

PACKAGE LEAFLET: INFORMATION FOR THE USER

B. Braun Melsungen AG · 34209 Melsungen, Germany

Glucose Intravenous Infusion BP 10% w/v

solution for infusion

Glucose (as glucose monohydrate)

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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1. WHAT GLUCOSE INTRAVENOUS INFUSION BP 10% W/V SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

Glucose Intravenous Infusion BP 10% w/v solution for infusion is a solution that contains glucose for administration in the form of a vein drip (intravenous infusion).

You are given this medicine to provide you with carbohydrates if you are unable to eat and drink normally.

You may also be given it in order to raise an abnormally low blood sugar level.

The solution may also be used to dissolve or dilute medicines that are to be given to you by infusion.

Glucose solutions can also be used to replace body fluids lost for example from bleeding, severe vomiting, severe diarrhoea etc.

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE GLUCOSE INTRAVENOUS INFUSION BP 10% W/V SOLUTION FOR INFUSION

You will not receive Glucose Intravenous Infusion BP 10% w/v solution for infusion

if you have

- too high blood sugar level (hyperglycaemia) that needs more than 6 units of insulin per hour to be controlled
- delirium tremens associated with severe fluid deficit
- severely impaired blood circulation, i.e. states of shock and circulatory collapse
- high levels of acidic substances in your blood (acidosis)
- too much water in your body
- water in your lungs
- severe kidney failure (severe renal insufficiency) where no dialysis facilities are available
- acute heart failure.

This container contains a significant volume of air. To avoid the risk of air embolism, this product must not be administered by pressure infusion.

Warnings and precautions

Talk to your doctor or nurse before using Glucose Intravenous Infusion BP 10% w/v solution for infusion

You should not normally receive this medicine if you suffer or have recently suffered from stroke except your doctor considers it essential for your recovery.

Your levels of blood sugar, fluids, electrolytes (particularly potassium) and acid-base balance will be checked to make sure that these are correct before and during infusion. For this purpose blood samples may be taken from you. If necessary, your blood sugar will be controlled by insulin administration.

Before you receive this medicine any existing disorders of your body's fluid and salt content such as:

- too low potassium or sodium level in your blood (hypokalaemia, hyponatraemia)
- water deficiency and excessive losses of salts have to be corrected.

Your doctor will consider very carefully whether this medicine is suitable for you if you have:

- diabetes or any other kind of carbohydrate intolerance
- high blood volume
- any kind of impairment of your metabolism (e.g. after operations or injuries, with too little oxygen in your tissues, or with some organ diseases) where your blood may become acidic
- abnormally high concentrated blood serum (high serum osmolarity)
- impairment of kidney, or heart function.

Your doctor will take special care for you if your blood-brain barrier is damaged, because then this medicine may cause an increase of the pressure within your skull or the spinal cord.

If signs of vein irritation or inflammation of the wall of a vein at the site of infusion occur, your doctor will consider changing the infusion site.

Adequate supply of salts (in particular potassium, magnesium, phosphate) and vitamins (in particular vitamin -B₁) will be ensured.

Children

Special care will be taken when giving this medicine to children in the first and second year of life, because a sudden stop of high infusion rates can lead to very low blood sugar levels, especially in these children.

Other medicines and Glucose Intravenous Infusion BP 10% w/v solution for infusion

Tell your doctor if you are taking, have recently taken or might take any other medicines. Your doctor will take care only to add 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 and breast-feeding

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

Your doctor will decide carefully whether or not you should receive this solution if you are pregnant or breastfeeding your child.

Driving and using machines

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

3. HOW TO USE GLUCOSE INTRAVENOUS INFUSION BP 10% W/V SOLUTION FOR INFUSION

The amount of Glucose Intravenous Infusion BP 10% w/v solution for infusion you will be given will be determined by your doctor, depending upon your condition.

Dosage

For adults and **adolescents from 15th year of life**, the maximum amount is 40 ml per kg body weight per day.

The solution will be administered to you not faster than at a rate of 2.5 ml per kg body weight per hour.

For **children up to the 14th year of life** the maximum daily amount of this medicine will be determined according to the age the body weight, and the recommended total daily fluid intake.

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Method of administration

The solution will be administered to you through a small tube inserted into a vein (by intravenous infusion).

If you receive more Glucose Intravenous Infusion BP 10% w/v 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, glucose losses in urine, abnormally high concentrated body fluids, fluid deficit, impaired consciousness or unconsciousness due to extremely high blood sugar or too concentrated body fluids, excess fluid in the body with increased skin tension, venous congestion (heaviness and swelling of legs), tissue swelling (possibly with water on the lungs or swelling of the brain), and abnormally high or low blood electrolyte levels. Extreme overdosing may also lead to accumulation of fat in the liver.

If this occurs, your glucose infusion will be slowed down or stopped.

Your doctor will decide on any further treatment you may need, e.g. administration of insulin, fluid or salts.

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

4. POSSIBLE SIDE EFFECTS

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

The following side effects may occur when glucose is administered as an infusion:

Common: may affect up to 1 in 10 people

Local reactions at the injection site such as pain, vein irritation or inflammation (phlebitis, thrombophlebitis).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRRA 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 INTRAVENOUS INFUSION BP 10% W/V 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.

Do not use this medicine if the solution is not clear and colourless or almost colourless or if the bottle or its closure are damaged.

Do not store above 25 °C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Glucose Intravenous Infusion BP 10% w/v solution for infusion contains

- The active substance is glucose monohydrate. Per litre this medicine contains 110 g of glucose monohydrate, equivalent to 100g of glucose.
- The other ingredient is water for injections.

Energy	1675 kJ/l \triangle 400 kcal/l
Theoretical osmolality	555 mOsm/l
Titration acidity (to pH 7.4)	< 0.5 mmol/l
pH	3.5 – 5.5

What Glucose Intravenous Infusion BP 10% w/v solution for infusion looks like and contents of the pack

Glucose Intravenous Infusion BP 10% w/v solution for infusion is a solution for infusion (for administration by a vein drip).

It is a clear, colourless or almost colourless solution of glucose monohydrate in water.

It comes in

- colourless plastic (polyethylene) bottles containing 500 ml or 1000 ml, supplied in packs of 10 × 500 ml, 10 × 1000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

PA Holder:

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

PA Number:

PA 179/1/28

Manufacturer:

B. Braun Melsungen AG
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Germany

This leaflet was last approved in 07/2014.

The following information is intended for healthcare professionals only:

Method of administration

Intravenous use. The solution can be infused via a large peripheral vein. If Glucose Intravenous Infusion BP 10% w/v solution for infusion is used as vehicle solution, the possibility of peripheral infusion depends on the characteristics of the mixture prepared.

Special warnings and precautions for use

Sudden discontinuation of high glucose infusion rates can lead to profound hypoglycaemia due to the accompanying high serum insulin concentrations. This applies especially to children less than 2 years of age, patients with diabetes mellitus and other disease states associated with impaired glucose homeostasis. In obvious cases the glucose infusion should be tapered off within the last 30 – 60 minutes of the infusion. As a precaution it is recommended that each individual patient be monitored for 30 minutes for hypoglycaemia on the first day of abrupt discontinuation of parenteral nutrition.

Shelf life after first opening the container

Administration should commence immediately after connecting the container to the giving set or infusion equipment.

Incompatibilities

Because of its acid pH, the solution may be incompatible with other medicinal products.

Erythrocyte concentrates must not be suspended in glucose solutions because of the risk of pseudo-agglutination.

For full information on this product please refer to the SmPC of Glucose Intravenous Infusion BP 10% w/v solution for infusion.

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