GlucaGen® HypoKit

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using GlucaGen® HypoKit?

GlucaGen® HypoKit contains the active ingredient glucagon hydrochloride. GlucaGen® HypoKit is used to treat severe hypoglycaemia (extremely low blood sugar levels, or a "hypo") in people using insulin or taking tablets to control their diabetes, who have become unconscious.

For more information, see Section 1. Why am I using GlucaGen® HypoKit? in the full CMI.

2. What should I know before I use GlucaGen® HypoKit?

Do not use if you have ever had an allergic reaction to GlucaGen® HypoKit or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or fast.

For more information, see Section 2. What should I know before I use GlucaGen® HypoKit?in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GlucaGen® HypoKit and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use GlucaGen® HypoKit?

The freeze-dried GlucaGen® powder should be dissolved in the water provided and then injected under the skin, into a muscle.

More instructions can be found in Section 4. How do I use GlucaGen® HypoKit? and 8. Instructions for use in the full CMI.

5. What should I know while using GlucaGen® HypoKit?

Things you should do	• Tell any doctor or pharmacist you visit that you keep a GlucaGen® HypoKit. • Check the expiry date printed on the pack. If your medicine has passed this date, do not use it.
Things you should not do	• Use the medicine if: it does not look like a powder or powdery tablet before adding the water; the powder does not dissolve properly after adding the water; the solution looks like a gel.
Driving or using machines	• If you are still experiencing the effects after a severe hypo, do not drive or operate machinery.
Drinking alcohol	• Glucagon will not work if your hypo is caused by excessive alcohol intake.
Looking after your medicine	• GlucaGen® HypoKit should be stored at room temperature (i.e. less than 25°C). Avoid freezing. • The GlucaGen® HypoKit powder vial should be stored in the original package to protect from light. • Due to the instability of GlucaGen® in solution, the product should be used immediately after reconstitution. Use once only and discard any residue. Do not store it for later use.

For more information, see Section 5. What should I know while using GlucaGen® HypoKit? in the full CMI.

6. Are there any side effects?

Common side effects include abdominal pain, nausea or vomiting. Serious allergic reactions or worsening hypo requires immediate medical attention.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

GlucaGen® HypoKit

Active ingredient(s): *Glucagon hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using GlucaGen® HypoKit. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GlucaGen® HypoKit.**

Where to find information in this leaflet:

1. Why am I using GlucaGen® HypoKit?
2. What should I know before I use GlucaGen® HypoKit?
3. What if I am taking other medicines?
4. How do I use GlucaGen® HypoKit?
5. What should I know while using GlucaGen® HypoKit?
6. Are there any side effects?
7. Product details
8. Instructions For Use

1. Why am I using GlucaGen® HypoKit?

GlucaGen® HypoKit contains the active ingredient glucagon hydrochloride. Glucagon is a natural hormone, which has the opposite effect to insulin in the human body.

It helps the body to convert glycogen into glucose (sugar) in the liver. Glucose is then released into the blood stream. This means that GlucaGen® HypoKit will only work to increase blood sugar if there are stores of glycogen in the liver.

Glucagon also reduces the movements of the smooth muscle in the digestive system and stimulates the production of insulin by the beta cells of the pancreas.

GlucaGen® HypoKit is used:

- **to treat severe hypoglycaemia** (extremely low blood sugar levels, or “hypos”) in people using insulin or taking tablets to control their diabetes, who have become unconscious
- **during medical investigations of the gastrointestinal tract to relax and slow down the movements of the stomach and bowel.** This makes it easier for your doctor to investigate your digestive tract
- **to stimulate the production of insulin by the beta cells**. It can therefore be used to find out how well the beta cells in the pancreas are working.

2. What should I know before I use GlucaGen® HypoKit?

Warnings

Do not use GlucaGen® HypoKit if you have:

- phaeochromocytoma (a rare tumour of the adrenal gland that raises blood pressure)
- glucagonoma (a pancreatic tumour that causes increased levels of glucagon)
- insulinoma (a tumour that causes increased levels of insulin)
- allergies to glucagon or any of the ingredients listed in the "Product details" section of this leaflet.

GlucaGen® will not work properly if:

- You have been fasting for a long time
- You have low levels of adrenaline
- You have chronic hypoglycaemia
- You have hypoglycaemia caused by drinking too much alcohol
- You have a tumour that releases glucagon or insulin.

Check with your doctor if:

- Any of the previous points apply to you
- you are taking a sulfonylurea tablet to treat your diabetes.

Tell your doctor before you are given GlucaGen® HypoKit in connection with medical investigations of your gastrointestinal tract if you:

- have diabetes
- have a heart condition.

GlucaGen® HypoKit should not be given via intravenous *infusion.*

You should not use or be given GlucaGen® HypoKit if:

- it does not look like a powder or powdery tablet before adding the water
- the powder does not dissolve properly after adding the water, or the solution looks like a gel
- the expiry date ("Expiry") printed on the pack and on the vial has passed
- the packaging is damaged or shows signs of tampering, the tamper-proof plastic caps of the vials are loose or missing, or the cover on the syringe needle is missing.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

GlucaGen® does not cross the human placenta and may be used in the treatment of a severe hypo during pregnancy.

