PACKAGE LEAFLET: INFORMATION FOR THE USER

20% w/v Glucose Intravenous Infusion BP
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. See section 4.

What is in this leaflet

1. WHAT 20% W/V GLUCOSE INTRAVENOUS INFUSION BP IS AND WHAT IT IS USED FOR

20% w/v Glucose Intravenous Infusion BP is a solution containing 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE 20% W/V GLUCOSE INTRAVENOUS INFUSION BP

YOU WILL NOT RECEIVE 20% W/V GLUCOSE INTRAVENOUS INFUSION BP IF YOU HAVE:
if you have:

- Excessively 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
- Acute heart failure

Warnings and precautions

When given this medicine, patients who are acutely ill, with pain, postoperative stress, infections, burns, nervous system, heart, liver and 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 hyponoatremia) 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 like meningitis (infection of the membranes surrounding the brain) or brain injury (intracranial bleeding, cerebral contusion) are at particular risk of 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 20% w/v Glucose Intravenous Infusion BP.

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

Your levels of blood sugar, fluids, electrolytes (especially 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 levels 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 kinds of organ diseases) where your blood may become acidic
- Abnormally high concentrated blood serum (high serum osmolarity)
- Impairment of kidney or heart failure.

Your doctor will take special care of 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.

Adequate supply of salts (in particular potassium, magnesium, phosphate) and vitamins (in particular vitamin B_1) will be ensured.

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 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 20% W/V GLUCOSE INTRAVENOUS INFUSION BP

Please 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 to treat cancer and autoimmune diseases
- Selective Serotonin Reuptake Inhibitors (SSRIs) to treat depression
- Antipsychotics for mental health disorders
- Opioid pain killers to relieve severe pain
- Non-steroidal anti-inflammatory drugs (NSAIDs) to relieve mild to moderate pain and to treat inflammation in your body,
- Desmopressin for the treatment of 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)'

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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 20% W/V GLUCOSE INTRAVENOUS INFUSION BP

The amount of 20% 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 (hyponatraemia). See also sections "Special care will be taken with 20% w/v Glucose Intravenous Infusion BP", "Taking or using other medicines" and "Possible side effects".

Dosage

For adults and adolescents from **15th year of life,** the maximum dose is 30 ml per kg body weight per day.

The solution will be administered to you not faster than at a rate of 1.25 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 their age and body weight.

Pre-term neonates:	18 g per kg body weight	90 ml per kg body weight
Term neonates:	15 g per kg body weight	75 ml per kg body weight
1st – 2nd year:	15 g per kg body weight	75 ml per kg body weight
3rd – 5th year:	12 g per kg body weight	60 ml per kg body weight
6th – 10th year:	10 g per kg body weight	50 ml per kg body weight
11th – 14th year:	8 g per kg body weight	40 ml per kg body weight

When determining the dose, the total daily fluid intake will be taken into account, according to the following recommendations for children:

1st day of life:	50 – 70 ml per kg body weight per day
2nd day of life:	70 – 90 ml per kg body weight per day
3rd day of life:	80 – 100 ml per kg body weight per day
4th day of life:	100 – 120 ml per kg body weight per day
From 5th day of life:	100 – 130 ml per kg body weight per day
1st year:	100 – 140 ml per kg body weight per day
2nd year:	80 – 120 ml per kg body weight per day
3rd – 5th year:	80 – 100 ml per kg body weight per day
6th – 12th year:	60 – 80 ml per kg body weight per day
13th – 18th year:	50 – 70 ml per kg body weight per day

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).

During intravenous feeding you will also receive other foodstuffs like amino acids for building up protein, fat emulsions, so-called essential fatty acids, salts, vitamins and trace elements, as required.

If you receive more 20% w/v Glucose Intravenous Infusion BP than you should

It is unlikely that this occurs because your doctor will determine your daily dose.

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.

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

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 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 20% W/V GLUCOSE INTRAVENOUS INFUSION BP

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

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.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What 20% w/v Glucose Intravenous Infusion BP contains

The active substance is glucose monohydrate.
Per litre this medicine contains 220 g of glucose monohydrate, equivalent to 200 g of glucose.

