

PACKAGE LEAFLET: INFORMATION FOR THE USER

10% w/v Glucose Intravenous Infusion BP 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. 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.

In this leaflet:

1. What 10% w/v Glucose Intravenous Infusion BP is and what it is used for
2. What you need to know before you receive 10% w/v Glucose Intravenous Infusion BP
3. How to use 10% w/v Glucose Intravenous Infusion BP
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1. WHAT 10% W/V GLUCOSE INTRAVENOUS INFUSION BP IS AND WHAT IT IS USED FOR

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

You may receive this medicine to provide you with carbohydrates and fluid when you are unable to eat and drink normally.

Other medicines may be added to 10% w/v Glucose Intravenous Infusion BP in order to deliver them to you.

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

YOU WILL NOT RECEIVE 10% W/V GLUCOSE INTRAVENOUS INFUSION BP if you have:

- An allergy to any of the active substances or any of the other ingredients of this medicine, especially corn.
- 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 tissues (hyperhydration)
- Water in your lungs
- Acute heart failure.

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, pharmacist or nurse before using 10% w/v Glucose Intravenous Infusion BP.

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.

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

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.

Talk to your doctor, pharmacist or nurse before using 10% w/v Glucose Intravenous Infusion BP, if you have a corn allergy.

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.

Special care will be taken when giving this medicine to newborn babies especially premature babies, which are at risk of low or high blood sugar levels.

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

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.

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 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. Your blood sugar will be checked when you receive this medicine.

Breast-feeding

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

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

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

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 (hypo-

natraemia). See also sections “Warnings and precautions”, “Other medicines and Glucose B. Braun 100 mg/ml” and “Possible side effects”.

Dosage

The amount of 10% w/v Glucose Intravenous Infusion BP you will be given will be determined by your doctor.

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.

When this medicine is given to you to supply you with carbohydrate the following dosage recommendation will be used: For **adults and adolescents from 15th year of life**, The solution will be administered to you not faster than at a rate of 0.25 g of glucose per kg bodyweight per hour.

Use in children

If 10% w/v Glucose Intravenous Infusion BP is given to your child the dosage will be determined by your doctor.

Special conditions

If you have an impairment of your metabolism (e.g. after operations or injuries, with too little oxygen in your tissues, or with some organ diseases), your dosage of glucose will be adjusted to keep the blood glucose level close to normal values.

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 10% w/v Glucose Intravenous Infusion BP 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 product, ask your doctor or pharmacist or nurse.

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)

- 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

Metabolism and nutrition disorders

When you are very undernourished and receive full doses of glucose from the very beginning of intravenous feeding, this could lead to decreases of blood potassium, magnesium and phosphate levels.

A decrease of blood potassium could also occur when you are receiving insulin together with glucose.

Stopping glucose administration suddenly and/or administration of insulin may cause your blood glucose level to drop especially if you have a reduced glucose tolerance.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE 10% W/V GLUCOSE INTRAVENOUS INFUSION BP

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and the 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.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater. Ask your doctor, pharmacist or nurse 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 10% w/v Glucose Intravenous Infusion BP contains

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

Energy:	1675 kJ/l \cong 400 kcal/l
Theoretical osmolarity:	555 mOsm/l
Titration acidity (to pH 7.4)	< 0.5 mmol/l
pH	3.5 - 5.5

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

10% w/v Glucose Intravenous Infusion BP 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 is available in plastic (polyethylene) bottles containing 500 ml or 1000 ml.

Pack sizes: 10 × 500 ml, 10 × 1000 ml

Nat all pack sizes may be available.

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