

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml of solution contains 0.9% w/v of Sodium Chloride B.P.

3 PHARMACEUTICAL FORM

Clear, colourless, sterile solution intended for parenteral administration to human beings.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- 1) For use in prophylactic and replacement therapy requiring the use of isotonic saline solution.
- 2) In the reconstitution, dilution and making up of certain drugs.
- 3) As a saline irrigant.
- 4) As a priming fluid for haemodialysis procedures and to initiate and terminate blood transfusions.

4.2 Posology and method of administration

Route of administration: For intravenous administration, or as appropriate to the reconstituted drug.

In prophylaxis or replacement therapy of extracellular fluid deficits, the dosage of Sodium Chloride 0.9% w/v Solution for Injection is dependent on the age, weight, clinical status and degree of deficiency, and must be determined on an individual basis.

4.3 Contraindications

There are no absolute contra-indications to the use of Sodium Chloride 0.9% w/v Solution for Injection.

4.4 Special warnings and precautions for use

Sodium Chloride 0.9% w/v Solution for Injection should be administered with caution to patients with congestive cardiac failure, pre-eclampsia hypertension, peripheral and pulmonary oedema and impaired renal function.

Care is also required when administering this solution to very young or to the elderly patients.

Pseudohyponatraemia is a condition in which spuriously low concentrations of sodium are found when plasma sodium is measured by conventional methods. It may occur when there is an abnormally high concentration of large molecules and hence an abnormally low percentage of plasma water. This may occur in hyperlipaemia and hyperproteinaemia and has also been reported in patients with diabetes mellitus. Correct values may be obtained by referring the concentration to plasma water.

Before use, ensure that the container is undamaged and the contents clear in appearance. After use, discard any remaining solution.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant administration of other sodium salts may contribute to the sodium load.

Only use as a pharmaceutical diluent where indicated in the manufacturer's literature.

4.6 Pregnancy and lactation

The solution is physiological saline and may be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Injudicious intravenous saline therapy (e.g. post-operatively and in patients with impaired cardiac or renal function) may cause hypernatraemia. Osmotically induced water shifts decrease intracellular volume, resulting in dehydration of internal organs, especially the brain, which may lead to thrombosis and haemorrhage.

General adverse effects of sodium chloride excess in the body include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivary and lachrymal secretions, sweating, fever, hypotension, tachycardia, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. Excess chloride in the body may cause a loss of bicarbonate, with an acidifying effect. With judicious use of intravenous saline therapy, these side effects can be avoided.

If administered sub-cutaneously, any addition to the isotonic solution could render it hypertonic and cause pain at the site of injection.

Administration of large doses may give rise to sodium accumulation, oedema, and hyperchloraemic acidosis.

4.9 Overdose

Injudicious intravenous saline therapy (e.g. post-operatively or in patients with impaired cardiac or renal function) may cause hypernatraemia. Osmotically induced water shift decreases intracellular volume, resulting in dehydration of internal organs, especially the brain, which may lead to thrombosis and haemorrhage. General adverse effects of sodium chloride excess in the body include: nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivary and lachrymal secretions, sweating, fever, hypotension, tachycardia, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. Excess chloride in the body may cause a loss of bicarbonate, with an acidifying effect.

With judicious use of intravenous saline therapy, these effects can be avoided.

Diuretics may be used to treat oedema resulting from isotonic expansion, and appropriate replacement therapy should be employed to avoid fluid and electrolyte imbalance. Treatment of hypervolaemic hypernatraemia requires removal of sodium in excess of water and can be achieved by replacing diuretic-induced sodium and water losses with only water. The basic aim of therapy is to restore the volume and composition of the body fluids to normal.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The principal determinant of the effective osmolality of the extracellular fluids (and also of the intracellular fluids, since they remain in osmotic equilibrium with the extracellular fluids) is the extracellular fluid sodium concentration. The reason for this is because sodium is the most abundant positive ion of the extracellular fluid. Negative ion concentrations of the body fluids are adjusted to equal those of the positive ions by renal acid-base control mechanisms. Furthermore, glucose and urea, the most abundant of the non-ionic osmolar solutes in extracellular fluids, normally only represent about 3% of the total osmolality. Therefore, in effect, the extracellular fluid sodium ion concentration controls over 90% of the effective osmotic pressure of the extracellular fluid. Sodium chloride remains the most important single salt for prophylaxis or replacement therapy of deficits of extracellular fluid. Volume contraction, whether isotonic, hypotonic or hypertonic, may seriously impair the circulation (cardiac output falls and microcirculation is compromised) and prompt infusion of isotonic sodium chloride solution is indicated. Even with moderately severe hyponatraemia or hypernatraemia, the disorder may be corrected with isotonic saline solution, provided there is normal renal function to allow physiological adjustments to be made by the kidneys, resulting in the excretion of urine at a concentration appropriate to the underlying situation.

5.2 Pharmacokinetic properties

The homeostatic mechanisms involved in maintaining constant ion concentrations are well described in standard text books of physiology and biochemistry and are not, therefore, included in this report.

5.3 Preclinical safety data

No further relevant information other than that which is contained in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dilute Hydrochloric acid B.P.
Water for Injections B.P.

6.2 Incompatibilities

The addition of sodium chloride to mannitol 20 or 25% may cause precipitation of the mannitol.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C
Keep in outer carton

6.5 Nature and contents of container

2ml, 5ml and 10ml hermetically sealed translucent plastic ampoules, polypropylene Ph.Eur., packed in cardboard cartons to contain 10, 20, 50 and 100 ampoules.

6.6 Special precautions for disposal

For I.V. Injection
Solutions containing visible solid particles should not be used.
If only part of an ampoule is used, discard the remaining solution.
Use as directed by the physician.
Keep out of reach of children.

7 MARKETING AUTHORISATION HOLDER

Antigen International Ltd
Roscrea
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PL 02848/0157

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

11/ 10/1991

10 DATE OF REVISION OF THE TEXT

22/02/2010