SmPC

Country :	Lebanon
Date of approval :	13.05.2010
Procedure :	National

SUMMARY OF PRODUCT CHARACTERISTICS

1 - NAME OF THE MEDICINAL PRODUCT
SODIUM CHLORIDE PROAMP 0.10 g/ml (10%), concentrate for solution for infusion

2 - QUALITATIVE AND QUANTITATIVE COMPOSITION
Sodium chloride……..10.0 g
for 100 ml

A 20 ml ampoule contains 2 g of sodium chloride
For a full list of excipient, see section 6.1

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

Ionic composition
Sodium : 1.711 mmol/ml
Chlorides: 1.711 mmol/ml
Osmolarity 3420 mOsm/l
pH between 4.5 and 7

4- CLINICAL PARTICULARS

4.1 Therapeutic indications
This medicinal product is indicated in the following cases:
- Correction of severe hyponatremia when a limited supply of water is desired, by slow intravenous infusion;
- Sodium intake through a reduced volume in parenteral nutrition solutions.

4.2 Posology and method of administration
The dosage depends on the age, weight and clinical condition of the patient, and particularly on the sodium concentration in the serum and hydration status.
To be administered intravenously, dilute before use.
1 g of sodium chloride corresponds to 17.1 mmol of sodium ion.
The presence of symptoms and their severity determines the speed of correction of hyponatremia as well as the concentration and infusion rate to which the hypertonic solution should be used.
Most cases of osmotic demyelination syndromes reported occurred after a correction speed greater than 12 mmol sodium per liter per day was used. Higher correction speeds should therefore be avoided.

4.3 Contraindications
The administration of this solution is contraindicated in severe cases of fluid retention (hypernatremia) and especially in heart failure, oedemato-ascitic insufficiency in cirrhosis and pre-eclampsia/eclampsia.

4.4 Special warnings and special precautions for use
The intravenous solution must be diluted before use.
The container integrity and clarity of the solution must be checked beforehand.
The solution being hypertonic, the re-equilibration of sodium must not be performed too quickly.
A correction made too quickly can cause severe neurological side effects, such as osmotic demyelination syndrome (see

section 4.8).

Special precautions for use:
- Use this drug with caution in patients with cardiac disorders, pulmonary or peripheral edema, severe kidney problems.
- In the newborn and the elderly, the administration of the product requires closer monitoring.
- This treatment must be performed under strict medical supervision, with the dosage being adapted according to the electrolyte changes, particularly sodium and chloride ions.

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:
Risk of pulmonary and peripheral edema and risk of development of an osmotic demyelination syndrome (see section 4.9) if the infusion is too fast and / or too abundant.
Undesirable reactions may be associated with the administration procedure and can include: febrile response, infection at the injection site, local pain or reaction, vein irritation, vein thrombosis or phlebitis spreading from the injection site, extravasation and hypervolemia (increase in the blood volume).
General side effects of the excess of sodium are described in the overdose section.

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.
Clinical signs of osmotic demyelination syndrome are progressive: confusion, dysarthria, dysphagia, limb weakness and quadriplegia, delirium and finally coma. Clinical symptoms occur several days after correction of hyponatrémie.
Excessive administration of sodium chloride can cause hypernatremia and must be treated in a specialized environment.
This treatment consists in the monitoring of serum sodium and in the administration of glucose solution for infusion.
Excess chloride in the body may lead to a loss of bicarbonate with an acidifying effect.

5- PHARMACOLOGICAL PROPERTIES

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

SODIUM CHLORIDE PROAMP 0.10 g/ml (10%), concentrate for solution for infusion is an isotonic solution, the osmolarity of which is approximately 3420 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 0.10 g/ml (10%), concentrate for 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 0.10 g/ml (10%), concentrate for solution for infusion.
When a medicinal product is added to SODIUM CHLORIDE PROAMP 0.10 g/ml (10%), concentrate for solution for infusion, the mixture must be administered immediately.
Additives known to be incompatible should not be used.

6.3 Shelf life
3 years.
Use immediately after dilution.

6.4 Special precautions for storage
Store below +25°C.

6.5 Nature and contents of the container
20 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.