





Directions for Use

B. Braun Melsungen AG · Carl-Braun-Straße 1, 34212 Melsungen, Germany

Composition

1000 ml of solution contain

Active ingredients:

Glucose 50.0 g

(as glucose monohydrate 55.0 g)

Excipients:

Water for Injections

Carbohydrate content: 50.0 g/l Caloric value: 835 kJ/l = 200 kcal/l Theoretical osmolarity: 278 mOsm/l Titration acidity (to pH 7.4): < 0.5 mmol/l pH: 3.5 - 5.5

Pharmaceutical form

Solution for infusion

Pharmaco-therapeutic group

Vehicle solution

Indications

- Energy supply
- Hypertonic dehydration
- Vehicle solution for supplementary medication.

Contraindications

- Elevated blood sugar concentration (hyperglycaemia),
- Decreased blood potassium concentration (hypokalaemia),
- High concentration of acid substances in blood (Acidosis)

If it should be necessary to administer large volumes further contra-indications can arise on account of the glucose and/or fluid load:

- Hyperhydration,
- Simultaneous sodium and water deficiency (hypotonic dehydration).

Precautions for use

Patient monitoring should include regular checks of

B. Braun 5 % Glucose Intravenous Infusion

the blood glucose level, the water balance, serum electrolyte concentrations – in particular serum potassium –, and acid-base balance.

Glucose infusions should not be administered through the same infusion equipment, simultaneously with, before, or after administration of blood, because of the possibility of pseudo-agglutination. Electrolytes are to be supplemented as required. The compatibility of any additives to these solutions should be checked before use.

Interactions

Because B. Braun 5 % Glucose Intravenous Infusion has an acid pH, incompatibilities can occur on mixing with other medicaments.

Erythrocyte concentrates must not be suspended in B. Braun 5 % Glucose Intravenous Infusion because this can lead to pseudo-agglutination.

Dosage

Choose a volume that yields the desired concentration of the medicament for which B. Braun 5 % Glucose Intravenous Infusion is to be used as vehicle solution, taking also account of the maximum doses stated below.

Recommended daily dose

Up to 40 ml per kg body weight per day, corresponding to 2 g of glucose. The maximum dose corresponds to the maximum daily fluid intake.

Infusion rate

Up to 5 ml per kg BW/hour, corresponding to 0.25 g of glucose/kg BW/hour. This is equivalent to a maximum drop rate of 1.7 drops/kg BW/minute.

Method of administration

Intravenous infusion. The solution can be administered peripherally; however, the possibility of peripheral administration can be limited by the nature or the concentration of the dissolved drug.







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Overdose

Symptoms

Overdose may result in hyperhydration, electrolyte disorders, hyperglycaemia, glucosuria, and hyperosmolarity of the blood (up to hyperglycaemic hyperosmotic coma).

Emergency treatment, antidotes

Depending on type and severity of the disorders: Cessation of infusion, administration of electrolytes, diuretics, or insulin.

Pregnancy and Lactation

B. Braun 5 % Glucose Intravenous Infusion can be given in these situations if indicated as vehicle solution

Undesirable effects

None to be expected if the solution is used according to instructions.

Note:

Patients are advised to inform their doctor or pharmacist if they notice any adverse in connection with the administration of the product.

Pharmacodynamics

Low concentration glucose solutions are suitable diluents for drugs because glucose, as a natural substrate of the cells in the organism, is ubiquitously metabolized. Under physiological conditions glucose is the most important energy-supplying carbohydrate with a caloric value of 17 kJ/g or 4 kcal/g. In adults, the normal concentration of glucose in blood is reported to be 60 – 100 mg/100 ml, or 3.3 – 5.6 mmol/l (fasting).

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 post-operatively, 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.

Pharmacokinetics

On infusion glucose is first distributed in the intravascular space and then is taken up into the intracellular space. In glycolysis glucose is metabolized to pyruvate or to lactate. Lactate can be partially re-introduced into the glucose metabolism (Cori cycle). Under aerobic conditions pyruvate is completely oxidized to carbon dioxide and water. The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water).

Expiry date

The product must not be used beyond the expiry date stated on the labelling.

Instructions for storage / use / handling

Only to be used if solution is clear and container undamaged.

Product registration holder:

B. Braun Medical Industries Sdn. Bhd. 11900 Bayan Lepas, Penang Malaysia

Manufactured by: **B. Braun Melsungen AG** Carl-Braun-Straße 1, 34212 Melsungen,







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