

# GlucaGen® HypoKit

Glucagon, biosynthetic

## Active ingredient in each ml

Glucagon hydrochloride 1 mg (corresponding to 1 IU), biosynthetic.

## Other ingredients

Lactose monohydrate  
Sterilised water for injections  
Hydrochloric acid and/or Sodium hydroxide (to adjust pH)

## Pharmaceutical form

Powder and solvent for solution for injection in pre-filled syringe.

## Product characteristics

GlucaGen® 1 mg is supplied as a sterile, freeze-dried white powder of glucagon in a 2 ml vial and accompanying solvent in a 1.5 ml disposable syringe.

When the glucagon powder is reconstituted with the Sterilised water for injections it forms a solution of 1 mg (1 IU) glucagon in each ml to be injected under the skin or into a muscle. Glucagon is a high blood sugar agent that helps to release the glycogen in the liver to the blood as glucose.

## Produced by

Novo Nordisk A/S  
DK-2880 Bagsvaerd, Denmark

## What is GlucaGen® used for?

GlucaGen is used to treat severe hypoglycaemic (low blood sugar) reactions which may occur if you are a person with an insulin treated diabetes.

## Before you take GlucaGen®

### When you should not use GlucaGen®

Do not use GlucaGen if you are allergic to glucagon or any of the other ingredients, or if you have an adrenal gland tumour.

## Precautions

GlucaGen works to treat hypoglycaemia when there is liver glycogen. GlucaGen will not work properly if you are fasting, or have low levels of adrenaline, chronic hypoglycaemia or hypoglycaemia caused by drinking too much alcohol. Because GlucaGen depletes glycogen stores, you must be given sugar by mouth as soon as you are able to take it after you have responded to the treatment. This will prevent the occurrence of secondary hypoglycaemia. Take extra care if you use GlucaGen and have a tumour that releases glucagon or insulin. Do not use the solution if in rare cases it looks like a gel or if any of the powder has not dissolved properly.

The vial has a protective, tamperproof plastic cap. To be able to reconstitute the glucagon powder you must remove the plastic cap. If it is loose or missing when you buy the vial, return it to your local pharmacy.

## Other medicines

The effect of injected GlucaGen is not known to be influenced by other medicines than insulin and Indomethacin. GlucaGen may increase the anticoagulant effect of warfarin.

## Pregnancy and breast-feeding

GlucaGen does not cross the human placenta barrier, and may be used in the treatment of severe hypoglycaemia during pregnancy. Breast-feeding following treatment of severe hypoglycaemic reactions with GlucaGen does not put your baby at risk.

## Driving

GlucaGen is not known to produce any effect on your ability to drive and to operate machines.

## Warning

Keep out of reach of children.

## How to take GlucaGen®

### Treatment of severe hypoglycaemia (low blood sugar) in persons with diabetes

#### Administration to the patient by relative(s)

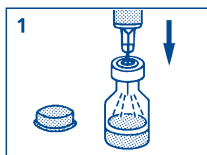
Make sure that your relatives or close friends know that if you get a severe hypoglycaemic reaction medical assistance must always be sought. Your doctor may have given you GlucaGen so that your friends or relatives can give you the injection if you become hypoglycaemic and are unable to take sugar by mouth.

Inject all = 1 ml (adults and children over 25 kg) or half = ½ ml (children below 25 kg or 6 - 8 years) under the skin or into the upper and outer muscle of the thigh. Tell your friends or relatives that you must be given sugar by mouth as soon as you are able to take it after you have responded to treatment. This will prevent the return of the hypoglycaemia.

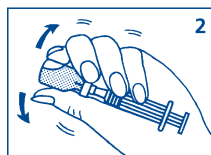
#### Administration by medical personnel

Administer 1 mg (adults and children over 25 kg) or 0.5 mg (children below 25 kg or 6 - 8 years) by s.c. or i.m. injection. If the patient does not respond within 10 minutes a medical doctor must be contacted and intravenous glucose should be given. When the patient has responded to the treatment give oral carbohydrate to restore the liver glycogen and prevent relapse of hypoglycaemia.

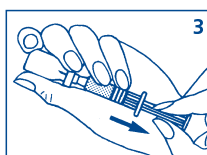
## Preparing the solution to inject



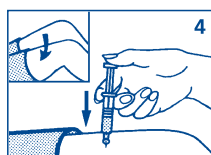
1. Snap the orange cap off the vial. Pull the needle cover off the syringe. Insert the needle through the rubber stopper of the vial containing GlucaGen and inject all the liquid from the syringe into the vial.



2. Without taking the needle out of the vial, gently shake the vial until the GlucaGen has completely dissolved, and the solution is clear.



3. Make sure the plunger is completely down. Draw all the solution back into the syringe. Be careful not to pull the plunger out of the syringe.



4. Make an air shot and inject. Please refer to the previous paragraph for instructions on dosage.

## Side effects

Severe side effects are very rare, although nausea and vomiting may occur occasionally especially with doses above 1 mg or with rapid injection (less than 1 minute).

You may also have rapid heart beat for a short while. Side effects indicating toxicity of GlucaGen have not been reported.

A few people may be allergic to GlucaGen.

If you have any other reactions which you think have been caused by GlucaGen, please tell your doctor or local pharmacy.

## Overdose

If you have been given too much GlucaGen it may cause nausea and vomiting.

Specific treatment is not usually necessary.

The serum potassium may decrease and should be monitored and corrected if needed.

## Expiry date

Never use GlucaGen after the expiry date printed on the pack.

## Storage

GlucaGen (as a powder) should be stored between 2°C and 8°C. Avoid freezing to prevent damage to the syringe. The GlucaGen vial should be protected from light. GlucaGen HypoKit can be stored at room temperature (up to 25°C) for 18 months provided that the expiry date is not exceeded. Reconstituted GlucaGen should be used immediately after preparation. Do not store for later use.

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