

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

**GlucaGen® HypoKit® 1 mg  
Powder and solvent for solution for injection**

**Active ingredient:**

glucagon 1 mg (as hydrochloride)

**Inactive ingredients and allergens in this medicine:** See section 6 'Additional information'. Also see section 2 under 'Important information about some of this medicine's ingredients'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

**1. What is this medicine intended for?**

GlucaGen HypoKit is used for the treatment of severe hypoglycaemia reactions which may occur in patients with diabetes who are treated with insulin.

GlucaGen HypoKit is intended for immediate, emergency use in children and adults with diabetes who use insulin. It is for use when these patients have passed out (become unconscious) because of very low blood sugar level.

This effect is called "severe hypoglycaemia". GlucaGen HypoKit is used when the patients are not able to take sugar by mouth.

**Therapeutic group:** pancreatic hormones, glycogenolytic hormones.

GlucaGen HypoKit contains the active ingredient "glucagon". Glucagon is a natural hormone which has the opposite effect of insulin in the human body. It helps the liver to change something called "glycogen" into glucose (sugar). Glucose is then released into the blood stream – this makes the blood sugar level rise.

**For medical professionals:** See section 7.

**2. Before using this medicine**

**Important information**

- Make sure that your family members, people you work with or close friends know about GlucaGen HypoKit. Tell them that if you pass out (become unconscious) they should use GlucaGen HypoKit straight away.
- Show your family members and others where you keep this kit and how to use it. They must act quickly – being unconscious for a long time it may be harmful for you. It is important they are proficient with and know how to use GlucaGen HypoKit before you need it.
- The syringe does not contain GlucaGen. Prior to injecting, the water in the syringe must be mixed with the compacted GlucaGen powder in the vial. Tell your family members and others to follow the instructions in section 3 "How to use this medicine?"
- Any mixed GlucaGen that is not used must be thrown away.
- After using GlucaGen HypoKit, you or someone else must contact your doctor. You need to find out why you had very low blood sugar level and how to prevent it from happening again.

**Do not use this medicine if:**

- you are sensitive (allergic) to glucagon or to any of the other ingredients in this medicine (for a list of inactive ingredients, see section 6).
- you have a tumour in your adrenal gland.

If any of these apply to you, do not use GlucaGen HypoKit.

**Special warnings about using this medicine**

Talk to your doctor, pharmacist or nurse before you use GlucaGen HypoKit.

**GlucaGen will not work properly if:**

- you have been fasting for a long time
- you have low levels of adrenaline
- you have low blood sugar level caused by drinking too much alcohol
- you have a tumour that secretes glucagon or insulin.

If any of these apply to you, talk to your doctor or pharmacist.

**Drug interactions**

**tell your doctor or pharmacist if you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements.**

The following medicines can affect the way GlucaGen HypoKit works:

- insulin – used to treat diabetes
- indomethacin – used to treat joint pain and stiffness

GlucaGen HypoKit may affect the following medicines:

- warfarin – used to prevent blood clots. GlucaGen may increase the blood-thinning effect of warfarin.
- beta-blockers – used to treat high blood pressure and irregular heartbeat. GlucaGen HypoKit may increase your blood pressure and pulse, but this will only last a short time.

If any of the above apply to you (or if you are not sure), talk to your doctor or pharmacist before you are being treated with GlucaGen Hypokit.

**Tell your doctor or pharmacist** if you are taking, have recently taken, or might take any other medicines.

**Pregnancy and breastfeeding**

If you have very low blood sugar level when you are pregnant or breastfeeding, think you might be pregnant, or are planning to have a baby, you can use GlucaGen HypoKit in case of serious hypoglycaemia.

Ask your doctor or pharmacist for advice before taking any medicines, if you are pregnant.

**Driving and using machines**

Wait until the effects of very low blood sugar level have worn off, before driving or using any tools or machines.

**Important information about some of this medicine's ingredients**

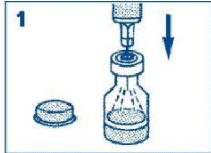
This medicine contains lactose. If you are sensitive to lactose, tell your doctor before you take this medicine (see section 6).

GlucaGen contains less than 1 mmol sodium (23 mg) per maximum dose (2 ml), that is to say essentially 'sodium-free'.

### 3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. Dissolve this medicine before you take it.

#### Preparing and giving the injection



1. Remove the plastic cap from the vial. Pull the needle cover off the syringe. Do not remove the plastic back-stop that prevents the plunger from being pulled out of the syringe. Insert the needle through the rubber stopper (within the marked circle) 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 GlucaGen has completely dissolved, and the solution is clear.



