

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

B. Braun Melsungen AG · 34209 Melsungen, Germany

**Glucose B. Braun 500 mg/ml 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 B. Braun 500 mg/ml Concentrate for Solution for Infusion is and what it is used for
2. What you need to know before you use Glucose B. Braun 500 mg/ml Concentrate for Solution for Infusion
3. How to use Glucose B. Braun 500 mg/ml Concentrate for Solution for Infusion
4. Possible side effects
5. How to store Glucose B. Braun 500 mg/ml Concentrate for Solution for Infusion
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**1. What Glucose B. Braun 500 mg/ml Concentrate for Solution for Infusion is and what it is used for**

Glucose B. Braun 500 mg/ml is a concentrate which is usually 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 B. Braun 500 mg/ml Concentrate for Solution for Infusion****Do not use B. Braun 500 mg/ml Concentrate for Solution for Infusion**

if you have

- too high blood sugar level (hyperglycaemia)
- high levels of lactic acid in your blood (lactic acidosis)

**Warnings and precautions**

Talk to your doctor before using Glucose B. Braun 500 mg/ml 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 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.

**Other medicines and B. Braun 500 mg/ml 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.

**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 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 B. Braun 500 mg/ml 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 B. Braun 500 mg/ml Concentrate for Solution for Infusion**

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.

**Use in children and adolescents**

If you are critically ill, your dosage of glucose will be limited to 6 mg per kg body weight per minute.

**Method of administration**

The solution will be administered to you after dilution. It may be given to you as additive to solutions you receive through a small tube inserted into one of your veins (by intravenous infusion). This is done to avoid vein irritation.

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In emergency cases your doctor might inject the solution slowly into one of your large central veins (central intravenous injection).

#### If you receive more Glucose B. Braun 500 mg/ml Concentrate for Solution for Infusion

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 (dehydration), increase in the osmolarity of a body fluid (hyperosmolarity), complications of *diabetes mellitus* (hyperglycaemic hyperosmolar coma) and imbalances of the ionized salts in the body. 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.

General disorders of unknown frequency can occur such as: 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

#### 5. How to store Glucose B. Braun 500 mg/ml 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 B. Braun 500 mg/ml Concentrate for Solution for Infusion contains

- The active substance in Glucose B. Braun 500 mg/ml Concentrate for Solution for Infusion is glucose (as Glucose Monohydrate). 100 ml of solution contains 50.0 g of glucose (as Glucose Monohydrate , 55.0 g).

- The other ingredient is water for injections.

Caloric value	8375 KJ/l = 2000 Kcal/l
Theoretical osmolarity	2775 mOsm/l
Titration acidity (to pH 7.4)	< 1.5 mmol/l
pH	3.5 - 5.5

##### What Glucose B. Braun 500 mg/ml Concentrate for Solution for Infusion looks like and contents of the pack

Glucose B. Braun 500 mg/ml 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, 100 ml, supplied in packs of 20 x 50 ml, 20 x 100 ml,
- plastic (polyethylene) ampoules containing 20 ml supplied in packs of 20 x 20 ml

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in April 2016

#### The following information is intended for medical or health-care professionals only:

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 to maintain a blood glucose concentration between 4 and 11 mmol/l.

In already dehydrated delirium tremens patients, glucose injections should only be given in case of emergency.

Patients with suspected or confirmed malnutrition should receive thiamine supplementation while treated with parenteral glucose. In patients with acute hypoglycaemia restoration of normoglycemia is a priority.

#### Incompatibilities

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 pseudoagglutination.

#### 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.

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