SmPC

Country :	Lebanon
Date of approval :	22.06.2009
Procedure :	National

SUMMARY OF PRODUCT CHARACTERISTICS

1 - NAME OF THE MEDICINAL PRODUCT
SODIUM CHLORIDE PROAMP 0.9 %, solution for infusion

2 - QUALITATIVE AND QUANTITATIVE COMPOSITION
Sodium chloride……..0.9 g
for 100 ml

A 10 ml ampoule contains 0.09 g of sodium chloride
For a full list of excipient, see section 6.1

3- PHARMACEUTICAL FORM
Solution for infusion
Clear solution free of visible particles, odourless.

Ionic composition
Sodium : 154 mmol/l
Chlorides: 154 mmol/l
Osmolarity 308 mOsm/l
pH between 4.5 and 7

4- CLINICAL PARTICULARS

4.1 Therapeutic indications
Vehicle or diluent for compatible drugs for parenteral administration intravenously, intramuscularly or subcutaneously.

4.2 Posology and method of administration
The dose may be expressed in mEq or mmol sodium, sodium mass or mass of sodium salt (1 g NaCl = 394 mg Na, 17.1 mEq or 17.1 mmol of Na and Cl).
When SODIUM CHLORIDE PROAMP 0.9% is used as a diluent for injections of other drugs, the dosage administered and the rate of injection will depend primarily on the nature and dose of medication prescribed.

Method of administration
Intravenous, intramuscular, or subcutaneous

4.3 Contraindications
The solution is contraindicated in patients presenting with hypernatremia or hyperchloremia.
In addition, take into account the contraindications related to the medicinal product added.

4.4 Special warnings and special precautions for use
Premature or at-term neonates may retain excess sodium due to the immaturity of renal function. Consequently, in premature or at-term neonates, repeated infusions of sodium chloride should only be administered after measuring the serum sodium concentration.
Sodium chloride should be used with precaution in patients with hypertension, heart failure, pulmonary or peripheral oedema, impaired renal function, pre-eclampsia, hyperaldosteronism, liver cirrhosis, hypervolemia, urinary tract obstruction, hypoproteinemia, or other illnesses and treatments (for ex. corticosteroids) associated with sodium retention.

4.5 Interaction with other medicinal products and other forms of interaction
Not applicable

4.6 Pregnancy and lactation
This product can be used during pregnancy and breastfeeding, if needed.

4.7 Effects on ability to drive and use machines
Not applicable

4.8 Side effects
General disorders related to the administration site:
Undesirable reactions may be associated with the administration procedure and include febrile response, infection at the injection site, local pain or reaction, vein irritation, vein thrombosis or phlebitis spreading from the injection site, and extravasation.
The administration of large doses can lead to an accumulation of sodium, with edema and hyperchloremic acidosis.
When sodium SODIUM CHLORIDE PROAMP 0.9% is used as a diluent for injectable preparations of other medicinal products, the type of the additive determines the probability of the onset of other undesirable effects.
In case of an undesirable reaction to the medicinal product added, discontinue the infusion, evaluate the patient, initiate appropriate corrective measures and keep the rest of the solution for analysis, if necessary.

4.9 Overdose
The general undesirable effects of excess sodium include nausea, vomiting, diarrhoea, abdominal cramps, thirst, decrease in saliva and tear secretion, sweating, fever, tachycardia, hypertension, renal failure, pulmonary and peripheral oedema, respiratory arrest, headache, dizziness, impatience, irritability, syncope, muscle contraction and stiffness, convulsions, coma and death.
Excessive administration of sodium chloride may cause hypernatremia and must be treated by a specialised doctor.
Excess chloride in the body may lead to a loss of bicarbonate with an acidifying effect.
When SODIUM CHLORIDE PROAMP 0.9% is used as a diluent for injectable preparations of other medicinal products, the signs and symptoms of excessive infusion are related to the type of additive used. In case of accidental excessive infusion, discontinue treatment and observe the patient for any onset of clinical signs and symptoms related to the medicinal product administered. Initiate symptomatic treatment and appropriate care, depending on the needs.

5- PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic class: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS/ ELECTROLYTE SOLUTIONS/ SODIUM CHLORIDE
ATC Code: B05XA03

SODIUM CHLORIDE PROAMP 0.9%, solution for infusion is an isotonic solution, the osmolarity of which is approximately 308 mOsm/L.
The pharmacodynamic properties of the solution are those of sodium and chloride ions, which maintain the water and electrolyte balance.
Ions such as sodium cross the cellular membrane through various transport mechanisms, among which is the sodium pump (Na+, K+ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology as well as in renal metabolism.

5.2 Pharmacokinetic properties
Sodium is primarily excreted by the kidneys, but renal reabsorption is significant.
Low quantities of sodium are eliminated in the faeces and sweat.

5.3 Preclinical safety data
No special data, since sodium chloride is a physiological component of plasma.

6- PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Water for injectable preparations.

6.2 Incompatibilities

As with any parenteral solution, the compatibility of the additives with the solution must be verified before the addition of the medicinal product.

The doctor is responsible for assessing the incompatibility of an additive medicinal product vis-à-vis SODIUM CHLORIDE PROAMP 0.9% solution for infusion, by checking for any change in colour and/or any formation of precipitate, insoluble complex or crystals. Also refer to the leaflet accompanying the medicinal product that is to be added.

Before the addition of a medicinal product, verify that it is soluble and stable in water at the pH of SODIUM CHLORIDE PROAMP 0.9%, solution for infusion.

When a medicinal product is added to SODIUM CHLORIDE PROAMP 0.9%, solution for infusion, the mixture must be administered immediately.

Additives known to be incompatible should not be used.

6.3 Shelf life

3 years.

Immediate use after solution.

6.4 Special precautions for storage

Store below +25°C.

6.5 Nature and contents of the container

10 ml ampoules (polypropylene) ; box of 10, 20, 50, 100.

All pack sizes may not be marketed

6.6 Special precautions for disposal and other handling

No special requirements.