While breast-feeding, very small amounts of glucagon may reach the mother’s milk if she is treated with glucagon for a severe hypo. However, any glucagon in the milk will be broken down in the baby’s digestive tract making it harmless. Breast-feeding following treatment of a severe hypo with GlucaGen® HypoKit does not put your baby at risk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking:

- warfarin - used to prevent blood clots
- beta-blockers - used to treat high blood pressure or other heart conditions
- insulin – used to treat diabetes
- indomethacin – used to reduce the pain and inflammation of various conditions e.g. arthritis.

These medicines may be affected by GlucaGen® HypoKit or may affect how well GlucaGen® HypoKit works. Your doctor or pharmacist will be able to tell you what to do if you use GlucaGen® HypoKit while taking other medicines.

4. How do I use GlucaGen® HypoKit?

The freeze-dried GlucaGen® powder should be dissolved in the water provided and then injected under the skin, into a muscle or - *by a medical person only* - into a vein.

Read the 'Instructions for use' section of this leaflet carefully in order to correctly prepare GlucaGen® HypoKit for injection.

What to do in case of severe hypoglycaemia (a severe "hypo")

The first **symptoms of a hypo** can come on suddenly. They may include: cold sweat, cool pale skin, fatigue, nervousness or tremor, drowsiness, anxious feeling, unusual tiredness and weakness, confusion, difficulty in concentration, excessive hunger, vision changes, headache, nausea or rapid heart beat.

If you experience any of the symptoms mentioned above you should immediately take sugary food or drink e.g., lollies, biscuits or fruit juice. **So always carry one of these with you.**

Tell your relatives, friends and close workmates that you have diabetes and how they can help you if you have a severe hypo. Make sure they know you should not be given anything to eat or drink if you are unconscious because you could choke.

If you are unconscious, you should be turned on your side and your relatives, friends or workmates should get medical help immediately.

An injection of GlucaGen® HypoKit may speed up recovery from unconsciousness. This can be given by someone who has been instructed in its use. Make sure that your family, friends, carer or co-workers know how to use GlucaGen® and where it is kept before an emergency arises.

Injection by a non-medical person:

Always use GlucaGen® HypoKit exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Inject the dose into the fatty tissue just below the skin of the thigh, buttocks or upper arm.

Adults and children above 25 kg: Inject full dose (1 mL, marked on syringe as 1/1).

Children below 25 kg: Inject half dose (1/2 mL, marked on syringe as 1/2).

The patient will normally respond within 10 minutes to the injection of glucagon. Sugary food or drink should be given when the patient regains consciousness. This will help to build up liver glucose stores again and prevent relapse.

Medical help must be sought for an unconscious person.

If GlucaGen® HypoKit has been used, tell your doctor or diabetes educator as you may require a change to your diabetes treatment.

Injection by a medical person:

Give 0.5-1 mg by subcutaneous, intramuscular or intravenous injection. If the patient does not respond within 10 minutes intravenous glucose should be given. When the patient has responded to treatment, oral carbohydrate should be given to restore the liver glycogen and prevent secondary hypoglycaemia.

Using GlucaGen® HypoKit for diagnostic tests

Note that a syringe with a thinner needle and a finer graduation may be more suitable for use in diagnostic procedures.

Investigations of the digestive tract:

Your doctor will determine how much glucagon you should be given. The dose will depend on your body weight, the test and the time it will take. Doses usually vary from 0.2-2 mg depending on the diagnostic technique used and how the injection is given. The diagnostic dose for relaxation of the stomach, duodenal bulb, duodenum and small bowel is 0.2-0.5 mg given intravenously or 1 mg given intramuscularly; the usual dose to relax the colon is 0.5-0.75 mg intravenously or 1-2 mg intramuscularly.

The effect after an injection of 0.2–0.5 mg into a vein starts within one minute and lasts for between 5 and 20 minutes depending on the organ under examination. The effect after an injection into the muscle of

1–2 mg starts after 5-15 minutes and lasts about 10-40 minutes depending on the organ.

Stimulation of insulin production:

1 mg of glucagon is injected into a vein in a fasting person. Plasma C peptide is measured before and 6 minutes after injection.

When the diagnostic test is completed:

If you have been fasting, you should be given oral carbohydrate when the diagnostic test has been completed to restore the liver glycogen and prevent occurrence of secondary hypoglycaemia. In the case of severe hypoglycaemia, intravenous glucose may be required.

If you use too much GlucaGen® HypoKit

If you think that you have used too much GlucaGen® HypoKit, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre on 13 11 26 (Australia) or 0800 764 766 (New Zealand), or
- contact your doctor, or
- go to the Accident and Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you have been given too much glucagon, it may cause nausea and vomiting. Specific treatment is not usually necessary. The levels of potassium in the blood may decrease. Patients on beta-blocker medicines may experience a short term increase in blood pressure.

