free flex

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 side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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 to 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.

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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
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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

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.
Do not store above 25°C.
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, 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 x 50 ml; 1, 40, 50, 55, 60 x 100 ml; 1, 20, 25, 30, 35, 40 x 250 ml; 1, 15, 20 x 500 ml; 1, 8, 10 x 1000 ml bags.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Fresenius Kabi Limited,
Cestrian Court, Eastgate Way, Manor Park,
Runcorn, Cheshire, WA7 1NT
United Kingdom

Manufacturer:

FRESENIUS KABI NORGE AS
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1788 Halden
Norway

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FRESENIUS KABI

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

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 FRESENIUS 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 damaged 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.