3. Make sure the plunger is completely down. While keeping the needle in the liquid, slowly withdraw all the solution back into the syringe. Do not pull the plunger out of the syringe. It is important to remove any air bubbles from the syringe:
  - With the needle pointing upwards, tap the syringe with your finger.
  - Push the plunger slightly to release any air that has collected at the top of the syringe.

Continue to push the plunger until you have the correct dose for injection. A small amount of liquid will be pushed out from the syringe when you do this.

See *How much to use*, below.



4. Inject the dose under the skin or into a muscle.
5. Turn the unconscious person on their side to prevent choking.
6. Give the person a high sugar snack like sweets, biscuits or fruit juice as soon as he or she regains consciousness and is able to swallow. The high sugar snack will prevent the low blood sugar level happening again.

After using GlucaGen HypoKit, you or someone else must contact your doctor. You need to find out why you had very low blood sugar level and how to prevent it from happening again.

### How much to use

The recommended dose is:

- **Adults:** Inject all of the medicine (1 ml) – marked “1” on the syringe.
- **Children younger than 8 years or children older than 8 years who weigh less than 25 kg:** inject half of the medicine (0.5 ml) – marked “0.5” on the syringe.
- **Children older than 8 years or children younger than 8 years who weigh more than 25 kg:** Inject all of the medicine (1 ml) – marked “1” on the syringe.

**Do not exceed the recommended dose.**

### If you have accidentally taken a higher dose

Too much GlucaGen may lead to nausea and cause you to vomit. Specific treatment is not usually necessary.

If a child has accidentally taken some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment as recommended by your doctor.

**Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## 4. Side effects

Like all medicines, using GlucaGen HypoKit 1 mg may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them. The following side effects may happen with this medicine:

**Tell your doctor immediately if you notice any of the following serious side effects:**

**Very rare:** may affect up to 1 in 10,000 users

- allergic reaction – the signs may include wheezing, sweating, rapid heartbeat, rash, swollen face, and collapse.

► **Talk to a doctor immediately** if you notice any of the above serious side effects.

### Other side effects

**Common:** may affect up to 1 in 10 users

- nausea.

**Uncommon:** may affect up to 1 in 100 users

- vomiting.

**Rare:** may affect up to 1 in 1,000 users

- abdominal pain.

**Side effects whose frequency is not known:** side effects whose frequency has not been established yet

- injection site reaction

► **If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

**Side effects and interactions with other medicines in children and infants:**

Parents must report the treating doctor of any side effect and about any other medicine that their child is being given.

**Reporting side effects**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which refers to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>.

**5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the label. The expiry date refers to the last day of that month.
- Store below 25°C.
- Store in the original package in order to protect the medicine from light.
- Do not freeze in order to prevent damage to the product.
- Use immediately after mixing – do not store for later use.
- Do not use if the mixed solution looks like a gel or if any of the powder has not dissolved properly.
- Do not use if the plastic cap is loose or missing when you receive the product – return the product to your local pharmacy.
- Do not throw away the medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Additional information**

**What GlucaGen contains:**

- The active ingredient is glucagon 1 mg as hydrochloride, produced in yeast using recombinant DNA.

**In addition to the active ingredient, this medicine also contains:**

lactose monohydrate (107 mg), water for injections, hydrochloric acid and/or sodium hydroxide (for pH adjustment).

**What the medicine looks like and contents of the pack:**

GlucaGen is supplied as a sterile white powder of glucagon in a vial, with a solvent in a disposable syringe. The powder is compacted. Once mixed, the solution contains glucagon 1 mg/ml.

**Registration holder's name and address:**

Novo Nordisk Ltd.  
1 Atir Yeda St.  
Kfar Saba 4464301

**Manufacturer's name and address:**

Novo Nordisk A/S  
Novo Allé, DK-2880, Bagsværd, Denmark

Revised in March 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:  
GlucaGen HypoKit 1 mg: 102-38-28662

## **7. Additional information for medical professionals**

Medical professionals should refer to all the sections above before reading this additional information.

**Due to the instability of GlucaGen in solution, the product should be given immediately after reconstitution.**

Do not attempt to put the cap back on the needle of the used syringe. Place the used syringe in the orange box and dispose of the used needle in a sharps container.

### **Treatment of severe hypoglycaemia**

Administer the medicine by subcutaneous or intramuscular injection. If the patient does not respond within 10 minutes, 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.

GlucaGen HypoKit IL PIL MAR 2023-Notification