

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glucose 5% w/v Solution for Infusion Anhydrous glucose (as glucose monohydrate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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

1. What GLUCOSE 5% is and what it is used for

GLUCOSE 5 % is a sterile, colourless solution for infusion.

It is used where there has been excessive water loss from the body (dehydration) and for prevent it. It is used as a solvent and carrier for other compatible drugs for parenteral administration of medicines. This infusion may also be for the prevention and treatment of ketosis (acetone in the blood) during malnutrition.

2. What you need to know before you use GLUCOSE 5%

Do not use GLUCOSE 5% in case of:

- water retention
- glucose intolerance.

Your doctor will check these.

Warnings and precautions:

Tell your doctor if you:

- suffer from diabetes
- suffer from acute illness, pain, post-operative stress, infections, burns, diseases of the central nervous system
- have any type of heart-, liver- or kidney disease
- have been treated with a medicine increasing the effect of vasopressin (a hormone regulating the body's water retention) because this may increase the risk of hospital-acquired low sodium levels in the blood (hyponatraemia).

Your doctor may want to do regular blood and urine tests to check your condition.

Your doctor or nurse will make sure that the solution is given to you properly.

All patients should be closely monitored. In cases where normal regulation of the water content of the

blood is disturbed due to increased secretion of vasopressin, also called Antidiuretic Hormone (ADH), the infusion of fluids with a low concentration of sodium chloride (hypotonic fluids) may result in a low level of sodium in the blood (hyponatraemia). This can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death; therefore these symptoms (acute symptomatic hyponatraemic encephalopathy) are considered a medical emergency. (see also section “Possible side effects” below).

Children, women in the fertile age and patients with brain diseases such as meningitis, brain bleeding, brain contusion and brain oedema are at particular risk of severe and life-threatening brain swelling caused by acute hyponatraemia.

Other medicines and GLUCOSE 5%:

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Drugs leading to an increased vasopressin effect (see also section “Warnings and precautions” above), e.g.:

- Drugs stimulating vasopressin release (e.g. antipsychotics, narcotics)
- Drugs potentiating vasopressin action (e.g. non-steroidal anti-inflammatory drugs)
- Drugs acting like vasopressin, so-called vasopressin analogues

Other medicinal products increasing the risk of hyponatraemia including diuretics in general and antiepileptics.

Pregnancy and breast-feeding

GLUCOSE 5% can be used during pregnancy or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine should be given with special caution for pregnant women during labour particularly if combined with oxytocin (a hormone which may be given to induce labour and to control bleeding) due to the risk of hyponatraemia.

Driving and using machines

Not relevant.

3. How to use GLUCOSE 5%

You will receive your medicine by slow intravenous infusion ('IV drip'). The rate at which the infusion is given and the volume infused will depend on your own specific requirements. Your doctor will decide on the correct dose for you to receive.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following undesirable effects may occur. The frequency of occurrence cannot be estimated from the available data:

- hyperglycaemia (too much sugar in the blood),
- polyuria (frequent emission of urine)
- Headache, nausea, seizures, lethargy. This can be caused by low level of sodium in the blood. When sodium levels in the blood become very low, water enters the brain cells and causes them to swell. This results in increased pressure in the skull and causes hyponatremic encephalopathy.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie

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

5. How to store GLUCOSE 5%

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 label after EXP. The expiry date refers to the last day of that month.

[For glass Bottles and flexible Bags] : Do not store above 25°C.

[For polyethylene bottles]: no special storage conditions.

Your doctor or nurse will ensure the solution is clear and free from particles before use.

Any solution remaining after treatment should be discarded.

Do not throw away any medicines 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. Contents of the pack and other information

What GLUCOSE 5% contains

- The active substance is :

Glucose anhydrous 50 g/l

As glucose monohydrate 55 g/l

Osmolality:300 mosmol/kg

Osmolarity: 278 mosmol/l

Carbohydrate caloric content: 200 kcal/l

pH = 3.5 - 6.5

- The other ingredients are: hydrochloric acid, concentrated, sodium hydroxide, water for injections.

What GLUCOSE 5% looks like and contents of the pack:

GLUCOSE 5 % is a clear solution, non coloured to slightly yellow, for infusion.

1, 30 × 125 ml filled at 50 ml; 1, 10, 30 × 125 ml filled at 100 ml; 1, 12 × 250 ml filled at 125 ml ; 1, 10, 30 × 125 ml ; 1, 10, 12 × 250 ml ; 1, 10, 12× 500 ml ; 1 ; 6 × 1000 ml glass bottle.

1, 10, 40 x 100 ml; 1, 10, 20, 30 x 250 ml; 1, 10, 20 x 500 ml; 1, 10 x 1000 ml polyethylene bottles.

1, 40, 60, 65, 70 × 50 ml ; 1, 40, 50, 55, 60 × 100 ml ; 1, 20, 25, 30, 35, 40 × 250 ml ; 1, 15, 20 × 500 ml ; 1, 8, 10 × 1000 ml bags.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Fresenius Kabi
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Else-Kroener Strasse 1,
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Germany

Manufacturer :

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FRESENIUS KABI DEUTSCHLAND

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FRESENIUS KABI NORGE AS

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1788 Halden
Norway

This leaflet was last revised in 01/2024.

The following information is intended for medical or healthcare professionals only:

Posology and method of administration

Intravenous infusion by peripheral or central vein.

Posology is to be adapted according to patient's clinical status, body weight, diet and any possible other treatments.

Infusion rate must not exceed a volume corresponding to 0.5 g of glucose per minute.

