Baxter

Package leaflet: Information for the patient

Glucose 5% w/v Intravenous Infusion BP

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 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.

What is in this leaflet:

1. What Glucose 5% Infusion is and what it is used for

Glucose 5% Infusion is a solution of sugar (glucose) in water. Glucose is one of the body's sources of energy. This solution for infusion provides 200 kilocalories per litre.

Glucose 5% Infusion is used:

- as a source of fluid and sugar (carbohydrate)
- to dilute or to deliver other medicines that can be given by infusion

2. What you need to know before you are given Glucose 5% Infusion

Do NOT receive Glucose 5% 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)
- states of glucose intolerance, for example: when the body's metabolism does not function correctly, e.g. due to severe illness (metabolic stress)
- hyperosmolar coma (unconsciousness). This is a type of coma that can occur if you have diabetes and do not receive enough medicine.
- a higher amount of sugar in the blood than normal (hyperglycaemia)
- a higher level of lactate in the blood than normal (hyperlactataemia)
- intolerance (hypersensitivity) to glucose. This is 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.

Warnings and precautions

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

- excess water in the body (water intoxication)
- if you are diabetic or have high levels of sugar in the blood (hyperglcaemia)
- if your kidneys do not work as well as normal
- if you have sepsis, trauma or shock
- low levels of electrolytes (sodium, potassium, phosphorus, magnesium) in the blood
- head injury within the past 24 hours

- 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) in your body. This can happen if you suffer from chronic alcoholism.
- allergy to corn (Glucose 5% 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 5% 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:
  - children
  - 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 take blood and urine samples to monitor:
- the amount of electrolytes, such as 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)

As Glucose 5% 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 blood sugar levels
- if necessary, give extra potassium

Glucose 5% Infusion must not be given through the same needle as a blood transfusion. This can damage the red blood cells or cause them to clump together.

Your doctor will take into account if you are receiving parenteral nutrition (nutrition given by infusion into a vein).

During long term treatment with Glucose 5% Infusion you may need to be given extra nutrition.

Children

Glucose 5% Infusion should be given with special care in children.

Children must be given Glucose 5% 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 the Glucose 5% 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 a 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 5% 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 5% Infusion

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

Glucose 5% Infusion and other medicines taken at the same time can affect each other.

Do not take Glucose 5% 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 5% 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 5% Infusion 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 5% Infusion on fertility. However, no effect on fertility is expected.

Lactation

There are no adequate data of using Glucose 5% Infusion 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 5% Infusion

You will be given Glucose 5% Infusion 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, condition, the reason for treatment and whether or not the infusion is being used to deliver or dilute another medicine. The amount you are given may also be affected by other treatments you are receiving.

You should NOT be given Glucose 5% Infusion if there are particles floating in the solution or if the pack is damaged in any way.

Glucose 5% 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.

Glucose 5% Infusion should be given slowly to prevent you producing too much urine (osmotic diuresis).

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 5% Infusion from a bag that has been partly used.

If you receive more Glucose 5% Infusion than you should

If you are given too much Glucose 5% Infusion (over-infusion) or it is given too fast, this may lead to the following symptoms:

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

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 5% 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 5% 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)
- changes in the amounts of the electrolytes (electrolyte disturbances) in the blood
- higher than normal amounts of sugar in the blood (hyperglycaemia)
- loss of water from the body (dehydration)
- an excess of fluid in the blood vessels (hypervolaemia)
- excessive urination (polyuria)
- 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 2 “Warning and precautions”)
- reactions due to the administration technique:
  - reactions at the infusion site:
    - Irritation of the vein into which the solution is infused. 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)
    - 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

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.

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

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 5% Infusion

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

50 ml and 100 ml bags: Do not store above 30°C.

250 ml, 500 ml and 1000 ml bags: This medicinal product does not require any special storage conditions.

Glucose 5% Infusion should NOT be given to you after the expiry date which is stated on the bag after EXP. The expiry date refers to the last day of that month.

You should not be given Glucose 5% 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 5% Infusion contains

- The active substance is sugar (glucose): 50 g per litre.

The only other ingredient is water for injections.

What Glucose 5% Infusion looks like and contents of the pack

Glucose 5% 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:

- 50 ml
- 100 ml
- 250 ml
- 500 ml
- 1000 ml

Pack sizes:

- 50 bags of 50 ml per carton.
- 75 bags of 50 ml per carton.
- 1 bag of 50 ml.
- 50 bags of 100 ml per carton.
- 60 bags of 100 ml per carton.
- 1 bag of 100 ml.
- 30 bags of 250 ml per carton.
- 1 bag of 250 ml.
- 20 bags of 500 ml per carton.
- 1 bag of 500 ml.
- 10 bags of 1000 ml per carton.
- 12 bags of 1000 ml per carton.
- 1 bag of 1000 ml.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturers

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

Manufacturers for Great Britain:

Baxter S.A.
Boulevard René Branquart, 80
7860 Lessines
Belgium

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

Bieffe Medital S.A.
Ctra de Biescas-Senegüé
22666 Sabiñánigo (Huesca)
Spain

Vantive Manufacturing Limited
Moneen Road
Castlebar
County Mayo
Ireland

Bieffe Medital S.p.A.
Via Nuova Provinciale
23034 Grosotto (SO)
Italy

Manufacturers for Ireland and Malta:

Baxter S.A.
Boulevard René Branquart, 80
7860 Lessines
Belgium

Bieffe Medital S.A.
Ctra de Biescas-Senegüé
22666 Sabiñánigo (Huesca)
Spain

Vantive Manufacturing Limited
Moneen Road
Castlebar
County Mayo
Ireland

Bieffe Medital S.p.A.
Via Nuova Provinciale
23034 Grosotto (SO)
Italy

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For information about Glucose 5% 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 5% w/v Intravenous Infusion BP

The following information is intended for healthcare professionals only:

Handling and Preparation

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 in series connections. 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 additive is used, verify final osmolarity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

Adding other medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

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 5% Infusion 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 impaired.

c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration

Use sterile material for preparation and administration.

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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 (see Paragraph 5 "Incompatibilities of additive medications" below).

To add medication before administration

a. Disinfect medication port.
b. Using syringe with an appropriate needle, puncture re-sealable 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.

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 an appropriate 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 5% 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

As with all parenteral solutions, before adding medications, compatibility of these additives with the solution in Viaflo container must be assessed.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Glucose 5% Infusion by checking for eventual colour change and/or eventual appearance of precipitate, insoluble complexes or crystals. The Instructions for Use of the medication to be added must be consulted.

Before adding a drug, verify it is soluble and stable in water at the pH of Glucose 5% Infusion.

When a compatible medication is added to Glucose 5% Infusion, the solution must be administered immediately.

Those additives known to be incompatible should not be used.

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