Baxter

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Glucose 50% w/v Concentrate for Solution for Infusion
Anhydrous Glucose 50% w/v

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.

Throughout this leaflet, Glucose 50% w/v Concentrate for Solution for Infusion will be called Glucose Concentrate.

What is in this leaflet

1. What Glucose Concentrate is and what it is used for

Glucose Concentrate is a sterile solution of concentrated glucose. The glucose is used to provide energy and to increase the amount of sugar in your blood.

Glucose Concentrate is used if:

- you are unable to take enough food by mouth. It is mixed with other nutrition solutions that will be given to you by infusion through your vein.
- you have increased fluid pressure in your skull and are unconscious due to having low blood sugar. It will provide relief from the symptoms.

2. What you need to know before you are given Glucose Concentrate

Do NOT receive Glucose Concentrate if you are suffering from any of the following conditions:

- a significantly higher level of sugar in your blood than normal (hyperglycaemia).
- sensitivity (hypersensitivity) to glucose. The glucose in this product is derived from corn.

Warnings and precautions

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

- diabetes.
- kidney disease.
- an acute critical illness that has started recently and could be life-threatening.
- high pressure within the skull (intracranial hypertension).
- if you have had a 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 (oliguiria or anuria).
- excess water in the body (water intoxication).
- low level of sodium in the blood (hyponatraemia).
- allergy to corn (Glucose Concentrate contains sugar derived from corn).
- precipitates. Because of the potential for life-threatening events, caution should be taken to ensure that precipitates have not formed in any parenteral nutrient admixture.
- liver disorders. There have been reports of liver problems and liver failure in patients who take intravenous nutrition therapy. If you suffer symptoms such as nausea, vomiting, abdominal pain, yellowing of the skin or eyes, contact your doctor immediately.
- catheter infection/sepsis. Certain medications and illnesses can increase the risk of developing infection or sepsis (bacteria in the blood). There is a particular risk of infection or sepsis when a tube (intravenous catheter) is placed in your vein. Your doctor will carefully watch you for any signs of infection. Patients who require parenteral nutrition (giving nutrition through a tube in your vein) may be more likely to develop infections from their medical conditions. Using aseptic (“germ-free”) techniques when placing and caring for the catheter and when making the nutritional formula (TPN) can reduce the risk of infection.
- 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 solutions").

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.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before having Glucose Concentrate.

When you are given Glucose Concentrate, 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 your blood and urine (changes in acid-base balance).

Your doctor will adjust how much Glucose Concentrate you are given according to the results of these tests. These tests will also tell your doctor if you need extra potassium, an electrolyte (salt) in your blood. If required, this can be given into a vein.

As Glucose Concentrate contains sugar (glucose), it can cause a high level of sugar in your 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 you 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 a low level of vitamin B1 (thiamine). This can happen if you suffer from chronic alcoholism.

Children

Glucose Concentrate should be given with special care in children.

Children must be given Glucose Concentrate 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 Concentrate is used to deliver or dilute another medicine, or if other medicines are given at the same time, this may affect the dose.

When the Glucose Concentrate 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 the newborn 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 enterocolitits), 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 Concentrate are at a higher risk of developing a low sodium level in the blood (hypoosmotic hyponatraemia) and a disorder affecting the brain due to low levels of sodium (hyponatraemic encephalopathy).

Other medicines and Glucose Concentrate

Tell your doctor or nurse if you are using, have recently used or might use other medicines. Glucose Concentrate and other medicines taken at the same time can affect each other.

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).

Having blood transfusions while you are having Glucose Concentrate

Whilst you are having Glucose Concentrate you will not be given a blood transfusion through

the same tubing as the Glucose Concentrate. Also, blood will not be given before or after using the same infusion tube, as this may make the blood clot.

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

Fertility

There are no adequate data of the effect of Glucose on fertility.

Lactation

There are no adequate data of the effect of Glucose Concentrate during breast-feeding. Glucose Concentrate have been used during breast-feeding.

Driving and using machines

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

3. How you will be given Glucose Concentrate

Glucose Concentrate will be given to you by a doctor or nurse.

The usual dose

Your doctor will decide how much of the medicine you will need and for how long it will be given to you. The dose will depend on:

- your age and weight
- the reason you are being given the medicine

How Glucose Concentrate is prepared and given

- Glucose Concentrate will be diluted with other nutrition solutions before it is given to you.
- The dilution will be done under sterile conditions by a trained and qualified person.
- The diluted solution will be stored at 2 to 8°C and used within 24 hours of mixing.

It will be given to you via a plastic tube, which will be placed very carefully into your vein, usually in your chest.

Your doctor will check that any medicines added to your infusion are compatible with Glucose Concentrate.

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).

If you are given more Glucose Concentrate than you should have

If you are given too much Glucose Concentrate (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 level 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 your symptoms.

4. Possible side effects

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

Side effects can include:

- hypersensitivity reactions, including a serious allergic reaction called anaphylaxis (potential manifestation in patients with allergy to corn).
- 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 hyponatraemic encephalopathy). Hyponatraemia can lead to irreversible brain injury and death due to cerebral oedema swelling (see also in the section “Warning and precautions”)
- a high level of sugar in the blood (hyperglycaemia).
- an excess of fluid in the blood vessels (haemodilution and hypervolaemia).
- sugar in your urine (glycosuria).
- reactions related to the route of administration:
  - fever, febrile reaction (pyrexia).
  - infection at the site of injection.
  - escape of the Glucose 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 and redness in the area of the clot.
  - irritation and inflammation of the vein into which the solution was 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.
- formation of small particles blocking lung blood vessels.

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 nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Malta:

ADR Reporting

Website: www.medicinesauthority.gov.mt/aprportal

United Kingdom:

Yellow Card Scheme

www.mhra.gov.uk/yellowcard

5. How Glucose Concentrate is stored

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

Hospital staff will ensure that the product is stored and disposed of correctly and not used after the expiry date stated on the product. The storage conditions should you need them are given below.

- Do not store above 25°C.
- Store in original packaging.
- Do not use Glucose Concentrate after the expiry date that is stated on the label. The expiry date refers to the last date of that month.
- Glucose Concentrate must not be used if the solution is not clear or the bag is damaged.

Each bag will be used once. Any left-over concentrate will be discarded.

6. Contents of the pack and other information

This leaflet does not contain all the information about for this medicine. If you have any questions or are not sure about anything, ask your healthcare professional.

What Glucose Concentrate contains

The active substance is Glucose Monohydrate 55% w/v (550 g per 1000 ml), which is equivalent to Anhydrous Glucose 50% w/v (500 g per 1000 ml).

The other ingredient is sterile water (called 'water for Injections'). Glucose Concentrate can also sometimes contain small amount of hydrochloric acid. This is added to adjust the pH of the Concentrate.

What Glucose Concentrate looks like and contents of the pack

Glucose Concentrate is as a clear, slightly yellow solution. It is available in flexible plastic bags, which contain 500 ml, 1000 ml, 1500 ml, 2000 ml or 3000 ml of concentrate. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

The Marketing Authorisation holder is:
Baxter Healthcare Ltd
Caxton Way, Thetford
Norfolk, IP24 3SE
United Kingdom

Send all enquires to this address.

Glucose Concentrate can be made at either of these addresses:

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

Baxter Healthcare S.A.
Castlebar, Co. Mayo
Ireland

This leaflet was last revised in 10/2018.

For information about Glucose Concentrate or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder:

Tel: +44 (0)1635 206345.