DIRECTIONS FOR USE

Glucose Intravenous Infusion B.P. 10% w/v

1. NAME OF THE MEDICINAL PRODUCT

Glucose Intravenous Infusion B.P. 10% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml of solution contains:

Glucose monohydrate	110.0 g
(equivalent to glucose)	(100.0 g)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion
Clear and colourless solution, free from particles

Energy	1675 kJ/l	≙ 400 kcal/l
Theoretical osmolarity		555 mOsm/l

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Administration of glucose for caloric support
- Therapy of hypoglycaemia
- Vehicle solution for compatible medicinal products

4.2 Posology and method of administration

Posology

The dosage of the solution depends on the patient's individual glucose and fluid requirements.

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 Intravenous Infusion B.P. 10% w/v may become hypotonic after administration due to glucose metabolisation in the body (see sections 4.4. 4.5 and 4.8).

Vehicle solution for compatible medicinal products

The volume to be chosen depends on the desired concentration of the medicinal product for which the solution is to be used as vehicle having regard to the maximum dose stated above. The dose and administration rate depend on the properties of the prescribed additive.

Therapy of hypoglycemia

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.

Glucose for caloric support / component of parenteral nutrition

Maximum infusion rate

Adults and adolescents from 15th year of life

The maximum rate of 0.25 g of glucose per kg bodyweight per hour (4 mg glucose/kg/min) should not be exceeded in order to avoid exceeding the glucose oxidation capacity of the patient.

Paediatric population

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.

Elderly patients

Basically, the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age.

Patients with impaired glucose metabolism

If the oxidative metabolism of glucose is impaired (e.g. in the early post-operative or post-traumatic period or in the presence of hypoxia or organ failure), the dosage should be adjusted to keep the blood glucose level close to normal values. Close monitoring of blood glucose levels is recommended in order to prevent hyperglycaemia.

Method of administration

Intravenous use. The solution can be infused via a large peripheral vein.

4.3 Contraindications

- Hypersensitivity to the active substance. See section 4.4 and 4.8 for corn allergies
- Hyperglycaemia, not responding to insulin doses of up to 6 units insulin/hour
- Delirium tremens if such patients are already dehydrated
- Acute states of shock and collapse
- Metabolic acidosis

Since the administration of glucose solutions is accompanied by the administration of free water, further contraindications may arise e.g.:

- Hyperhydration
- Pulmonary oedema
- Acute congestive heart failure

4.4 Special warnings and precautions for use

Special Warnings

Glucose Intravenous Infusion B.P. 10% w/v is a hypertonic solution. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization (see section 4.2).

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Due to the risk of developing a severe lactic acidosis and/or a Wernicke encephalopathy a preexisting thiamine (Vitamin B_1) deficiency must be corrected before infusion of glucose containing solutions.

Hyponatraemia:

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

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.

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.

If signs of vein irritation, phlebitis or thrombophlebitis appear during peripheral venous infusion, change of the infusion site should be considered.

Please note: If this solution is used as vehicle solution, the safety information of the additive provided by the respective manufacturer have to be taken into account.

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 longterm adverse events or fatal overdosage.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with medicinal products with an influence on glucose metabolism should be considered.

Drugs leading to an increased vasopressin effect.
The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).

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- Drugs stimulating vasopressin release, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues, e.g.: Desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine. Prescribers should refer to the information provided with the product concerned.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited data from the use of glucose solutions in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). The use of Glucose Intravenous Infusion B.P. 10% w/v may be considered during pregnancy, if clinically needed.

Nevertheless, an intrapartum infusion of glucose solution may predispose the infant to an increased risk of hypoglycaemia at 2 h of age. Therefore, it is recommended that during intrapartum glucose administration the blood glucose levels of the mothers should be monitored closely and kept in physiological limits to prevent maternal and foetal hyperglycaemia and subsequent risk of neonatal hypoglycaemia.

Glucose Intravenous Infusion B.P. 10% w/v should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

Careful monitoring of blood glucose is necessary.

Breast-feeding

Glucose/metabolites are excreted in human milk, but at therapeutic doses of Glucose Intravenous Infusion B.P. 10% w/v no effects on the breastfed newborns/infants are anticipated.
Glucose B. Braun can be used during breast-feeding as indicated.

Fertility

No special precautions.

4.7 Effects on ability to drive and use machines

The solution has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

General

Undesirable effects are listed according to their frequencies as follows:

Very common	(≥ 1/10)
Common	(≥ 1/100 to < 1/10)
Uncommon	(≥ 1/1000 to < 1/100)
Rare	(≥ 1/10000 to < 1/1000)
Very rare	(< 1/10000)
Not known	(cannot be estimated from the available data)

General disorders and administration site conditions:
Not known: Local reactions at the site of administration, including local pain, vein irritation, thrombophlebitis or tissue necrosis in case of extravasation.

