SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 0.9% w/v

Each 2ml ampoule contains a total content of sodium chloride of 18mg

Each 5ml ampoule contains a total content of sodium chloride of 45mg

Each 10ml ampoule contains a total content of sodium chloride of 90mg

Each 20ml ampoule contains a total content of sodium chloride of 180mg

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Injection.

Clear glass ampoules containing, 2ml, 5ml, 10ml or 20ml Sodium Chloride 0.9% w/v Solution for Injection

Clear colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For use in prophylactic and replacement therapy, requiring the use of isotonic saline solution.

In the reconstitution, dilution and making up of certain drugs.

As a saline irrigant.

As a priming fluid for haemodialysis procedures and to initiate and terminate blood transfusions.

4.2 Posology and method of administration

For intravenous, intramuscular or subcutaneous use

In the 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 the individual basis.

4.3 Contraindications

There are no absolute contraindications to 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, impaired renal function or oedema with sodium retention. Care is also required with administering this solution to very young or to 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.

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 known.

4.8 Undesirable effects

Injudicious intravenous saline therapy (e.g. post-operative and 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 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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 side effects can be avoided.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code B05XA03 - Electrolyte solutions

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 that 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.

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 here.

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

Sodium hydroxide (for pH adjustment)

Hydrochloric acid (for pH adjustment)

6.2 Incompatibilities

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

6.3 Shelf life

5 years

6.4 Special precautions for storage

Store below 25° C. Keep the ampoules in the outer carton. Do not refrigerate or freeze

6.5 Nature and contents of container

Type I clear glass ampoules, 2ml, 5ml, 10ml and 20ml.

Packed in cardboard cartons to contain 10 or 20 ampoules.

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

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Nexus, Gloucester Business Park
Gloucester, GL3 4AG
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 1502 / 0068

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/03/2008

10 DATE OF REVISION OF THE TEXT

10/08/2020