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Directions for Use

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

B. Braun 0.45 % Sodium Chloride and 5 % Glucose Intravenous Infusion B.P.

Composition
1000 ml of solution contain

Active ingredients:	
Sodium Chloride	4.5 g
Glucose	50.0 g
(as glucose monohydrate 55.0 g)	
Excipient:	
Water for Injections	
Electrolyte concentrations:	
Sodium	77 mmol/l
Chloride	77 mmol/l
Carbohydrate content	50 g/l
Caloric value:	835 kJ/l ≙ 200 kcal/l
Theoretical osmolarity:	432 mOsm/l
Titration acidity:	< 0.5 mmol/l
pH:	3.5 – 5.5

Pharmaceutical form
Solution for infusion

Pharmaco-therapeutic group
Solution for fluid, electrolyte and carbohydrate supply

Indications
- Hypertonic dehydration
- Isotonic dehydration
- Partial coverage of energy requirements
- Vehicle solution for compatible electrolyte concentrates and medicaments

Contraindications
B. Braun 0.45 % Sodium Chloride and 5 % Glucose Intravenous Infusion B.P. must not be used in cases of:
- hyperhydration states
- hypotonic dehydration
- hypokalaemia

Special warnings and precautions for use
B. Braun 0.45 % Sodium Chloride and 5 % Glucose Intravenous Infusion B.P. should only be administered with caution in cases of
- hyponatraemia
- persistent hyperglycaemia not responding to insulin doses of up to 6 i.u./hour

Clinical supervision should include checks of the serum ionogram and the water balance. Special attention should be paid to regular monitoring of the serum potassium concentration.

In post-operative and post-traumatic conditions and in conditions of impaired glucose tolerance: only administer with monitoring of blood glucose level.
For correction of hypertonic dehydration, solutions containing not less than 70 mmol/l of sodium should be used. The time for correction should not be shorter than 48 hours.

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

Interactions
When mixing with other medicaments it should be remembered that B. Braun 0.45 % Sodium Chloride and 5 % Glucose Intravenous Infusion B.P. has an acid pH which can cause precipitation in the mixture.

Dosage
The dose is adjusted according to the fluid, electrolyte and energy requirements:

Maximum dose:
40 ml/kg BW per day, corresponding to 2 g glucose/kg BW per day

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Infusion and drop rate:
Not more than 5 ml/kg BW per hour, corresponding to 0.25 g glucose/kg BW per hour or not more than 1.7 drops/kg BW per min.
Partial coverage of energy requirements, i. e. substitution of the obligatory daily glucose requirements, is only possible with the maximum dose stated above.
For the use of this solution as vehicle solution, the instructions for use relating to the medicament to be added should be observed.

Method 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 the solution is used according to instructions.

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

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

Instructions for storage / use / handling
Do not store above 30 °C.
Only to be used if solution is clear and the container or its closure do not show visible signs of damage.
For single use only. Discard unused contents.

Date of last revision: 11.2018

General guidelines on the carbohydrate intake:
The total input of carbohydrates should be restricted to 350 to 400 g per day under normal metabolic conditions. In conditions of impaired glucose metabolism, e.g. in postoperative/posttraumatic stress, in hypoxic states or organ insufficiency, 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 the 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. 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 ca. 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

Product registration holder:
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Manufactured by:
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