Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glucose 10% w/v Solution for Infusion

Active substance: glucose

Read all of this leaflet carefully before you are given 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This medicine is called 'Glucose 10% w/v Solution for Infusion', but will be referred to as 'Glucose 10% Infusion' throughout the remainder of this leaflet.

What is in this leaflet:

1. What Glucose 10% Infusion is and what it is used for
2. What you need to know before you are given Glucose 10% Infusion
3. How you will be given Glucose 10% Infusion
4. Possible side effects
5. How to store Glucose 10% Infusion
6. Contents of the pack and other information

1. What Glucose 10% Infusion is and what it is used for

Glucose 10% Infusion is a solution of sugar (glucose) in water. Glucose is one of the body's sources of energy. This solution for infusion provides 400 kilocalories per litre.

Glucose 10% Infusion is used to:

- provide a source of sugar (carbohydrate) alone or, as required, for parenteral nutrition. Parenteral nutrition is used to feed patients who are unable to eat. It is given as a slow injection (infusion) into a vein
- prevent or treat a low level of sugar in the blood (hypoglycaemia, that is causing symptoms, but is not life-threatening)
- give you extra fluid if your body does not have enough water (you are dehydrated), and you need extra sugar (carbohydrate)
- water down/dilute other medicines to be given into a vein

2. What you need to know before you are given Glucose 10% Infusion

Do NOT receive Glucose 10% Infusion if you are suffering from any of the following conditions:

- diabetes that is not adequately treated, allowing your blood sugar levels to rise above normal (uncompensated diabetes)
- unconsciousness (hyperosmolar coma). This is a type of coma that can occur if you have diabetes and do not receive enough medicine.
- thinning of the blood due to the addition of too much fluid (haemodilution)
- when there is too much fluid in the spaces around the cells of the body (extracellular hyperhydration)
- when there is a larger volume of blood in the blood vessels than there should be (hypervolaemia)
- a higher level of sugar in the blood than normal (hyperglycaemia)
- a higher level of lactate, a chemical found in the blood, than there should be (hyperlactataemia)
- severe kidney failure (when your kidneys do not work well and you require dialysis)
- uncompensated heart failure. This is heart failure that is not adequately treated and causes symptoms such as:
  - shortness of breath
  - swelling of the ankles
- build up of fluid under the skin, affecting all parts of the body including your brain and lungs (general oedema)
- liver disease that causes fluid to build up within the abdomen (ascitic cirrhosis)
- any condition which affects the way your body controls your sugar levels
- intolerance (hypersensitivity) to glucose. This can occur in patients with an allergy to corn.

If another medicine is added to your solution for infusion, always read the Package Leaflet of that medicine. This way you can check to see if that medicine is safe for you to take.

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Warnings and precautions

Glucose 10% Infusion is a hypertonic (concentrated) solution. Your doctor will take this into account when calculating how much solution to give you.

Please tell your doctor if you have or have had any of the following medical conditions.

- diabetes
- kidney disease
- an illness that has started recently and could be life-threatening (acute critical illness)
- a high pressure within the skull (intracranial hypertension)
- tell your doctor if you had head injury in the past 24 hours
- a stroke due to a clot in a blood vessel in the brain (ischaemic stroke)
- heart disease (heart failure)
- lung disease (respiratory failure)
- reduced production of urine (oliguria or anuria)
- excess water in the body (water intoxication)
- low levels of sodium in the blood (hyponatraemia)
- allergy to corn (Glucose 10% Infusion contains sugar derived from corn)
- if you have a condition that could cause high levels of vasopressin, a hormone regulating fluid in your body. You may have too much vasopressin in your body because, for example,
  - you have had a sudden and serious illness,
  - you are in pain,
  - you have had surgery,
  - you have infections, burns, brain disease
  - diseases linked to your heart, liver, kidneys or central nervous system,
  - because you are taking certain medicines (see also below "other medicines and Glucose 10% Infusion")

This may increase the risk of low level of sodium in your blood and can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain and death. Brain swelling increases the risk of death and brain damage. People who are at higher risk of brain swelling are.