Metabolism and nutrition disorders:

Not known: Hospital Acquired Hyponatraemia*
*Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

Neurological disorders:

Not known: Hyponatraemic encephalopathy

Note

Patients should inform their doctor or nurse if they notice any of these reactions or other adverse reactions.

4.9 Overdose

Symptoms of glucose overdose

Excessive glucose infusions can cause hyperglycaemia, glucosuria, hyperosmolar dehydration and in extreme case overdose can lead to hyperglycaemic-hyperosmolar coma.

Symptoms of fluid overdose

Fluid overdose may result in hyperhydration with increased skin tension, venous congestion, oedema – possibly also lung or brain oedema – dilution of serum electrolytes, electrolyte imbalances, notably hyponatraemia and hypokalaemia (see section **4.4**), and acid-base imbalances.
Clinical symptoms of water intoxication may occur like nausea, vomiting and spasms.

Further symptoms of overdose may arise depending on the nature of the additive.

Treatment

The primary therapeutic measure is dose reduction or cessation of infusion, depending on the severity of the symptoms. Disorders of the carbohydrate and electrolyte metabolism are treated by insulin administration and appropriate electrolyte substitution, respectively.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions for parenteral nutrition, carbohydrates, ATC code: B05B A03

Pharmacodynamic effects

Glucose is metabolized ubiquitously as the natural substrate of the cells of the body. Under physiological conditions glucose is the most important energy-supplying carbohydrate with a caloric value of approx. 16.7 kJ/g or 4 kcal/g. In adults, the normal concentration of glucose in blood is reported to be 70 – 100 mg/dl or 3.9 to 5.6 mmol/l (fasting).

5.2 Pharmacokinetic properties

Absorption

Since the solution is administered intravenously, its bioavailability is 100%.

Distribution

After infusion, glucose is first distributed in the intravascular space and then is taken up into the intracellular space.

Biotransformation

In glycolysis, glucose is metabolized to pyruvate. Under aerobic conditions pyruvate is completely oxidized to carbon dioxide and water. In case of hypoxia, pyruvate is converted to lactate. Lactate can be partially reintroduced into the glucose metabolism (Cori cycle). Glucose utilisation disturbances (glucose intolerance) can occur under conditions of pathological metabolism. These mainly include diabetes mellitus and states of metabolic stress (e.g. intra-, and postoperatively, severe disease, injury), hormonally mediated depression of glucose tolerance, which can even lead to hyperglycaemia without exogenous supply of the substrate. Hyperglycaemia can – depending on its severity – lead to osmotically mediated renal fluid losses with consecutive hypertonic dehydration, to hyperosmotic disorders up to and including hyperosmotic coma.
Metabolism of glucose and electrolytes are closely related to each other. Insulin facilitates potassium influx into cells. Phosphate and magnesium are involved in the enzymatic reactions associated with glucose utilization. Potassium, phosphate and magnesium requirements may therefore increase following glucose administration and may therefore have to be monitored and supplemented according to individual needs. Especially cardiac and neurological functions may be impaired without supplementation.

Elimination

The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water).
Practically no glucose is excreted renally by healthy persons. In pathological metabolic conditions associated with hyperglycaemia (e.g. diabetes mellitus, postaggression metabolism), glucose is also excreted via the kidneys (glucosuria) when the maximum tubular reabsorption capacity is exceeded (at blood glucose levels higher than 160-180 mg/dl or 8.8-9.9 mmol/l).

5.3 Preclinical safety data

No non-clinical studies have been carried out with Glucose Intravenous Infusion B.P. 10% w/v. Glucose is a physiological component of animal and human plasma. Limited toxicological data with different glucose solutions for injection reveal at therapeutic doses no special hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 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. See also section 4.4.

6.3 Shelf life

Unopened

3 years

After first opening the container

Not applicable, see section 6.6.

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.

6.4 Special precautions for storage

The product should not be stored above the temperature stated on the label.

For storage conditions after dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Bottles of colourless low-density polyethylene,
contents: 100 ml, 250 ml, 500 ml, 1000 ml
available in packs of:
20 × 100 ml
30 × 250 ml
10 × 500 ml
10 × 1000 ml
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Containers are for single use only. Discard containers and any unused content after use. Do not re-connect partially used containers.

Only to be used if the solution is clear and colourless or slightly yellowish and if the bottle and its closure are undamaged.

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

When adding additives observe usual precautions of asepsis strictly.

7. DATE OF REVISION OF THE TEXT

05.2025

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