Fluid balance, serum glucose, serum sodium and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for products with lower sodium concentration compared to serum sodium concentration. After infusion of GLUCOSE 5 % a rapid active glucose transport into the body cells occurs. This condition promotes an effect which can be considered as supply of free water and can lead to severe hyponatraemia

Contraindications

Administration of this medicine is contraindicated in the following cases:

- Water overload.
- Glucose intolerance.

Special warnings and precautions for use

Special warnings:

Use a slow infusion rate because of the risk of undesirable osmotic diuresis.

Before use, check that the solution is clear and that the container and its stopper are undamaged ; any damage or partially used container must be discarded.

Precautions for use:

Monitor clinical and laboratory (blood and urine) parameters, in particular water/sodium balance, blood glucose, urinary glucose and acetone, plasma potassium and plasma phosphate.

If necessary, provide parenteral supplements of insulin and potassium.

In diabetics, monitor blood and urinary glucose and possibly adjust the dosage of insulin.

Do not administer blood simultaneously using the same infusion kit because of the risk of pseudo-agglutination.

Precautions for using bag :

- do not use an air entry;
- flush the infusion system in order to avoid any passage of air.
- do not connect in series since the residual of the first container might be carried on by the solution coming from the second container, with the risk of air embolism.
- for single use only; do not reconnect partially used container.

Interactions with other medicinal products and other forms of interaction

Physico-chemical incompatibilities:

It is up to the physician to determine the incompatibility of an added medicine regarding 5% glucose solution, by checking for any possible color change and/or possible formation of precipitate, insoluble complex or crystals.

Before adding any medicine, check that the pH zone in which it is effective corresponds to that of 5 % glucose solution (pH = 3.5 – 6.5).

Also check the package leaflet of the medicine to be added.

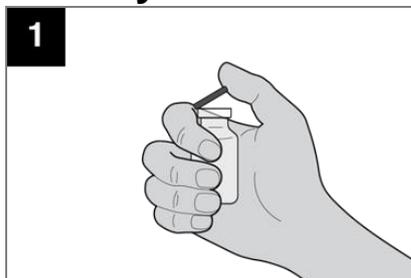
Once a medicine is added to 5 % glucose solution, the mixture must be administered immediately.

Preparation instructions prior to administration – bags with vial adapter:

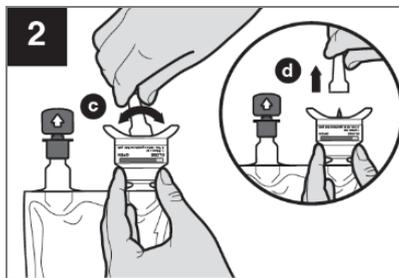
Only for Single Dose Powdered or Liquid (up to 10 mL) Drug Vials with 20mm Closures

Use Aseptic Technique

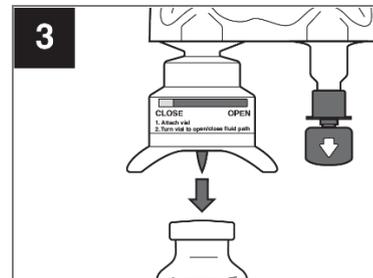
Assembly



- **Remove the Vial Cover.**
 - a. Remove the Vial Cover.
 - b. Disinfect the stopper.



- **Tilt and pull the Vial Adapter Cap to remove.**
 - c. Gently tilt the Adapter Cap back and forth to break the seals and dislodge it from place.
 - d. Once dislodged, pull the Adapter Cap straight off.
 - e. **Check the Vial Adapter for any**



- **Push Vial Adapter down into the top of the Vial.**
 - f. Hold the Vial upright firmly.
 - g. Push the Adapter down into the Vial until it snaps in place.
- DO NOT TWIST.**
- h. Lightly pull the Vial to ensure it is completely secure.

moisture. Discard if moisture is found.

- i. Squeeze the Bag and check that the Vial is still dry.
- j. Use only if Vial is fully secure and dry.

Reconstitution



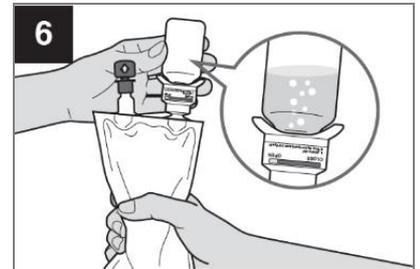
- **Turn the Vial to the right to open.**
 - k. Turn the Vial to the right until the Yellow Indicator is in the OPEN position.



- **For a powdered Drug Vial, squeeze the Bag until the Vial is half full of solution.**

Note: For liquid Drug Vials, skip Step 5 and proceed directly to Step 6.

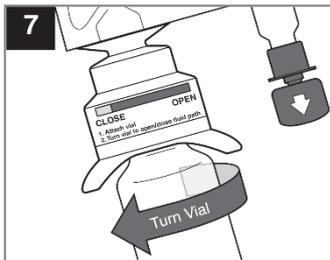
- l. Hold the Bag, keeping the Vial upright.
- m. Squeeze the Bag until Vial is **half full** of solution.
- n. Shake the Vial to suspend the drug in solution.



- **With the Vial upside down, squeeze and release the Bag to drain the solution from the Vial.**

- o. Turn the bag so the Vial is upside down.
- p. Squeeze the Bag to force air into the Vial.
- q. Release the Bag to drain the suspended drug from the Vial into the Bag.
- r. Repeat steps 5 and 6 until the Vial is **empty** of drug and solution is thoroughly mixed. **Ensure drug is completely dissolved.**

Do not remove the Drug Vial.



- **Turn the Vial to the left to close.**
 - s. Turn the Vial to the left until the Yellow Indicator is in the CLOSE position to prevent backflow.