- young people,
- women (particularly if you are of a fertile age)
- people who have problems with their brain fluid levels, for example, because of meningitis, bleeding in the skull or a brain injury

When you are given this infusion, your doctor will monitor:

- the amount of electrolytes, such as sodium and potassium, in your blood (your plasma electrolytes)
- the amount of sugar (glucose)
- the amount of fluid in your body (your fluid balance)
- the acidity of the blood and urine (changes in acid-base balance)

Your doctor will adjust how much solution for infusion you are given according to the results of these tests. These tests will also tell the doctor if you need extra potassium, a chemical in the blood. If required, this can be given into a vein.

As Glucose 10% Infusion contains sugar (glucose), it can cause a high level of sugar in the blood (hyperglycaemia). If this occurs, your doctor may:

- adjust the speed of infusion
- give insulin to reduce the amount of sugar in your blood
- if necessary, give extra potassium

This is particularly important:

- if you are diabetic
- if your kidneys do not work as well as normal
- if you have recently had a stroke (acute ischaemic stroke). High levels of sugar in the blood can worsen the effects of stroke and affect recovery
- if you have metabolic disturbances due to starvation or due to a diet which does not provide the right proportion of the necessary nutrients (malnutrition)
- if you have low levels of thiamine (vitamin B1). This can happen if you suffer from chronic alcoholism.

This solution should not be given to you through the same needle with a blood transfusion. This can damage the red blood cells or cause them to clump together.

Children

Glucose 10% Infusion should be given with special care in children.

Children must be given Glucose 10% Infusion by a doctor or nurse. The amount given must be decided by a doctor specialising in the care of children and will depend upon the child's age, weight, and condition. If Glucose 10% Infusion is used to deliver or dilute another medicine, or if other medicines are given at the same time, this may also affect the dose.

When this infusion is given to children the child's doctor will take blood and urine samples to monitor the amount of electrolytes such as potassium in the blood (plasma electrolytes).

Newborns, especially those born premature and with low birth weight, are at increased risk of developing a too low or too high level of sugar in the blood (hypo- or hyperglycaemia) and, therefore, need close monitoring during treatment with intravenous glucose solutions, to ensure adequate control of the sugar levels in order to avoid potential long term adverse effects. Low sugar levels in newborns can cause prolonged seizures, coma and brain damage. High sugar levels have been associated with bleeding into the brain, bacterial and

fungal infection, damage to the eye (retinopathy of prematurity), infections in the intestinal track (necrotizing enterocolitis), lung problems (bronchopulmonary dysplasia), prolonged length of hospital stay and death.

When administered to a newborn baby, the solution bag could be connected to an infusion pump device, which allows exact delivery of the required quantity of solution across the defined time interval. Your doctor or nurse will be monitoring the device to ensure safe administration.

Children (including neonates and older children) who are given Glucose 10% Infusion are at higher risk of developing a low sodium level in the blood (hypoosmotic hyponatraemia) and a disorder affecting the brain due to low plasma levels of sodium (hyponatraemic encephalopathy).

Other medicines and Glucose 10% Infusion

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

Glucose 10% Infusion and other medicines taken at the same time can affect each other.

Do not take Glucose 10% Infusion with certain hormones (catecholamines) including adrenaline or steroids as they can increase the level of sugar in your blood.

Some medicines act on the hormone vasopressin. These may include:

- anti-diabetic medication (chlorpropamide)
- cholesterol medicine (clofibrate)
- some cancer drugs (vincristine, ifosfamide, cyclophosphamide)
- selective serotonin reuptake inhibitors (used to treat depression)
- antipsychotics or opioids for severe pain relief
- medicines for pain and/or inflammation (also known as NSAIDs)
- medicines that imitate or strengthen the effects of vasopressin such as desmopressin (used to treat increased thirst and urination), terlipressin (used to treat bleeding of the gullet) and oxytocin (used to induce labour)
- anti-epileptic medication (carbamazepine and oxcarbazepine)
- diuretics (water tablets).

Glucose 10% Infusion with food and drink

You should ask your doctor about what you can eat or drink.

Pregnancy, breast-feeding and fertility

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

Pregnancy

Glucose solution can be used during pregnancy. However, caution should be taken when glucose solution is used during child birth.

Fertility

There are no adequate data of the effect of Glucose on fertility. However, no effect on fertility is expected.

Lactation

There are no adequate data of using Glucose solution during breast-feeding. However, no effect on breast-feeding is expected. Glucose solution can be used during breast-feeding.

If another medicine is to be added to your solution for infusion during pregnancy or breast-feeding you should:

- consult your doctor
- read the Package Leaflet of the medicine that is to be added.

