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Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

0.9% Sodium Chloride Intravenous Infusion BP

Composition

1000 ml of solution contain

Sodium Chloride	9.0 g

Excipients:

Water for Injections

Theoretical osmolarity:	308 mOsm/l
Titration acidity (to pH 7.4):	< 0.3 mmol/l
pH:	4.5 - 7.0

Electrolyte concentrations:

Sodium	154 mmol/l
Chloride	154 mmol/l

Product Description

A clear, colourless aqueous solution.

Pharmaceutical form

Solution for infusion

Pharmaco-therapeutic group

Solution for fluid and electrolyte supply, vehicle solution

Pharmacodynamics

Sodium is the primary cation of the extracellular space and together with various anions, regulates the size of this. Sodium and potassium are the major mediators of bioelectric processes within the body.

The sodium content and the liquid metabolism of the body are closely coupled to each other. Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body.

An increase in the sodium content of the body also means reduction of the body's free water content independent of the serum osmolality.

A 0.9 per cent sodium chloride solution has the same osmolarity as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume remains in the intravascular space. Therefore the haemodynamic effect of the solution is of short duration only.

Pharmacokinetics

The total sodium content of the body is ca. 80 mmol/kg of which ca. 97 % is extracellular and ca. 3 % intracellular. The daily turnover is ca. 100 - 180 mmol (corresponding to 1.5 - 2.5 mmol/kg body weight).

The kidneys are the major regulator of the sodium and water balances. In co-operation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) and the hypothetical natriuretic hormone they are primarily responsible for keeping the volume of the extracellular space constant and regulating its fluid composition.

Chloride is exchanged for hydrogen carbonate in the tubule system and is, thus, involved in the regulation of the acid base balance.

Indications

- Fluid and electrolyte substitution in hypochloraemic alkalosis;
- Chloride losses;
- Short-term intravascular volume substitution;
- Hypotonic dehydration;
- Isotonic dehydration;
- Vehicle solution for compatible electrolyte concentrates and medicaments;
- Externally for wound irrigation and moistening of wound dressings.

Contraindications

Hyperhydration, hypernatraemia, hypokalaemia, acidotic situations, hypertension.

Pregnancy and Lactation

0.9% Sodium Chloride Intravenous Infusion can be used as indicated.

Special warnings and precautions for use

0.9 % Sodium Chloride Intravenous Infusion BP should only be administered with caution in cases of

- hypokalaemia
- hypernatraemia
- hyperchloraemia
- disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalized oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency.

Clinical monitoring should include checks of the serum ionogram, the water balance, and the acid-base status.

High infusion rates should be avoided in cases of hypertonic dehydration because of possible increases of plasma osmolarity and plasma sodium concentration.

* In case of pressure infusion, which may be necessary in vital emergencies, all air must be removed from the container and the infusion set before the solution is administered.

Interactions

When mixing with other medicaments, physical or chemical incompatibilities should be considered.

Dosage

The dose is adjusted according to the actual requirements of water and electrolytes:

Maximum daily dose:

40 ml/kg BW, corresponding to 6 mmol of sodium per kg BW

Infusion rate:

Up to 5 ml/kg BW/h, corresponding to 1.7 drops/kg BW/min

The amount of solution to be used for wound irrigation or moistening depends on actual requirements

Overdose

Symptoms

Overdose may result in hypernatraemia, hyperchloraemia, overhydration, hyperosmolarity of the serum and metabolic acidosis.

Emergency treatment, antidotes

Immediate cessation of administration, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and asid-base imbalances.

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Undesirable effects
Administration of larger amounts may lead to hypernatraemia and hyperchloraemia.

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

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

Storage:
Do not store above 30 °C.
Only to be used if solution is clear and the container undamaged.

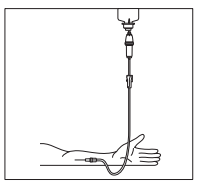
Presentation
100 ml, 250 ml, 500 ml, 1000 ml plastic container.
100 ml, 250 ml, 500 ml or 1000 ml PVC bag.

Date of last revision: 05.2008

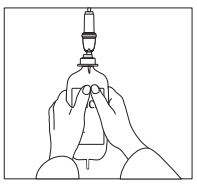
General guidelines on fluid and electrolyte intake:
A level of 30 ml of the solution per kg body weight per day only covers the physiological basic fluid requirements. Post-operatively and in intensive care patients there is an increased requirement for fluid intake on account of the limited concentrating 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. 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 approx. 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.

Instructions for Handling the Ecoflac plus Container

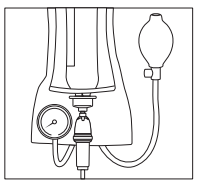
1. Gravity infusion
- Insert infusion set, fill half of drip chamber, fill infusion tube avoiding bubbles.
- Close air vent of infusion set.
- Connect infusion tube to cannula/catheter.
- Open clamp and start infusion with air vent closed



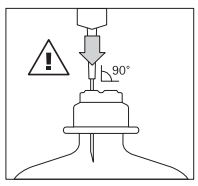
2. Pressure infusion
- Insert infusion set.
- Hold container upright.
- Leave clamp open, expel air from container and fill half of drip chamber.
- Turn container and expel air from infusion device.
- Close clamp.



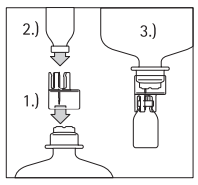
- Place container in pressure cuff.
- Build up pressure.
- Open clamp and start infusion.



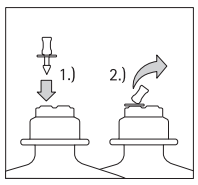
3. Admixture of additives
Addition via cannula
- Insert cannula vertically.



Addition using the transfer cap (Ecoflac® Mix)
1.) Attach transfer cap to the container.
2.) Attach vial to the other end (click!).
3.) Transfer solution into the vial containing the additive by pressing the Ecoflac® plus container. Dissolve additive completely. Turn Ecoflac® plus container with attached vial upside down. Press air into the vial until all solution has been transferred into the Ecoflac® plus container.



Documentation of addition and re-sealing the injection port with Ecopin®
1.) Insert Ecopin® into injection port
2.) Break off handle



Product registration holder
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Manufactured by:
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