The other ingredients are hydrochloric acid and water for injections.

Caloric value	3350 kJ/l ≙ 800 kcal/l
Theoretical osmolarity	1110 mOsm/l
Titration acidity (to pH 7.4)	< 1 mmol/l
pH	3.5 - 5.5

What 20% w/v Glucose Intravenous Infusion BP looks like and contents of the pack

20% w/v Glucose Intravenous Infusion BP is a solution for infusion (for administration by a vein drip).
It is a clear, colourless or slightly yellowish 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

Marketing Authorisation Holder

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34212 Melsungen, Germany

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The following information is intended for 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. 20% w/v Glucose Intravenous Infusion BP may become hypotonic after administration due to glucose metabolisation in the body (see Summary of Product Characteristics sections 4.4. 4.5 and 4.8).

Method of administration
Intravenous use. For central venous infusion only.

Use in paediatric population
For treatment of hypoglycaemia in children, use of 10% glucose solution is recommended.
For use of 20% w/v Glucose Intravenous Infusion BP in neonates, due account should be taken of the high osmolarity of the solution.

Special warnings and precautions for use

General
Administration of glucose solutions is not recommended after acute ischaemic strokes as hyperglycaemia has been reported to worsen ischaemic brain damage and impair recovery.

Application of hyperosmolar glucose solutions in patients with damaged haematoencephalic barrier may lead to increase of intracranial/intraspinal pressure.

Glucose infusions should not be started before existing fluid and electrolyte deficiencies like hypotonic dehydration, hyponatraemia and hypokalaemia have adequately been corrected.

This solution should be used with caution in patients with
- Hypervolaemia
- Renal insufficiency
- Cardiac insufficiency
- Increased serum osmolarity
- Known subclinical diabetes mellitus or carbohydrate intolerance for any reason.

Unstable metabolism (e.g. postoperatively or after injuries, hypoxia, organ insufficiencies) impairs oxidative metabolism of glucose and may lead to metabolic acidosis.

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

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 patients with 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.

Clinical monitoring should include blood glucose, serum electrolytes, fluid and acid-base balance in general. A focus should be put on the sodium level as glucose solutions provide free water to the body and may therefore cause or worsen hyponatraemia. Frequency and kind of laboratory testing depend on the overall condition of the patient, the prevailing metabolic situation, the administered dose and the duration of treatment. Also monitor total volume and amount of glucose administered.

Parenteral nutrition in malnourished or depleted patients with full doses and full infusion rates from the very beginning and without adequate supplementation of potassium, magnesium and phosphate may lead to the refeeding syndrome, characterized by hypokalaemia, hypophosphataemia and hypomagnesaemia. Clinical manifestations may develop within a few days of starting parenteral nutrition. In such patients, infusion regimens should be built up gradually. Adequate supplementation of electrolytes according to deviations from normal values is necessary.

Special attention should be paid to hypokalaemia. Then, supplementation of potassium is mandatory.

Electrolytes and vitamins must be supplied as necessary. Vitamin B, especially thiamine, is needed for glucose metabolism.

Glucose infusions should not be administered through the same infusion equipment, simultaneously before, or after administration of blood, because of the possibility of pseudo-agglutination.

It should be noted that this solution constitutes only one component of parenteral nutrition. In total parenteral nutrition, glucose infusions should always be combined with an adequate supply of amino acids, lipids, electrolytes, vitamins and trace elements.

Paediatric population
For treatment of hypoglycaemia in children, use of 10% glucose solution is recommended.
Children in the 1st and 2nd year of life are especially at risk for rebound hypoglycaemia after abrupt discontinuation of high infusion rates, see above.

Shelf life after first opening the container
Administration should commence immediately after connecting the container to the giving set or infusion equipment.

Shelf life after reconstitution or 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.
Observe the directions given by the manufacturer of the respective additive or drug to be diluted.

Incompatibilities
Because glucose solutions have an acidic pH, incompatibilities can occur on mixing with other medicinal products and with blood. Information on compatibility can be requested from the manufacturer of the added drug.
Erythrocyte concentrates must not be suspended in glucose solutions because of the risk of pseudo-agglutination.