# PACKAGE LEAFLET: INFORMATION FOR THE USER

**Glucose 50% w/v sterile concentrate, concentrate for solution for infusion**
Glucose

**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 or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**


## 1. What Glucose 50% w/v sterile concentrate, concentrate for solution for infusion is and what it is used for

Glucose 50% w/v sterile concentrate is a concentrate which needs to be diluted by your doctor. He/she will prepare a solution that contains glucose for you so he/she can give it into one of your veins (intravenous infusion). In case of an emergency treatment he/she might inject it slowly into one of your large central veins (central intravenous injection).
You are given this medicine in order to raise an abnormally low blood sugar level.

## 2. What you need to know before you use Glucose 50% w/v sterile concentrate, concentrate for solution for infusion

**Do not use Glucose 50% w/v sterile concentrate, concentrate for solution for infusion** if you have

- high levels of lactic acid in your blood (lactic acidosis)

**Warnings and precautions**
When given this medicine, patients who are acutely ill, with pain, postoperative stress, infections, burns, diseases of the nervous system, heart, liver or kidney, and patients

who are on medicines working like vasopressin (a hormone which regulates the amount of body fluids), are at particular risk of developing an abnormally low level of sodium in the blood (acute hyponatraemia) which can lead to a life-threatening swelling of the brain (hyponatraemic encephalopathy, brain oedema).

Women of childbearing potential and patients with serious brain conditions such as an infection of the membranes surrounding the brain (meningitis) or brain injury (intracranial bleeding, cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by an abnormally low level of sodium in the blood.

Talk to your doctor before using Glucose 50% w/v sterile concentrate, concentrate for solution for infusion.

Your levels of blood sugar, electrolytes (especially potassium) and acid-base balance will be monitored. Your doctor will correct your fluid and electrolyte balance before and during administration if necessary. For this purpose blood samples may be taken from you.

Your doctor will avoid to give you this solution in case you have head injury (intracranial or intraspinal haemorrhage) in the first 24 to 48 hours. Only if you have a very low blood glucose level (hypoglycaemia) and do not receive nutritional support, your doctor might give you the solution.

Your doctor will take special care if your kidneys are not working properly or if you are a dialysis patient.

**Children**
Children are at particular risk of the severe and life-threatening brain swelling caused by an abnormally low level of sodium in the blood.

Glucose 50% w/v sterile concentrate, **after dilution**, can be used in your child. If you have any further questions on the use of this medicine in children, ask your doctor or pharmacist.

**Other medicines and Glucose 50% w/v sterile concentrate, concentrate for solution for infusion**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor will take care only to add those drugs or additives to the solution that mix well with it.

Packed red blood cells will not be added to this solution nor is it infused together with, immediately before or after blood through the same tubing.

Your doctor will only administer this solution with caution if you are taking one of the following medicines that work like vasopressin or increase the effect of vasopressin and increase the risk of low blood sodium levels (hyponatraemia):

- Carbamazepine and oxcarbazepine, used to treat epilepsy
- Clofibrate, used to treat high blood fat levels
- Vincristine and ifosfamide, used as anticancer treatments
- Cyclophosphamide, used to treat cancer and autoimmune diseases
- Selective Serotonin Reuptake Inhibitors (SSRIs), used to treat depression
- Antipsychotics, used to treat mental health disorders
- Opioid pain killers, used to relieve severe pain
- Non-steroidal anti-inflammatory drugs (NSAIDs), used to relieve mild to moderate pain and to treat inflammation in your body
- Desmopressin, used to treat diabetes insipidus (extreme thirst and the continuous production of large volumes of dilute urine)
- Oxytocin, used during labour
- Vasopressin and Terlipressin, used to treat 'bleeding oesophageal varices' (enlarged veins in your food pipe caused by liver problems)
- 3,4-methylenedioxy-N-methamphetamine, (MDMA, 'ecstasy'), an illegal drug
- Diuretics or water tablets (medicines which increase the amount of urine)'

**Pregnancy, breast-feeding and fertility**

Pregnancy
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. Your doctor will decide carefully whether or not you should receive this solution.

Breast-feeding
Glucose and its metabolites are excreted into human milk, but no effects are expected. Glucose 50% w/v sterile concentrate, concentrate for solution for infusion can be used during breast-feeding as indicated.

Fertility
Glucose does not affect fertility.