Driving and using machines

Ask your doctor or nurse for advice before driving or using machines.

3. How you will be given Glucose 10% Infusion

Glucose 10% Infusion will be given to you by a doctor or nurse. Your doctor will decide on how much you need and when it is to be given. This will depend on your age, weight, clinical condition and the reason for treatment. The amount you are given may also be affected by other treatments you are receiving.

You should NOT be given Glucose 10% Infusion if there are particles floating in the solution or if the pack is damaged in any way.

Glucose 10% Infusion will usually be given to you through a plastic tube attached to a needle in a vein. Usually a vein in your arm is used to give you the infusion. However, your doctor may use another method to give you the medicine.

Before and during the infusion, your doctor will monitor:

- the amount of fluid in your body
- the acidity of your blood and urine
- the amount of electrolytes in your body (particularly sodium, in patients with high levels of the hormone vasopressin, or are taking other medicines which increase the effects of vasopressin).

Any unused solution should be thrown away. You should NOT be given an infusion of Glucose 10% Infusion from a bag that has been partly used.

If you receive more Glucose 10% Infusion than you should

If you are given too much Glucose 10% Infusion (over-infusion) or it is given too fast, or too often, this may lead to the following symptoms:

- build up of liquid in the tissues causing swelling (oedema) or water intoxication with lower levels than normal of sodium in the blood (hyponatraemia).
- a higher amount of sugar in the blood than normal (hyperglycaemia)
- the blood becomes too concentrated (hyperosmolarity)
- sugar in the urine (hyperglycosuria)
- an increase in the amount of urine you produce (osmotic diuresis)
- a loss of water from the body (dehydration)

If you develop any of these symptoms, you must inform your doctor immediately. Your infusion will be stopped or reduced. Insulin should be administered and you will be given treatment depending on the symptoms.

If a medicine has been added to your Glucose 10% Infusion before over-infusion occurs, that medicine may also cause symptoms. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

Stop receiving your Glucose 10% Infusion

Your doctor will decide when to stop giving you this infusion.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

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

The side effects can include:

- hypersensitivity reactions, including a serious allergic reaction called anaphylaxis (potential manifestation in patients with allergy to corn)
  - difficulty breathing
  - swelling of the skin of the face, lips and swelling of the throat
  - fever (pyrexia)
  - hives (urticaria)
  - skin rash
  - redness of the skin (erythema)
  - chills
- changes in the levels of the electrolytes in the blood (electrolyte disturbances), including:
  - low levels of sodium in the blood that may be acquired during hospitalization (nosocomial hyponatraemia) and related neurological disorder (acute hyponatremic encephalopathy). Hyponatraemia can lead to irreversible brain injury and death due to cerebral oedema/swelling (see also in the section “Warning and precautions”)
  - a low level of potassium in the blood (hypokalaemia)
  - a low level of magnesium in the blood (hypomagnesaemia)
  - a low level of phosphate in the blood (hypophosphataemia)
- a high level of sugar in the blood (hyperglycaemia)
- an excess of fluid in the blood vessels (haemodilution and hypervolaemia)
- sugar in the urine (glycosuria)
- reactions related to the route of administration:
  - fever, febrile reaction (pyrexia)
  - infection at the site of injection
  - escape of the infusion solution into the tissues around the vein (extravasation). This can damage the tissues and cause scarring
  - the formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling or redness in the area of the clot
  - irritation and inflammation of the vein into which the solution is infused (phlebitis). This can cause redness, pain or burning and swelling along the path of the vein into which the solution is infused
- local pain or reaction (redness or swelling at the site of infusion shivering)
- sweating

If a medicine has been added to the solution for infusion, the added medicine may also cause side effects. These side effects will depend on the medicine that has been added. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

If any side effects occur, the infusion must be stopped.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom:
Via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

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Ireland:
HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

Malta:
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Glucose 10% Infusion

Keep this medicine out of the sight and reach of children.

This medicinal product does not have any special storage conditions.

Glucose 10% Infusion should NOT be given to you after the expiry date which is stated on the bag and the carton after EXP. The expiry date refers to the last day of that month.

You should not be given Glucose 10% Infusion if there are particles floating in the solution or if the unit is damaged in any way.

