56/12261947/0298

Directions for Use

B. Braun Melsungen AG · D-34209 Melsungen, Germany

0.45% w/v Sodium Chloride and 2.5% w/v Glucose Intravenous Infusion

Composition

1000 ml of solution contain

Active ingredients:

Sodium chloride	4.5 g
Glucose monohydrate for parenteral use (equivalent to anhydrous glucose, 25.0 g)	27.5 g

Excipients:
Water for injections

Caloric value:	418 kJ/l = 100 kcal/l
Theoretical osmolarity:	293 mOsm/l
Titration acidity:	< 0.5 mmol/l
pH:	3.5 – 5.5

Electrolyte concentrations:

Sodium	77 mmol/l
Chloride	77 mmol/l

Pharmaceutical form

Solution for infusion in polyethylene containers,contents: 500 ml

Pharmaco-therapeutic group

Solution for fluid and electroyte supply, vehicle solution

Indications

Hypertonic dehydration;
Isotonic dehydration;
Vehicle solution for compatible electrolyte concentrates and medicaments.

Contraindications

0.45 % w/v Sodium Chloride and 2.5 % w/v Glucose Intravenous Infusion must not be used in cases of

– hyperhydration
– hypotonic dehydration
– hypokalaemia

Precautions for use

It is necessary to monitor the serum ionogram and water balance.

In post-operative and post-traumatic conditions and in conditions of impaired glucose tolerance: only administer with monitoring of blood glucose level.

Special attention should be paid to regular monitoring of the serum potassium concentration.

Interactions

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

When mixing with other medicaments it should be remembered that 0.45 % w/v Sodium Chloride and 2.5 % w/v Glucose Intravenous Infusion has an acid pH, which can cause precipitation in the mixture.

Special warnings

0.45 % w/v Sodium Chloride and 2.5 % w/v Glucose Intravenous Infusion should only be administered with caution in cases of

–hyponatraemia
–hyperglycaemia not responding to insulin doses of up to 6 units/hour.

Dosage

In accordance with fluid, electrolyte and energy requirements:

Not more than 40 ml/kg body weight per day, corresponding to 1 g glucose/kg body weight per day.

Infusion and drop rate:
Not more than 5 mg/kg body weight per hour, corresponding to 0.125 g glucose/kg body weight per hour or not more than 1.7 drops/kg body weight per min.

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Method and route of administration

Intravenous infusion

Overdose

Symptoms

Overdose may result in hyperhydration with increased skin tension, venous congestion, oedema - possibly also lung or brain oedema -, hypokalaemia and acid-base imbalances, and hyperglycaemia.

Emergency treatment, antidotes

Immediate cessation of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances, administration of insulin if necessary.

Undesirable effects

None to be expected if contraindications, dosage instructions and precautions for use are duly observed.

Expiry date

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

Storage

Do not store above 25 °C

Instructions for use

The product is supplied in single-dose containers. Discard unused contents.

The solution is only to be used if it is clear and the container or its closure do not show visible signs of damage.

Date of last revision
02.98

General guidelines on carbohydrate intake:

The total input of carbohydrates should not exceed 350 to 400 g per day under normal metabolic conditions. In conditions of impaired glucose metabolism, e.g. after operations or injuries, in hypoxic states or in the presence of organ malfunctions, the daily dose should be reduced to 200 - 300 g; individual adaptation of the dose requires adequate monitoring.

The following dose limitations should be observed for the administration of glucose to adults:
0.25 g glucose/kg body weight per hour and up to 6 g/kg body weight per day.

General guidelines on fluid and electrolyte intake:

A level of 30 ml of the solution per kg body weight per day only covers the physiological basic fluid requirements. Post-operatively and in intensive care patients there is an increased requirement for fluid intake on account of the limited concentrating capacity of the kidneys and the increased excretion of metabolites, so that it is necessary to increase the fluid intake to about 40 ml/kg body weight per day. Additional losses (e.g. due to fever, diarrhoea, fistulae, vomiting etc.) must be compensated for by a still higher, individually adapted fluid intake. The actual and individual fluid requirement is determined by the stepwise monitoring necessary in every case (e.g. urine excretion, osmolarity in serum and urine, determination of substances excreted).

The basic substitution of the most important cations sodium and potassium amounts to about 1.5 – 3 mmol/kg body weight per day and 0.8 – 1.0 mmol/kg body weight per day respectively. The actual requirement during infusion therapy depends on appropriate determinations of the electrolyte balance and on the laboratory monitoring of the plasma concentrations.

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