Package leaflet: Information for the user Glucose Intravenous Infusion BP 5% w/v 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, 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. See section 4.

What is in this leaflet

1. What Glucose Intravenous Infusion BP 5% w/v is and what it is used for

Glucose Intravenous Infusion BP 5% w/v is a sterile solution of glucose in water which can be used to give you fluids and glucose, or can be used as a solution to dissolve other medicines in. Glucose Intravenous Infusion BP 5% w/v will be given to you in the form of a vein drip (that is, by intravenous infusion).

2. What you need to know before you use Glucose Intravenous Infusion BP 5% w/v

You will not receive Glucose Intravenous Infusion BP 5% w/v

If you have:

- too high blood sugar level (hyperglycaemia) that needs more than 6 units of insulin per hour to be controlled
- high levels of lactic acid in your blood (lactic acidosis)

You should not receive large amounts of this solution if you have

- too much water in your body (hypotonic hyperhydration or isotonic hyperhydration)
- acute heart failure (acute congestive heart failure)
- water in your lungs (pulmonary oedema)

Glucose Intravenous Infusion BP 5% w/v must not be used alone for the treatment of fluid deficits, since it does not contain any salts (electrolytes).

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, pharmacist or nurse before using Glucose Intravenous Infusion BP 5% w/v.

This medicine must not be used to treat fluid deficits without adequate administration of salts (see also “You will not receive Glucose Intravenous Infusion BP 5% w/v” above), since this

may markedly reduce the salt concentration in your blood (in particular potassium and sodium). A lack of salts can lead to problems with your heart and damage your brain. Especially children, elderly patients and patients in poor general condition are at risk.

Your levels of blood sugar, fluid, electrolytes (particularly sodium and potassium) and acid-base balance will be checked to make sure that these are correct during infusion. For this purpose blood samples may be taken from you. An adequate supply of vitamins (especially vitamin B_1) will be ensured.

If necessary, your blood sugar will be controlled by insulin administration. Your doctor will consider that your blood potassium level may decrease in this case.

Your doctor will consider very carefully whether this medicine is suitable for you if you have:
- diabetes mellitus
- any kind of impairment of your glucose metabolism (e.g. after operations or injuries)
- impairment of your kidney function.

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

If you are also receiving blood transfusions these will be administered to you through another tube.

Your doctor will consider the safety information of the medicine dissolved or diluted in Glucose Intravenous Infusion BP 5% w/v.

Children
Since children may have an impaired ability to regulate fluids and electrolytes, special care will be taken when giving this medicine to them. Body fluid levels, urine production and the electrolyte concentrations in the blood and the urine will be checked carefully.
In some conditions (pain, anxiety, after surgery, nausea, vomiting, fever, sepsis, reduced blood volume, breathing disorders, infections of the central nervous system, metabolism disorders, hormone disorders) the body may produce more of a certain hormone (ADH) which increases water retention. When in addition solutions with only low salt concentrations like this medicine are given, the sodium concentration in the body may become too low (hyponatraemia). This may lead to headache, nausea, seizures, lethargy, coma, swelling of the brain caused by an excess of water (cerebral oedema) and death and is considered a medical emergency.

Other medicines and Glucose Intravenous Infusion BP 5% w/v

Please tell your doctor if you are taking, or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Your doctor will consider that some medicines may influence glucose metabolism.

The safety information of the medicine dissolved or diluted in Glucose Intravenous Infusion BP 5% w/v has to be taken into account.

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.

Pregnancy

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

Breastfeeding
Your doctor will decide carefully whether or not you should receive this solution if you are breast-feeding your child.

Driving and using machines

This medicinal product has no effect on ability to drive and use machines.

The safety information of any medicine dissolved or diluted in Glucose Intravenous Infusion BP 5% w/v has to be taken into account.

3. How to use Glucose Intravenous Infusion BP 5% w/v

Dosage
The amount of Glucose Intravenous Infusion BP 5% w/v you will be given will be determined by your doctor.

When this medicine is given to you to supply you with fluids, the amount of solution you receive depends on your age, your weight and your medical and physical status. The maximum doses stated below will be considered.

When this medicine is used to dissolve or dilute other medicines given to you, the amount of solution you receive depends on the concentration of the medicine to be dissolved or diluted. The maximum doses stated below will be considered.

