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Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

20 % w/v Glucose Intravenous Infusion

Composition

1000 ml of solution contain

Active substance:

Glucose	200.0 g
(as glucose monohydrate 220.0 g)	

Excipients:

Hydrochloric acid, water for injections

Carbohydrate content	200 g/l
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

Pharmaceutical form

Solution for infusion

Pharmaco-therapeutic group

Carbohydrate solution for parenteral nutrition

Indications

- Energy supply by means of glucose,
- Carbohydrate component in parenteral nutrition,
- Therapy of hypoglycaemia.

Contraindications

- Elevated blood sugar concentration (hyperglycaemia), requiring more than 6 units of insulin per hour for correction
- Decreased blood potassium concentration (hypokalaemia)
- High concentration of acid substances in blood (Acidosis)
- Hyperhydration
- Simultaneous sodium and water deficiency (hypotonic dehydration)

Special warnings and precautions for use

This solution should only be administered with caution to patients with increased serum osmolarity.

Patient monitoring should include regular checks of the blood glucose level, depending on the prevailing metabolic condition and the administered dose.

Patient monitoring should also include regular checks of the water balance, the serum electrolyte concentrations - In particular serum potassium -, and the 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.

Interactions

Because 20 % w/v Glucose Intravenous Infusion has an acid pH, it may be incompatible with other medicaments.

Erythrocyte concentrates must not be suspended in this solution because of the possibility of pseudo-agglutination.

Dosage

This solution is only one component of parenteral nutrition. For complete parenteral nutrition, simultaneous administration of amino acids, electrolytes, vitamins, essential fatty acids, and trace elements is required.

The dosage should be adjusted according to the individual glucose and fluid requirements.

Adults:

Maximum daily dose

Up to 30 ml per kg body weight per day, corresponding to 6 g of glucose per kg body weight per day.

In the presence of metabolic disorders, e.g. in the postoperative/post-traumatic phase, in hypoxia, or in the presence of organ failure, the glucose oxidation may be impaired, which may be associated with hyperglycaemia and insulin resistance and possibly with an increased mortality. In such cases, reduction of the glucose intake to 2 - 4 g of glucose per kg body weight per day may be required. The blood glucose level should not exceed 110 mg/100 ml (6.1 mmol/l).

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Maximum infusion rate
Up to 1.25 ml, corresponding to 0.25 g of glucose, per kg body weight per hour. The corresponding maximum drop rate is 0.4 drops per kg body weight per minute.
Thus for a patient weighing 70 kg the infusion rate may be up to 87 ml per hour or approx. 28 drops per minute, corresponding to 17.5 g of glucose per hour.
In the setting of parentral nutrition, the total fluid administration may only exceptionally exceed 40 ml per kg body weight per day.

Children
For the use in neonates, due account should be taken of the high osmolarity of the solution (see Composition above).

Maximum daily doses
The maximum daily dose is to be adjusted according to the total volume of the infusion solutions to be administered. The maximum daily glucose doses (taking account, however, of the limitations of fluid intake stated below) are:
Pre-term neonates: up to 18 g of glucose/kg BW, corresponding to 90 ml/kg body weight (BW)
Term neonates: up to 15 g of glucose/kg BW, corresponding to 75 ml/kg BW
1st - 2nd year: up to 15 g of glucose/kg BW, corresponding to 75 ml/kg BW
3rd - 5th year: up to 12 g of glucose/kg BW, corresponding to 60 ml/kg BW
6th - 10th year: up to 10 g of glucose/kg BW, corresponding to 50 ml/kg BW
10th - 14th year: up to 8 g of glucose/kg BW, corresponding to 40 ml/kg BW

When determining the dose, care should be taken that total parenteral fluid administration does not exceed the following values.

The basic fluid requirements are for:
1st day of life: 50 - 70 ml/kg BW/day
2nd day of life: 70 - 90 ml/kg BW/day
3rd day of life: 80 - 100 ml/kg BW/day
4th day of life: 100 - 120 ml/kg BW/day
from 5th day of life: 100 - 130 ml/kg BW/day
1st year: 100 - 140 ml/kg BW/day
2nd year: 80 - 120 ml/kg BW/day
3rd - 5th year: 80 - 100 ml/kg BW/day
6th - 10th year: 60 - 80 ml/kg BW/day
10th - 14th year: 50 - 70 ml/kg BW/day

During administration of carbohydrate solutions, regular blood glucose monitoring is mandatory, irrespective of the concentration of the solution administered.

Method of administration
Intravenous use via central venous catheter

Overdose

Symptoms
Overdose may lead to hyperglycaemia, hyperosmolarity of the serum, hyperglycaemic or hyperosmotic coma, hyperhydration, and electrolyte imbalances.

Emergency treatment, antidotes
The primary therapy is dose reduction. Disorders of the glucose metabolism and of the electrolyte balance can be corrected by administration of insulin and appropriate supplementation of electrolytes.

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

Note:
Patients should inform their doctor or pharmacist if they notice any adverse effect in connection with the administration of this medicine.

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

Instructions for use / handling
The solution is supplied in single-use containers. Unused contents must be discarded and not be stored for later use.
Only to be used if solution is clear and the container undamaged.

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