### How to recognise hypoglycaemia

If hypoglycaemia occurs your child will experience 'warning symptoms', and the people around him or her should be on the lookout for symptoms such as changes in behaviour or physical reactions.

These are listed in the table below:

- Shaking, sweating or clamminess
- Feeling anxious, restless or confused
- Poor concentration
- Fast or irregular heart rate
- Excessive hunger
- 🐕 Headache

- 🕏 Feeling faint or dizzy
- Blurred vision
- Nausea or vomiting
- Tiredness
- **Seizures**
- Loss of consciousness

In younger children, the most important symptoms to look out for are your child becoming pale, stopping playing and remaining seated, or becoming sleepy.

If the hypoglycaemia is severe, your child may be less alert or awake (have reduced consciousness) or have a seizure (fit). Both of these can be alarming but they are usually not dangerous for your child. See 'How to deal with hypoglycaemia' for advice on managing this situation.

Symptoms of hypoglycaemia that occur during the night can be restlessness, anxiety or excitability, nightmares, bed wetting, or tiredness in the morning.

To recognise and confirm hypoglycaemia, your child should be monitored at fingertip for blood sugar before each meal treatment initiation and until a well-tolerated dose of Increlex is established. If frequent symptoms of hypoglycaemia or severe hypoglycaemia occur, blood sugar monitoring should continue regardless of eating condition and if possible, at the time of the event. See 'how to prevent hypoglycaemia'

## Things to remember

- Increlex can cause hypoglycaemia, the medical name for a low blood sugar level
- There are changes in behaviour and physical symptoms that can help you to recognise hypoglycaemia if it occurs
- Hypoglycaemia is most likely to occur if your child is not eating enough or is taking physical exercise without eating sufficiently, so Increlex injections should be given shortly before or just after a meal
- If hypoglycaemia occurs, your child must eat or drink something containing sugar, such as fruit juice, sweets, glucose gel or tablets, which can be bought at a pharmacy
- In very rare cases of severe hypoglycaemia, your child may be unconscious or fitting. In these cases, DO NOT give anything by mouth you should give an injection of glucagon

#### Reporting of side effects

If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

By reporting side effects you can help provide more information on the safety of this medicine.



Information for parents, caregivers or for patients, about hypoglycaemia and what to do if it occurs

Information document as described in the Marketing Authorisation licence of Increlex®.



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

Hypoglycaemia is the medical name for a low blood sugar level. If your child has been prescribed Increlex you need to know about hypoglycaemia and how to deal with it if it occurs.

Increlex is related to insulin, a naturally occurring hormone in the body that controls blood sugar levels, so Increlex can affect blood sugar levels as well as having growth promoting effects. As a result, hypoglycaemia is a possible side effect of Increlex therapy.

The risk of hypoglycaemia is highest at the start of treatment, before the best dose of Increlex for your child has been found.

It is important that you read the following information because the chances of hypoglycaemia occurring, and any problems that it may cause if it does, can easily be minimised by taking some very simple precautions.

Before beginning treatment with Increlex, your doctor or nurse should explain to you how to treat hypoglycaemia.

## How to prevent hypoglycaemia

### Two of the most important risk factors for hypoglycaemia are:

- 1. Not eating enough e.g. delaying or missing meals
- 2. Physical exercise without eating sufficiently

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

- \$\frac{1}{2}\$ Increlex injections should be given shortly before or immediately after a meal (within 20 minutes)
- If an Increlex dose cannot be given shortly before or just after a meal, that dose should not be given. The following dose should be the usual one and not doubled to make up for the missed dose
- Until your child's doctor advises otherwise, vigorous physical activity should be avoided for 2-3 hours after the injection, especially at the beginning of treatment.
- If physical activity takes place after breakfast, a snack should be taken 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 hypoglycaemia occurs despite adequate food intake you should tell your child's doctor, who may reduce the dose of Increlex
- Your child should be monitored at fingertip for blood sugar before each meal at treatment initiation and until a well-tolerated dose is established. If frequent symptoms of hypoglycaemia or severe hypoglycaemia occur, capillary blood sugar monitoring at fingertip should continue regardless of eating condition and if possible, at the time of the event

# How to deal with hypoglycaemia should it occur

### If your child is conscious and able to swallow:

- Your child should have a sugary drink or snack, such as fruit juice, sweets or glucose tablets or gel which can be bought at a pharmacy
- After 10 to 15 minutes your child should be feeling better. If not, more sugar should be given. Once feeling better, a carbohydrate-containing snack should be given, if you are not having your main meal right away for example a slice of toast, biscuits or milk
- When you visit your child's doctor, you must tell him or her about all the occasions when hypoglycaemia may have occurred since your last visit. Keeping a record may help with this

# Examples of what your child should be given to treat hypoglycaemia:

🛂 Glucose gel	🖫 Sweets
🖫 Glucose tablets	🖫 Fruit juice

### If your child is unconscious or fitting:

In very rare cases severe hypoglycaemia can occur. Should it occur, your child may not be conscious enough to swallow. In such cases, you should not try to give your child anything to eat or drink, but instead should give an injection of glucagon.

Glucagon raises blood sugar levels when injected. The clinical team at your hospital may teach you how to use glucagon, in case you need to give it to your child.

If you have not been trained to give glucagon, or you have given your child glucagon but they have not improved within 10 minutes, **call for an ambulance**.

An unconscious child should be placed in the recovery position (on their side with head tilted back and knees bent). If your child has a seizure (fit) and they have never had one before, or in any event if a seizure lasts longer than 5 minutes, call for an ambulance.