5. What should I know while using GlucaGen® HypoKit?

Things to be careful of

- Do not give drinks or food to an unconscious person.
- GlucaGen® has the opposite effect to insulin. You need to take extra care if you are using GlucaGen® HypoKit in connection with endoscopy or radiography, if you are a person with diabetes, or if you are elderly and have a heart condition.
- GlucaGen® HypoKit will only work if there are stores of glucose (as glycogen) in the liver; therefore, it will not treat hypoglycaemia if you have been 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 sugary food or drink by mouth as soon as you are able to take it after you have responded to the treatment or after the diagnostic test is over. This will prevent the occurrence of secondary hypoglycaemia.

If you are not sure whether you should use or be given GlucaGen® HypoKit, ask your doctor, pharmacist or diabetes educator.

Driving or using machines

If you are still experiencing the effects after a severe hypo, do not drive or operate machinery.

Drinking alcohol

Glucagon will not work if your hypo is caused by excessive alcohol intake.

Looking after your medicine

- GlucaGen® HypoKit should be stored at room temperature (i.e. less than 25°C)
- **Avoid freezing to prevent damage to the glass syringe.**
- The GlucaGen® HypoKit powder vial should be stored in the original package to protect from light.
- The expiry date ("Expiry") is printed on the pack. If your medicine has passed this date, do not use it. **Check the expiry date from time to time to make sure that the glucagon in your GlucaGen® HypoKit has not expired, in case of an emergency.**

Due to the instability of GlucaGen® in solution, the product should be used immediately after reconstitution. **Use once only and discard any residue. Do not store it for later use.**

Keep it where young children cannot reach it.

When to discard your medicine

Use once only and discard any residue. Do not store it for later use.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
When GlucaGen® HypoKit is used to treat a severe hypo: • abdominal pain, nausea, vomiting • skin changes after injection at the injection site. **When GlucaGen® HypoKit is used in a diagnostic procedure:** • abdominal pain, nausea or vomiting • skin changes after injection at the injection site • mild to moderate hypoglycaemia (which can occur after a patient responds to treatment with GlucaGen® HypoKit. It can be more pronounced in patients who have fasted prior to a diagnostic procedure). • temporarily increased blood pressure • decreased blood pressure • increased heart rate • decreased heart rate	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
When GlucaGen® HypoKit is used to treat a severe hypo, or used in a diagnostic procedure:	**Call your doctor straight away, or go straight to the**

Serious side effects	What to do
• allergic reaction – signs are wheezing, sweating, rapid heart beat, rash, swollen face, collapse (anaphylactic reaction). • very rarely it has been reported that patients have developed hypoglycaemic coma or experienced heart attacks.	**Accident and Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available without a prescription, after speaking with your pharmacist.

What GlucaGen® HypoKit contains

Active ingredient (main ingredient)	glucagon 1 mg (corresponding to 1 IU), as hydrochloride
Other ingredients (inactive ingredients)	Powder vial also contains lactose monohydrate 107 mg, sodium hydroxide and/or hydrochloric acid.
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What GlucaGen® HypoKit looks like

GlucaGen® HypoKit is supplied as a single dose pack. It includes one vial containing a sterile white freeze-dried powder (GlucaGen®) and a disposable glass syringe pre-filled with water (water for injections). The powder may appear more like a powdery tablet upon settling.

When the glucagon powder is reconstituted with the water for injections, it forms a solution of 1mg (1 IU) glucagon in each mL. (Aust R 47105).

Who distributes GlucaGen® HypoKit

GlucaGen® HypoKit is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 10, 118 Mount Street, North Sydney, NSW 2060.

GlucaGen® HypoKit is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

PO Box 51-268

Pakuranga

Auckland

New Zealand

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Further Information

For further information call Novo Nordisk Medical Information on 1800 668 626 (Australia) or 0800 733 737 (New Zealand).

www.novonordisk.com.au

www.novonordisk.co.nz

You can also get more information about diabetes and insulin from Diabetes Australia and Diabetes New Zealand:

- freecall helpline 1300 136 588 (Australia)
- www.diabetesaustralia.com.au
- www.diabetes.org.nz

This leaflet was prepared in November 2025.

8. Instructions For Use

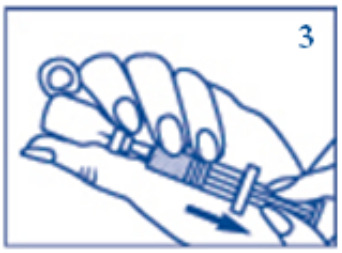
Active ingredient(s): *Glucagon hydrochloride*

Preparing GlucaGen® HypoKit for injection:

The glucagon solution should be prepared immediately before use. The freshly prepared glucagon solution should be clear. It should not be injected if it contains solid particles or looks like a gel. The glucagon solution should **not** be stored for later use.

1. Remove both of the plastic caps from the vial. Pull the needle cover off the syringe. Insert the needle through the rubber stopper (within the marked circle) of the vial containing GlucaGen® and inject all the water 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. 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 the injection. A small amount of liquid will be pushed out when you do this.

4. Inject the dose under the skin or into a muscle. Please refer to the instructions on how to inject the solution.