5/15242671/0118

Sodium Chloride

0.9% Solution for Intravenous Infusion
Electrolyte

Composition
Each 1000 mL of solution contains

Sodium chloride	9.00 g
Electrolytes:	
Sodium	154 mmol/L
Chloride	154 mmol/L

Excipients:
Water for injections

Pharmaceutical form
Solution for infusion
A clear, colourless aqueous solution

Theoretical osmolarity	308 mOsm/L
pH	4.5 – 7.0

Pharmacotherapeutic group:
Solutions affecting the electrolyte balance, electrolytes
ATC-code: B05B B01

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

Dosage and Method of Administration

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

Daily dose:
Up to 40 ml/kg body weight (BW) per day, corresponding to 6 mmol of sodium per kg BW

Infusion rate:
Up to 5 ml/kg BW/h.

Pressure infusion
In the management of acute volume deficiency, i.e. imminent or manifest hypovolaemicshock, higher doses and infusion rates may be applied, e.g. by pressure infusion.

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

Paediatric patients
The dose has to be adjusted according to the individual need of water and electrolytes as well as the patient`s age, weight and clinical condition.
When administering this solution the total daily fluid intake should be taken into account.

Method of administration
Intravenous use
When performing pressure infusion, using solution packed in a flexible container, all air must be expelled from the container and the giving set prior to starting the infusion.

Contraindications
0.9% Sodium Chloride Solution must not be administered to patients in states of
- hyperhydration.

Special warnings and precautions for use

Special warnings
General
0.9% Sodium Chloride Solution 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.

Precautions for use
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.

Interactions with other medicinal products and other forms of interaction
None known

B BRAUN

Schwarz
210x297 mm
5/15242671/0118
Lätus: 8405
Philippinen
Font size 9

Fertility, pregnancy and lactation

Pregnancy

There is a limited amount of data from the use of 0.9% Sodium Chloride Solution in pregnant women. Animal studies do not indicate direct or indirect harmful effects of 0.9% Sodium Chloride Solution with respect to reproductive toxicity.

As the concentrations of sodium and chloride are similar to that in human body no harmful effects are to be expected if the product is used as indicated.

Therefore 0.9% Sodium Chloride Solution can be used as indicated.

Nevertheless, caution has to be exercised in the presence of eclampsia (see section"Special warnings and precautions for use").

Lactation

As the concentration of sodium and chloride are similar to that in human body no harmful effects are to be expected if the product is used as indicated.

0.9% Sodium Chloride Solution can be used as indicated.

Effects on ability to drive and use machines

0.9% Sodium Chloride Solution has no influence on the ability to drive and use machines

Undesirable effects

Administration of large amounts may lead to hypernatraemia and hyperchloraemia (see section"Overdose").

Overdose

Symptoms

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

Treatment

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

Incompatibilities

When mixing with other medicinal products, possible incompatibilities should be considered.

Expiry date

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

After dilution or admixture of additives

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibilities of the user and would normally not be longer than 24 hours at 2 to 8 ° C, unless dilution has taken place in controlled and validated aseptic conditions.

Special precautions for storage

Store at temperatures not exceeding 30°C.

For storage conditions of the diluted medicinal product, see section above.

Availability

Plastic bottle 100mL, 500mL and 1L.

(Ecoflac Plus Twin Port)

DR-XY46124

Instructions for disposal and other handling

No special requirements for disposal.

The containers are for single use only. After use discard container and any remaining contents.

Only to be used if solution is clear, colourless and the container and its closure are undamaged.

Caution

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Seek medical attention immediately at the first sign of any adverse drug reaction.

Date of last revision:

October 2010

Imported by:
B. Braun Medical Supplies, Inc.
15th Floor Sun Life Centre
5th Ave. cor. Rizal Drive,
Bonifacio Global City, Taguig City

Manufactured by:
B. Braun Medical Industries Sdn. Bhd.
11900 Bayan Lepas, Penang,
Malaysia.

B BRAUN

Schwarz
210x297 mm
5/15242671/0118
Lätus: 8405
Philippinen
Font size 9