

PACKAGE INSERT TEMPLATE FOR SODIUM CHLORIDE 0.9% w/v INTRAVENOUS INFUSION

Brand or Product Name

[Product name]

Sodium Chloride 0.9% w/v Intravenous Infusion

Name and Strength of Active Substance(s)

Sodium Chloride 0.9% w/v

Electrolytes concentrations:

Sodiummmol/l

Chloride mmol/l

Product Description

[Visual description of the appearance of the product]

eg. A clear colourless aqueous solution.

Pharmacodynamics

Sodium chloride is a source of water and electrolyte. Sodium is the principle cation of extracellular fluid and chloride is the principle anion of extracellular fluid.

Sodium is the primary cation of the extracellular space and together with various anions regulates the size of this. Sodium is a major mediator of bioelectric processes within the body.

The sodium content and the liquid metabolism of the body are closely coupled to each other. Sodium content normally determines the volume of extracellular fluid, and important in the regulation of osmolarity, acid-base balance, and the membrane potential of cells. 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 % 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.

Updated August 2011

Pharmacokinetics

The total sodium content of the body is approximately 80 mmol/kg of which approximately 97 % is extracellular and approximately 3 % intracellular. The daily turnover is approximately 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.

Sodium Chloride administered intravenously directly into the circulation, the bioavailability of the components is 100%. Excess sodium is predominantly excreted by the kidneys, with small amounts lost in faeces and sweat

Indication

- For replenishing fluid and for restoring/maintaining the concentration of sodium and chloride ions (hyponatremia, chloride losses)
Fluid and electrolyte substitution in hypochloreaemic alkalosis
- Short-term intravascular volume substitution
- Hypovolemic shock
- Hypotonic dehydration or isotonic dehydration,
- Vehicle solution for compatible electrolyte concentrates and medicaments, solvent for the preparation or dilution of parenterally administered drugs
- Externally for wound irrigation and for moistening of wound tamponades and dressings.
- As a priming fluid for haemodialysis procedures and to initiate and terminate blood transfusions.

Recommended Dosage

The dosage is dependent on the age, weight, clinical status and degree of deficiency, and must be determined on an individual basis.

The dose and rate of infusion are adjusted according to the actual requirements of water and electrolytes. Monitoring of serum electrolytes is essential.

Adults

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

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In patients with chronic hyponatraemia the rate of infusion should be slow, so that the resulting increase of the serum sodium level is limited to a maximum of 0.35 mmol/l/h.

Children

In children the posology for adults should be used as a guide.

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

*The quantity to be chosen depends on the desired concentration of the medicament to be dissolved

*For use of this solution as solvent/diluent for compatible electrolyte concentrates or medicaments, the instructions for use relating to the medicament to be added should be observed

Mode of Administration

Intravenous infusion

Contraindications

Sodium Chloride injection is contraindicated in patients with conditions in which administration of sodium and chloride is detrimental

- Hyperhydration, hypernatremia, hypokalaemia, acidotic situations, hypertension
- Patients with cardiac or circulatory functional disorder such as decompensated heart failure (increase in circulatory blood volume may burden heart and worsen symptoms).
- Patients with renal disorder; acute renal failure with oliguria or anuria (overdose of water and sodium chloride, may worsen symptoms).

* When sodium chloride solution is used as a vehicle, contraindication related to the added medicinal product(s) should be considered.

Warnings and Precautions

Should be administered with caution in cases of

- hypokalaemia
- hypernatraemia
- hyperchloraemia
- disorders where restriction of sodium intake (other conditions and treatment associated with sodium retention) is indicated, such as cardiac insufficiency, generalized oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency

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- Premature or term infants may retain an excess of sodium due to immature renal function. In premature or term infants, repeated infusions of sodium chloride should therefore only be given after determination of the serum sodium level.
- Use in the elderly - elderly patients often have a physiological hypofunction and adverse reactions appear more readily, the careful administration such as slow or decreasing should be considered. (0.45%)

*Clinical and biological parameters, in particular serum-electrolytes, water balance, and the acid-base status should be monitored.

* 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

Concomitant administration of other sodium salts may contribute to the sodium load. The risk of hypernatraemia is exacerbated by the use of salt retaining drugs.

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

Lithium toxicity is made worse by sodium depletion

Statement on Usage During Pregnancy and Lactation

Pregnancy

No adverse reaction has been reported. However, these injections should be given to pregnant woman only if clearly needed

Lactation

World Health Organization Rating: Compatible with breastfeeding.

Adverse Effects / Undesirable Effects

Common:

- Cardiovascular: Phlebitis
- Dermatologic: Injection site extravasation, Injection site reaction
- Endocrine metabolic: Hypervolemia

Serious:

- Cardiovascular: Congestive heart failure

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- Endocrine metabolic: Hypernatremia, Overhydration
- Hematologic: Disseminated intravascular coagulation
- Respiratory: Respiratory distress

*Administration of larger amounts may lead to hypernatraemia and hyperchloraemia.

*Poor administration technique or local solution reactions may cause local tenderness, tissue necrosis, infection at the insertion site or extravasation .

*When infused through a peripheral vein over a long time thrombophlebitis can occur.

Overdose and Treatment

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

Symptoms of hypernatraemia may include restlessness, weakness, thirst, dry mouth, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypotension and tachycardia

Emergency treatment, antidotes

Immediate cessation of administration

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

**When sodium chloride 0.9 % is used as a diluent for injectable preparations of other drugs, the signs and symptoms of over infusion will be related to the nature of the additives being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant and supportive measures should be provided as necessary.

Incompatibilities

The compatibility of any additives to the solution should be checked before use.

Instructions for use and handling

*Administration should be carried out under regular and careful surveillance.

*Do not use unless the solution is clear and free from particles and the container is undamaged.

*Before use check for minute leaks by squeezing bag firmly (if applicable) and discard if leakage is detected

*The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

*Do not administer simultaneously with blood.

* For single use only. Discard unused contents. Do not reconnect partially used containers.

*Discontinue infusion if adverse reaction occurs.

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- *Administer immediately following the insertion of infusion set.
- *Solutions containing additives should be used immediately after preparation, unless preparation has taken place in controlled and validated aseptic conditions.
- *When additive is used, verify isotonicity prior to peripheral venous administration.

Storage Conditions

[eg Store below ...°C]

Dosage Forms and Packaging Available

[Packaging type & pack size]

Name and Address of Manufacturer

[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder

[Name & full address of marketing authorization holder]

Date of Revision of Package Insert

[day/month/year]