

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

GlucaGen Hypokit

Glucagon 1 mg Injection (Powder for solution for injection;

Solvent – Water For Injections (WFI)

Read all of this leaflet carefully before you start using GlucaGen Hypokit

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- GlucaGen Hypokit has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What GlucaGen Hypokit is and what it is used for
2. What you need to know before you use GlucaGen Hypokit
3. How to use GlucaGen Hypokit
4. Possible side effects
5. How to store GlucaGen Hypokit
6. Contents of the pack and other information

1. What GlucaGen Hypokit is and what it is used for

GlucaGen Hypokit is for immediate, emergency use in children and adults with very low blood sugar (hypoglycaemia). It is intended to treat people with diabetes using insulin that have become unconscious or are unable to ingest a source of sugar. GlucaGen Hypokit is also used during medical investigations of the gastrointestinal tract to relax and slow down the movements of the stomach and bowel in adults. This makes it easier for your doctor to investigate your digestive tract.

Glucagon is a natural hormone, which has the opposite effect of insulin in the human body. It helps the body to convert glycogen into glucose in the liver. Glucose is then released into the blood stream.

2. What you need to know before you use GlucaGen Hypokit

Do not administer GlucaGen Hypokit:

- If you are hypersensitive (allergic) to glucagon or any of the other ingredients of GlucaGen Hypokit.
- If you have phaeochromocytoma (a tumour of the adrenal gland).

Warnings and precautions

Talk to your doctor before you get GlucaGen Hypokit.

GlucaGen Hypokit will not work properly:

- If you have been fasting for a long time;
- If you have low levels of adrenaline;
- If you have low blood sugar (possibly caused by drinking too much alcohol);

- If you have a tumour that releases glucagon or insulin.

If any of these apply, get medical advice.

Other medicines and GlucaGen Hypokit

Some medicines may affect GlucaGen Hypokit:

Insulin: Reacts antagonistically towards GlucaGen Hypokit.

Indomethacin: GlucaGen Hypokit may lose its ability to raise blood glucose or paradoxically may even produce low blood sugar (hypoglycaemia).

GlucaGen Hypokit may affect another medicines:

Warfarin: GlucaGen Hypokit may increase the blood-thinning effect of warfarin.

Beta-blockers: GlucaGen Hypokit may increase blood pressure and pulse, this will only last a short time.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Pregnancy:

GlucaGen Hypokit can be used during pregnancy.

Breastfeeding:

GlucaGen Hypokit can be used during breast-feeding.

Driving and using machines

If you are still experiencing the effects after an event of very low blood sugar, do not drive a vehicle or use machinery.

3. HOW TO USE GlucaGen Hypokit

Always take GlucaGen Hypokit exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Do not share medicines prescribed for you with others.

Treatment of severe hypoglycaemia:

Administer by subcutaneous or intramuscular injection. When the patient has responded to the treatment, give oral carbohydrate to restore the liver glycogen and prevent relapse of hypoglycaemia.

Diagnostic procedures:

In (a) endoscopy and (b) radiography of the gastro-intestinal tract, the dosage of GlucaGen Hypokit will be prescribed by your doctor who will administer it. Oral carbohydrates should be given when the procedure has ended, if this is compatible with the diagnostic procedure concerned. Remember that GlucaGen Hypokit has the opposite effect of insulin. With endoscopy or radiography procedures, take extra care in administering GlucaGen Hypokit to patients with diabetes or to elderly people with a heart condition.

How much to use

The recommended dose is:

- Adults: inject all (1 ml), marked as 1 on the syringe;

- Children above 25 kg or older than 6 to 8 years: inject all (1 ml), marked as 1 on the syringe;
- Children below 25 kg or younger than 6 to 8 years: inject half (0,5 ml), marked as 0,5 on the syringe.

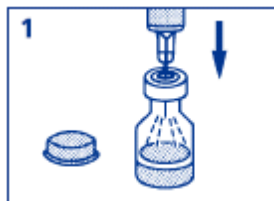
GlucaGen Hypokit 1 mg should be used immediately after preparation.

GlucaGen Hypokit Administration Guide

Snap-off Caps

The GlucaGen Hypokit vials are packed with a protective tamper-proof plastic cap. In order to inject Water for Injections into the vial with GlucaGen Hypokit, the cap must be removed.

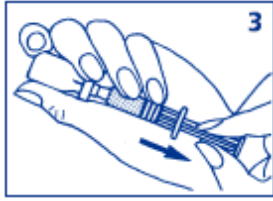
Do not use the injection if the cap is not securely fastened.



1. Pull the needle cover off the syringe. Do not remove the plastic back-stop from the syringe. Insert the needle through the rubber stopper (within the marked circle) of the vial. Inject the Water for Injections into vial containing freeze-dried GlucaGen Hypokit.



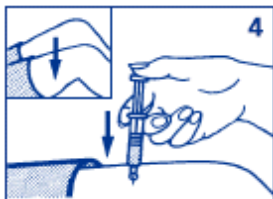
2. Without withdrawing the syringe, shake the vial until the contents are completely dissolved, and the solution is clear.



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 when you do this.



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. This is because GlucaGen Hypokit empties

glycogen stores. The high sugar snack will prevent relapse of the hypoglycaemia.

If you have the impression that the effect of GlucaGen Hypokit is too strong or too weak, talk to your doctor or pharmacist.

If you use more GlucaGen Hypokit than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Too much GlucaGen Hypokit may lead to nausea and cause you to throw up (vomit). Specific treatment is not usually necessary.

4. POSSIBLE SIDE EFFECTS

GlucaGen Hypokit can have side effects.

Not all side effects reported for GlucaGen Hypokit are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Other side effects include:

Frequent

- Feeling you are about to be sick (nausea).

Less frequent

- Being sick (vomiting).

Rare side effects (less than 1 in 1 000 people)

- Stomach (abdominal) pain.

Very rare side effects (less than 1 in 10 000 people)

- **Allergic reaction** – the signs may include wheezing, sweating, rapid heartbeat, rash, swollen face and collapse. **Get medical help immediately**, if any of these occur.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the “**6.04**

Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of GlucaGen Hypokit.

5. How to store GlucaGen Hypokit

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the pen label and carton after ‘EXP’. The expiry date refers to the last day of that month.

GlucaGen Hypokit should be stored at a temperature of 2 – 8 °C (in a refrigerator). The user can store GlucaGen Hypokit at a

temperature not exceeding 25 °C for 18 months provided that the expiry date is not exceeded.

Store in the original package in order to protect from light.

Avoid freezing to prevent damage to the syringe.

If, in rare cases, the reconstituted product shows any signs of fibril formation (viscous appearance) or insoluble matter, it should be discarded.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What GlucaGen Hypokit contains

The active substance is Glucagon 1 mg as hydrochloride.

Other ingredients are lactose monohydrate and Water For Injections.

What GlucaGen Hypokit looks like and contents of the pack

A pack containing 1 vial of glucagon 1 mg and an accompanying syringe containing 1 ml Water for Injections.

A sealed vial with a white or nearly white compacted powder.

Water for Injections: clear and colourless solution, without particles, in a syringe.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

N/A