

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **40% 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.

#### **In this leaflet:**

1. What 40% w/v Glucose Intravenous Infusion BP is and what it is used for
2. What you need to know before you receive 40% w/v Glucose Intravenous Infusion BP
3. How to use 40% w/v Glucose Intravenous Infusion BP
4. Possible side effects
5. How to store 40% w/v Glucose Intravenous Infusion BP
6. Contents of the pack and other information

#### **1. WHAT 40% W/V GLUCOSE INTRAVENOUS INFUSION BP IS AND WHAT IT IS USED FOR**

40% w/v Glucose Intravenous Infusion BP 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, especially if your energy needs are high or if you need restriction of fluid intake.

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

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE 40% W/V GLUCOSE INTRAVENOUS INFUSION BP**

##### **YOU WILL NOT RECEIVE THIS MEDICINE**

**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
- 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 40% w/v Glucose Intravenous Infusion BP, if you have a corn allergy.

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.

Adequate supply of salts (in particular potassium, magnesium, phosphate) and vitamins (in particular vitamin B<sub>1</sub>) 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 newborn babies especially premature babies, which are at risk of low or high blood sugar levels.

## **Other medicines and 40% 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 40% W/V GLUCOSE INTRAVENOUS INFUSION BP**

The amount of 40% 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 “Warnings and precautions”, “Other medicines and 40% w/v Glucose Intravenous Infusion BP” and “Possible side effects”.

#### **Dosage**

The amount of 40% w/v Glucose Intravenous Infusion BP you will be given will be determined by your doctor.

When this medicine is given to you for treatment of abnormally low blood sugar level (hypoglycaemia), the dose and the administration rate have to be adjusted according to your actual blood glucose concentration and your general condition.

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 a rate of 0.25 g of glucose per kg bodyweight per hour.

#### *Use in children*

If 40% 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).

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 40% 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 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](http://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 40% 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 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 use this medicine if the solution is not clear and colourless or slightly yellowish or if the bottle or its closure are damaged.

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 40 % w/v Glucose Intravenous Infusion BP contains**

- The active substance is glucose monohydrate.
- Per litre this medicine contains 440 g of glucose monohydrate, equivalent to 400 g of glucose.
- The other ingredients are hydrochloric acid to adjust the pH and water for injections.

Energy	6700 kJ/l $\triangleq$ 1600 kcal/l
Theoretical osmolarity	2220 mOsm/l
Titration acidity (to pH 7.4)	< 1 mmol/l
pH	3.5 - 5.5

### **What 40% w/v Glucose Intravenous Infusion BP looks like and contents of the pack**

40% 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.

Pack sizes: 10  $\times$  500 ml

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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. Glucose 400 mg/ml may become hypotonic after administration due to glucose metabolism in the body (see sections 4.4, 4.5 and 4.8).

### *Therapy of hypoglycaemia*

For the treatment of hypoglycaemia the dose and the administration rate have to be adjusted according to the actual blood glucose concentration and the general condition of the patient.

### *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. Newborns, especially preterm neonates with low birth weight, are especially at risk of hyperglycaemia or hypoglycaemia. Close monitoring of the blood glucose level is mandatory to avoid long term adverse events or fatal overdosage. Recommended parenteral glucose supply in (pre)term newborns in mg/kg per min (g/kg per day)

	Day 1 mg/kg per min (g/kg per day)	Day 2 onwards mg/kg per min (g/kg per day)
Preterm newborns	4-8 (5.8-11.5)	Target 8-10 (11.5-14.4) Min 4 (5.8); max 12 (17.3)
Term newborns	2.5-5 (3.6-7.2)	Target 5-10 (7.2-14.4) Min 2.5 (3.6); max 12 (17.3)

Recommended parenteral glucose supply in infants and children according to body weight and phase of illness (units are mg/kg/min (g/kg per day))

	Acute Phase	Stable Phase	Recovery phase
28 d - 10 kg	2-4 (2.9-5.8)	4-6 (5.8-8.6)	6-10 (8.6-14)
11-30 kg	1.5-2.5 (2.2-3.6)	2-4 (2.8-5.8)	3-6 (4.3-8.6)
31-45 kg	1-1.5 (1.4-2.2)	1.5-3 (2.2-4.3)	3-4 (4.3-5.8)
>45 kg	0.5-1 (0.7-1.4)	1-2(1.4-2.9)	2-3 (2.9-4.3)

Acute phase = resuscitation phase when the patient requires vital organ support (sedation, mechanical ventilation, vasopressors, fluid resuscitation).

Stable phase = patient is stable on, or can be weaned, from this vital support.

Recovery phase = patient who is mobilizing.

### *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.

Due to the risk of developing a severe lactic acidosis and/or a Wernicke encephalopathy a preexisting thiamine (Vitamin B1) deficiency must be corrected before infusion of glucose containing solutions.

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.

Hypersensitivity reactions, including anaphylactic/anaphylactoid reactions, have been reported with Glucose solutions (see section 4.8). Solutions containing glucose should therefore be used with caution, if at all, in patients with known allergy to corn or corn products (see section 4.3).

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

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 acid 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.