6/12226700/0711

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Sodium Chloride 9 mg/ml and Glucose 50 mg/ml B. Braun

Solution for Infusion

Composition
1000 ml of solution contain

Active ingredients:

Sodium Chloride	9.0 g
Glucose	50.0 g
(as glucose monohydrate, 55.0 g)	

Excipients:
Water for Injections

Electrolyte concentrations:

Sodium	154 mmol/l
Chloride	154 mmol/l

Pharmaceutical form
Solution for infusion
Clear, colourless aqueous solution

Energy:	835 kJ/l ≙ 200 kcal/l
Theoretical osmolarity:	586 mOsm/l
Acidity (titration to pH 7.4):	< 0.5 mmol/l
pH:	3.5 – 5.5

Pharmaco-therapeutic group
Solutions affecting the electrolyte balance
ATC code: B05B B02 (Electrolytes with carbohydrates)

Indications
- Fluid and electrolyte substitution in hypochloraemic alkalosis,
- Chloride losses,
- Hypotonic dehydration,
- Isotonic dehydration,
- Partial coverage of energy requirements,
- Vehicle solution for compatible electrolyte concentrates and medicaments.

Contraindications
Sodium Chloride 9 mg/ml and Glucose 50 mg/ml B. Braun must not be used in cases of:
- hyperhydration,
- hypertonic dehydration,
- untreated hypokalaemia,
- metabolic acidosis,
- persistent hyperglycaemia not responding to insulin doses of up to 6 units/hour,
- pulmonary or brain oedema,
- decompensated cardiac insufficiency.

Special warnings and precautions for use
Sodium Chloride 9 mg/ml and Glucose 50 mg/ml B. Braun Solution for Infusion should only be administered with caution in cases of:
- hypernatraemia,
- hyperchloraemia,
- disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalised oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency.

In patients with acute ischaemic stroke and hyperglycaemia the glucose level should be corrected before application of this solution

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.
Clinical monitoring should include checks of the serum electrolytes (especially potassium), glucose level and the acid-base 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.
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
Corticosteroids
Corticosteroids are associated with the retention of sodium and fluid .
When mixing with other medicinal products possible incompatibilities should be considered. It should be remembered that the solution has an acid pH which can cause precipitation in the mixture.

Pregnancy and lactation
Pregnancy
There is a limited amount of data from the use of this Sodium Chloride 9mg/ml and Glucose 50 mg/ml B. Braun in pregnant women. Animal studies relating to glucose and sodium chloride do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.
Therefore caution should be exercised when prescribing to pregnant women, especially in the presence of eclampsia (see section 'special warnings and precautions for use').
Careful monitoring of blood glucose is necessary.

Lactation
It is unknown wether Sodium Chloride 9 mg/ml and Glucose 50 mg/ml B. Braun or metabolites are excreted into breastmilk. As all active ingredients are present in human body, no negative effects are anticipated if used during lactation. Therefore, the solution can be used as indicated.

Effects on ability to drive and use machines
Sodium Chloride 9 mg/ml and Glucose 50 mg/ml B. Braun has no influence on the ability to drive and use machines.

Dosage
Adults
The dose is adjusted according to individual requirements of fluid, electrolyte and energy. Thus the patient`s age, weight, clinical and biological (acid-base balance) conditions and concomitant therapy should be taken into account.

Maximum daily dose
40 ml/kg body weight (BW) per day, corresponding to 2 g glucose/kg BW per day and 6 mmol of sodium /kg BW per day.

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Maximum Infusion rate:
5 ml/kg BW per hour, corresponding to 0.25 g glucose/kg BW per hour.
Partial coverage of energy requirements, i. e. substitution of the obligatory daily glucose requirements, is only possible with the maximum dose stated above.

Padiatric patients
The dose is adjusted according to the individual requirements of fluid, electrolytes and energy. Thus the patients age, weight, clinical and biological (acid-base balance) conditions and concomitant therapy should be taken into account.
When administering this solution the total daily fluid and glucose requirements should be taken into account.

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.

Other special patient groups
If the oxidative metabolism of glucose is impaired (e.g. in the early postoperative 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. See also section 'special warnings and precautions for use'.

Method of administration
Intravenous use
Hypertonic solutions should be administered in a large peripheral or central vein to diminish the risk of causing irritaion.

Overdose
Symptoms
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 hypernatraemia, hyperchloraemia (see section 'undesirable effects') and hypokalaemia, acid-base imbalances, hyperglycaemia, and hyperosmolarity of the serum (up to hyperglycaemic-hyperosmolar coma).

Treatment
Dependent on the severity of the disorders immediate stop of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances, administration of insulin if necessary.
In severe cases of overdose dialysis may be necessary.

Undesirable effects
Provided the solution is administered according to the directions given, adverse effects are not to be expected.

Note
Patients are advised to inform their doctor or pharmacist if they notice any adverse reaction not mentioned in this leaflet.

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

Instructions for disposal / storage / use / handling
No special requirements for disposal.
This medicinal product does not require any special storage conditions.
Only to be used if solution is clear and colourless and the container and its closure are undamaged.
The containers are for single use only. After use - discard container and any remaining contents.
Do not reconnect partially used containers.

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