Euro-Med 0.9% Sodium Chloride Solution for Intravenous Infusion

Formulation:

Each 100 ml contains:

Sodium Chloride …….. 900 mg

Electrolytes in 1000 ml

Sodium……. 154 mEq

Chloride …….. 154 mEq

Osmolarity: 308 mOsm/L

pH: 4.5 to 7.0

Description:

Clear, colourless sterile solution of Sodium Chloride in Water for Injection. It contains no antimicrobial agent. It contains not less than 95.0% and not more than 105.0% of the labelled amount of Sodium Chloride (NaCl).

Pharmacodynamics:

Sodium Chloride in water dissociates to provide Sodium (Na+) and Chloride (Cl-) ions. It is the principal salt involved in maintaining the osmotic tension of the blood and tissue. It is widely used as vehicle and diluent for injectable preparations of other drugs. 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 cooperation 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:

For replacement or maintenance of fluid and electrolytes.

Dosage:

Recommended dosage schedule

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.

Route of administration: Intravenous infusion

Contraindications:

None known.

Precautions:

Special warnings

0.9% w/v Sodium Chloride 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. 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 with Other Medicaments:

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

Pregnancy and Lactation:

Not contraindicated for use during pregnancy.

Side Effects:

Inappropriate and excessive administration of Sodium Chloride Solution may lead to hypernatraemia. This may occur as a result of existing renal function impairment, aldosteronism, brain injury or glucose overloading in parenteral feeding.

Symptoms and Treatment of 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 acid-base imbalances. In such an event, use of sodium-containing infusion should be ceased, and other sodium intake is controlled. Very occasionally in severe hypernatraemia, dialysis may be indicated.

Instructions for Use:

Use as directed by physician.

Storage Condition:

Store at temperature not exceeding 30°C.

Shelf Life:

5 years

Presentation:

500 ml round low density polyethylene container with rubber disc.
1000 ml rectangular low density polyethylene container with rubber disc.

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EURO-MED® LABORATORIES PHIL., INC.
Km. 36 Gen. Emilio Aguinaldo Highway
Dasmariñas, Cavite, Philippines