**Driving and using machines**
This medicine has no influence on the ability to drive and to use machines.

## 3. How to use Glucose 50% w/v sterile concentrate, concentrate for solution for infusion

Your doctor may monitor fluid balance, glucose and electrolyte levels (including sodium) in your blood before and during treatment, especially in patients with increased production of vasopressin (a hormone which regulates the amount of body fluids) and in patients who are on medicines working like vasopressin, because there is a risk of an abnormally low sodium level in your blood (hyponatraemia). See also

sections “Warnings and precautions”, “Other medicines and Glucose 50% w/v sterile concentrate, concentrate for solution for infusion” and “Possible side effects”.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
For the treatment of hypoglycaemia in adults, the dose has to be adjusted according to your current blood glucose concentration and your general condition.

**Use in children and adolescents**
For correction of hypoglycaemia in children, it is recommended to dilute the glucose concentrate to a strength not higher than 100 mg/ml.

**If you use more Glucose 50% w/v sterile concentrate, concentrate for solution for infusion than you should**
It is unlikely that this occurs because your doctor will determine your daily doses.

Overdose may result in too high levels of blood sugar (hyperglycemia), excretion of glucose in the urine (glucosuria), excessive loss of water from the body (hypertonic dehydration), complications of *diabetes mellitus* (hyperglycaemic hyperosmolar coma) and imbalances of the ionized salts in the body (electrolyte disorders).
If this occurs, your glucose infusion will be slowed down.
Your doctor will decide on any further treatment you may need, e.g. administration of insulin.

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

## 4. Possible side effects

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

Not known (frequency cannot be estimated from the available data)
- local reactions at the site of administration, including local pain, irritation or inflammation and clotting of the veins and gangrene in case of blood or fluid escape into tissue.
- Hospital-acquired abnormally low blood sodium levels (hyponatraemia)
- Brain swelling (brain oedema) due to abnormally low blood sodium levels (hyponatraemic encephalopathy). This may cause irreversible brain damage and death. The symptoms include: headache, feeling sick (nausea), vomiting, seizures, tiredness and lack of energy.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. 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 medicine.

## 5. How to store Glucose 50% w/v sterile concentrate, concentrate for solution for infusion

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 bottle and carton labels. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Only to be used if the solution is clear, colourless or slightly yellowish and the container and its closure are undamaged.
The containers are for single use only. Discard unused contents.

Do not throw away any medicines via wastewater. 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 50% w/v sterile concentrate, concentrate for solution for infusion contains

- The active substance in Glucose 50% w/v sterile concentrate, concentrate for solution for infusion is glucose (as Glucose Monohydrate).

50 ml of solution contains 25.0 g of glucose (as Glucose Monohydrate).

- The other ingredient is water for injections.

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| Energy | 420 kJ/50ml = 100 kcal/50 ml |
| Theoretical osmolarity | 2775 mOsm/l |
| Acidity (titration to pH 7.4) | < 1.5 mmol/l |
| pH | 3.5 - 5.5 |

### What Glucose 50% w/v sterile concentrate, concentrate for solution for infusion looks like and contents of the pack

Glucose 50% w/v sterile concentrate is a concentrate for solution for infusion (for administration by a vein drip after dilution).
It is a clear, colourless or slightly yellowish solution of glucose in water.

It comes in:
vials of colourless glass containing 50 ml,
supplied in packs of 20 x 50 ml

### Marketing Authorisation Holder and Manufacturer

PA Holder:

B. Braun Medical Ltd.
3 Naas Road Industrial Park
Dublin 12
Republic of Ireland

Manufacturer:
B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Germany

**This leaflet was last revised in September 2018.**

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

Fluid balance, serum glucose, 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 physiologically hypotonic fluids. Glucose 50% w/v sterile concentrate, concentrate for solution for infusion may become hypotonic after administration due to glucose metabolisation in the body (see sections 4.4, 4.5 and 4.8).

States of hyperglycaemia should be treated with insulin. The application of insulin causes additional shifts of potassium into the cells and may therefore cause or increase hypokalaemia.

Patients with acute stroke should be treated with caution as hyperglycaemia is associated with poor functional outcome in these patients.

Dehydration can be worsened by injection of hypertonic glucose solutions.

**Incompatibilities**
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. As the solution has an acid pH, it may be incompatible with other medicinal products.
Erythrocyte concentrates must not be suspended in glucose solutions because of the risk of pseudo-agglutination.
**Shelf life after first opening the container:**
The product should be used immediately after opening.

**Shelf life after dilution:**
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 ° C, unless dilution has taken place in controlled and validated aseptic conditions.

**Method of administration**
Intravenous infusion or slow intravenous injection after dilution.
Glucose concentrates must be administered diluted as additive to infusion solutions.
Hypertonic glucose solutions should be preferably administered via a central venous catheter.