment as soon as possible.
Treatment should be stopped if a tumor develops. If a new tumor, a skin lesion, or any other unexpected symptom develops during the treatment or after the treatment, refer immediately to the attending physician, as mecasermin may play a role in the development and progression of both benign and malignant tumors.

Hypoglycemia (a low blood sugar level)
The most common side effect is hypoglycemia, an abnormally low level of sugar in the blood. Hypoglycemia usually occurs in the early stages of treatment. Usually, hypoglycemia develops less often as the treatment continues.
The symptoms and signs of hypoglycemia may include some or all of the following:
Dizziness, fatigue, restlessness, irritability, hunger, trouble concentrating, sweating, nausea, and rapid or irregular heartbeats.
The occurrence of hypoglycemia can usually be avoided by administering each injection shortly before or immediately after a meal (within 20 minutes). Your child should always have a source of sugar, such as orange juice, glucose gel, sweets, or milk available in case symptoms of hypoglycemia occur. It is important that your child adhere to a well-balanced diet that includes protein and fat, such as meat and cheese, in addition to foods that contain sugar.
In cases of severe hypoglycemia, when symptoms do not improve or when they get worse even after eating or drinking a source of sugar, or if it is not possible for your child to drink fluids that contain sugar, medical attention should be obtained as your child may require an injection of glucagon to increase their blood sugar levels. Glucagon raises the level of sugar in the blood after it has been injected. The attending physician may teach you how to use glucagon, in case you need to administer it to your child.
If your child is unable to eat, for any reason, Increlex must not be administered. Do not increase the dose of Increlex to make up for one or more missed doses.
As a precaution, your child should avoid any high-risk activities such as intensive physical activity within the 2 to 3 hours after the administration, until a well-tolerated dose of Increlex has been established. This is particularly true at the start of treatment with Increlex or if the dose Increlex has been increased for any reason.
Intracranial hypertension (increased pressure in the brain)
High pressure in fluid around the brain (intracranial hypertension) can occur in some patients

Parents, patients and caregivers -

Answers to your questions

What is Increlex?

Increlex contains a recombinant (man-made) form of IGF-1, that is also called mecasermin. This substance has the same chemical structure and it acts in the same way as the IGF 1 naturally produced in the body.
Increlex is used to treat children who have growth problems caused by low blood levels of IGF-1.

How is Increlex administered?

Increlex is administered as an injection just under the skin (a subcutaneous injection), twice per day, every day. The medication must be administered shortly before or just after a meal. The reason is that Increlex has effects similar to insulin and therefore reduces blood sugar levels. The prescribed dose and frequency of Increlex injection must not be exceeded.

What are the possible side effects?

The possible side effects and the ways in which these side effects can be avoided are described below.
Tumors (cancerous and non-cancerous)
The risk of tumor development (cancerous or non-cancerous) may be higher in patients taking Increlex.
It is important that your child will not receive this medication if he / she:

- Is suffering, or if there is suspicion that he / she is suffering, from any kind of abnormal growth (tumors, cysts etc.)
- Is suffering from any symptoms of cancer or has suffered from cancer in the past
- Is suffering, or has suffered in the past, from medical conditions that may increase the risk of cancer.

The risk of tumor development (cancerous or non-cancerous) may also be higher in patients taking Increlex in a manner different from what is described in the package leaflet; for example, if Increlex is being taken at a dose higher than the dose noted in the leaflet, or if Increlex is being taken to treat a medical condition other than SPIGFD. Therefore, your child's attending physician should not prescribe Increlex unless they are sure that a definitive diagnosis of SPIGFD has been made (the physician may also measure the patient's blood IGF-1 level before the start of treatment).

Introduction

As a parent or caregiver, your greatest concern is for your child's welfare. Therefore, when you are told that there is a medical reason why your child is shorter than other children their age, it is only natural that you would want to know as much as possible, and in the greatest detail, about the medical condition and the treatment that has been prescribed.
This information sheet has been prepared to help you better understand the medical condition and the prescribed treatment. It includes a questions and answers section that you and your child can read and discuss together.

What is Severe primary IGF-1 deficiency?

Severe primary IGF-1 deficiency (SPIGFD) is one of the causes of short stature. Children with this medical condition are much shorter than other children their age. Children with SPIGFD have low blood levels of a hormone called IGF-1, but normal levels of another hormone, called growth hormone.
IGF-1 is insulin-like growth factor-1, a naturally occurring hormone that plays an important role in a child's growth. IGF-1 deficiency, or IGFD, is a term that describes lower than expected levels of IGF-1 in the blood. When IGF-1 levels are low, growth does not occur as it should. This clinical condition is called severe primary IGF-1 deficiency. or SPIGFD.
The term "primary" means that the lack of IGF-1 is not caused by other medical conditions; the term "severe" is used by physicians to classify the level of IGF-1.