6. Contents of the pack and other information

What Glucose 10% Infusion contains

The active substance is glucose (as monohydrate): 100 g per litre.

The only other ingredient is water for injections.

Formula per 250 ml
Glucose (as monohydrate): 25 g

Formula per 500 ml
Glucose (as monohydrate): 50 g

Formula per 1000 ml
Glucose (as monohydrate): 100 g

What Glucose 10% Infusion looks like and contents of the pack

Glucose 10% Infusion is a clear solution, free from visible particles. It is supplied in polyolefin/polyamide plastic bags (Viaflo). Each bag is wrapped in a sealed, protective, outer plastic overpouch.

The bag sizes are:
- 250 ml
- 500 ml
- 1000 ml

Pack sizes:
- 30 or 36 bags of 250 ml per carton
- 1 bag of 250 ml
- 20 or 24 bags of 500 ml per carton
- 1 bag of 500 ml
- 10 or 12 bags of 1000 ml per carton
- 1 bag of 1000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

United Kingdom
Baxter Healthcare Ltd
Caxton Way, Thetford,
Norfolk, IP24 3SE
United Kingdom

Ireland and Malta
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

Manufacturer:
Bieffe Medital S.A.
Ctra de Biescas, Senegüé
22666 Sabiñanigo (Huesca)
Spain

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For information about Glucose 10% Infusion or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder:
Tel: +44 (0)1635 206345.

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Glucose 10% w/v Solution for Infusion

The following information is intended for healthcare professionals only:

Handling and Preparation

The solution for infusion should be visually inspected before use.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.

Do not remove unit from overwrap until ready for use.

The inner bag maintains the sterility of the product.

Do not use plastic containers connected in series. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Electrolyte supplementation may be indicated according to the clinical needs of the patient.

Additives may be introduced before infusion or during infusion through the re-sealable medication port. When an additive is used, verify final osmolariy prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

In order to avoid potentially fatal over infusion of intravenous fluids to the neonate, special attention needs to be paid to the method of administration. When using a syringe pump to administer intravenous fluids or medicines to neonates, a bag of fluid should not be left connected to the syringe.

When using an infusion pump all clamps on the intravenous administration set must be closed before removing the administration set from the pump, or switching the pump off. This is required regardless of whether the administration set has an anti free flow device.

The intravenous infusion device and administration equipment must be frequently monitored.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

Do not store solutions containing additives.

When introducing additives to Glucose solution aseptic technique must be used.

Mix the solution thoroughly when additives have been introduced.

1. Opening

a. Remove the Viaflo container from the overpouch just before use.
b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be compromised.
c. Check the solution for limpidity and absence of foreign matter. If solution is not clear or contains foreign matter, discard the solution

2. Preparation for administration

Use sterile material for preparation and administration.

a. Suspend container from eyelet support.
b. Remove plastic protector from outlet port at bottom of container:
   – grip the small wing on the neck of the port with one hand,
   – grip the large wing on the cap with the other hand and twist,
   – the cap will pop off.
c. Use an aseptic method to set up the infusion.
d. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

Warning: Additives may be incompatible.

To add medication before administration

a. Disinfect medication port.
b. Using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle, puncture resealable medication port and inject.
c. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.
d. Caution: Do not store bags containing added medications.

To add medication during administration

a. Close clamp on the set.
b. Disinfect medication port.
c. Using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle, puncture re-sealable medication port and inject.
d. Remove container from IV pole and/or turn to an upright position.
e. Evacuate both ports by tapping gently while the container is in an upright position.
f. Mix solution and medication thoroughly.
g. Return container to in use position, re-open the clamp and continue administration.

4. In use shelf life: Additives

The chemical and physical stability of any additive at the pH of Glucose 10% Infusion in the Viaflo container should be established prior to use.

From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

5. Incompatibilities of additive medications

Glucose solution should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because haemolysis and clumping can occur.

Incompatibility of the medicinal product to be added with the solution in Viaflo container must be assessed before its addition.

In the absence of incompatibility studies, this solution medicinal product must not be mixed with other medicinal products.

The instructions for use of the medicinal product to be added must be consulted.

Before adding a drug, verify if it is soluble and stable in water at the pH range of the Glucose 10% Infusion (pH 3.5 to 6.5).

When a compatible medication is added to the Glucose 10% Infusion, the solution must be administered immediately.

Those additives known to be incompatible should not be used.

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