Adults

Maximum daily dose
Up to 40 ml per kg body weight per day, corresponding to 2 g glucose per kg body weight per day.

Maximum infusion rate
The maximum rate of infusion is 5 ml per kg body weight per hour, corresponding to 250 mg glucose per kg body weight per hour.

The total daily fluid and glucose requirements will be taken into account.

Use in children

If Glucose Intravenous Infusion BP 5% w/v is given to children, the dose should be as low as possible. Salts have to be supplied as needed. See also section 2, ‘Children’.

This medicine is for intravenous use (that is, it is administered through a small tube placed into a vein). It can be infused into peripheral veins. However, this possibility is limited by the nature of any medicine dissolved or diluted in Glucose Intravenous Infusion BP 5% w/v.

If you received more Glucose Intravenous Infusion BP 5% w/v than you should
It is unlikely that this occurs because your doctor will determine your daily doses.

Glucose overdose may result in:
- too high levels of blood sugar (hyperglycaemia)

- glucose losses in the urine (glucosuria)
- fluid deficit with abnormally high concentrated body fluids (hyperosmolar dehydration)
- impaired consciousness or unconsciousness due to extremely high blood sugar levels or too concentrated body fluids (hyperglycaemic-hyperosmolar coma)

Fluid overdose may result in excess fluid in the body with:
- increased skin tension
- heaviness and swelling of legs (venous congestion)
- tissue swelling (oedema), possibly with water on the lungs (lung oedema) or swelling of the brain (brain oedema)
- abnormally high or low blood electrolyte levels, for instance low sodium levels (hyponatraemia) or low potassium levels (hypokalaemia)
- disturbances of the acid-base balance

In case of overdose you may feel sick or suffer from vomiting and spasms.

Further signs of overdose may develop depending on the medicine dissolved or diluted in Glucose Intravenous Infusion BP 5% w/v.

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

Your doctor will decide on any further treatment you may need, e.g. administration of insulin, drugs to increase urine output (diuretics) or salts.

If you have any further questions on the use of this product, 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)
- abnormally high or low blood electrolyte levels, for instance not enough sodium (hyponatraemia) or not enough potassium (hypokalaemia)

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, Website: www.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 5% w/v

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

Do not store above 25 °C.

Store in the original container.

Only to be used if solution is clear and colourless or almost colourless and if the container and its closure are undamaged.

The containers are for single use only. Discard container and any remaining contents after use.

Do not throw away any medicines via wastewater or household waste. 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 Intravenous Infusion BP 5% w/v contains

– The active substance is glucose
Each 1000 ml of this medicine contains 50 g of glucose (equivalent to 55 g glucose monohydrate).

1 ml contains 50 mg glucose (equivalent to 55 mg glucose monohydrate).

– The other ingredient is
Water for injections

Energy:	837 kJ/l ≙ 200 kcal/l
Theoretical osmolarity:	278 mOsm/l
Acidity (titration to pH 7.4):	< 0.5 mmol/l NaOH
pH:	3.5-5.5

What Glucose Intravenous Infusion BP 5% w/v looks like and contents of the pack

Glucose Intravenous Infusion BP 5% w/v is a clear, colurless or almost colourless solution of glucose in water.

It comes in:

- colourless plastic (polyethylene) bottles containing 250 ml, 500 ml or 1000 ml, supplied in packs of:

10 × 250 ml
10 × 500 ml
10 × 1000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

PA Holder:
B. Braun Medical Limited
3 Naas Road Industrial Park
Dublin 12
Republic of Ireland

PA Number:
PA 179/1/3

Manufacturer:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen, Germany
or
B. Braun Medical S. A.
Carretera de Terrassa 121
08191 Rubí, Barcelona, Spain

This leaflet was last approved in 09/2023.

The following information is intended for healthcare professionals only:

Incompatibilities
Because Glucose Intravenous Infusion BP 5% w/v has an acidic pH, incompatibilities can occur on mixing with other medicinal products.
Erythrocyte concentrates must not be suspended in Glucose Intravenous Infusion BP 5% w/v because of the risk of pseudo-agglutination.

Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product
Administration should commence immediately after connecting the container to the giving set or infusion equipment.
When adding additives observe usual precautions of asepsis strictly.

Shelf life after first opening
Once containers are opened the contents must be used immediately.

Shelf life after addition of additives
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.

For complete information on this medicinal product please refer to the Summary of Product Characteristics.