1. Name of the medicinal product

Sodium Chloride intravenous infusion BP 0.9% w/v

2. Qualitative and quantitative composition

Each ml contains 9 mg Sodium Chloride BP.

3. Pharmaceutical form

Solution for infusion.

Clear, colourless solution for infusion

4. Clinical particulars

4.1 Therapeutic indications

Sodium Chloride 0.9% w/v Solution for Infusion BP is indicated:

- For fluid (water) and electrolyte replenishment.
- Used as a diluting agent for I.V. medication.
- Used for reconstitution of various I.V. injections.
- Flushing of I.V. ports and cannula.
- As nasal drops for relieving congestion in children and adults.
- Used to dilute various bronchodilator solutions (such as salbutamol, etc) for nebulization.
- Used for cleaning of small wounds
- Used as irrigation solution for eyes.
- Compresses (moistened gauze) of normal saline may also be used to reduce discomfort due to inflammation or skin irritation and to soften necrotic tissues.

4.2 Posology and method of administration

For fluid and electrolyte replenishment the dosage of Sodium Chloride 0.9% w/v Solution for Infusion is dependent on the age, weight, clinical status and degree of deficiency, and must be determined on an individual basis.

Administration:

Administration is usually via a central vein.

4.3 Contraindications

- Congestive heart failure
- Severe Hypertension
- Severe renal impairment
- Conditions of sodium retention and oedema
- Liver cirrhosis
- Irrigation during electrosurgical procedures

4.4 Special warnings and precautions for use

- The sodium chloride content of 0.9% Sodium Chloride Injection is 0.225 grams/ampoule. Care is therefore required in those cases where salt intake is restricted, such as in hypertensive patients.
- Infusion of large volumes may cause dilutional acidosis due to the dilution of the bicarbonate concentration in the plasma (as the preparation does not contain bicarbonate).
- Care is required in conditions where hypokalemia and/or hypocalcemia exists or may arise as the infusion of the product can decrease the concentration of these electrolytes.
- Caution should be exercised in patients with renal failure and in those with reduced urinary output due to obstructive urinary tract diseases.
- Continuous infusion of 0.9% Sodium Chloride Injection may cause hypernatremia, unless free water is supplied along with it.
- Sodium chloride should be administered with care to patients with congestive heart failure, hypertension, peripheral or pulmonary oedema, impaired renal function, urinary tract obstruction, pre-eclampsia and very young or elderly patients.
- Intravenous infusion during or immediately after surgery may result in sodium retention.

- Data sheet of specific medication should be referred to, before dilution, reconstitution or nebulization.

4.5 Pregnancy and lactation

Safety in pregnancy has not been established. Use is recommended only when clearly indicated.

But in general, the solution is physiological saline and may be used during pregnancy and lactation.

4.6 Interaction with Other Medicinal Products And Other Forms Of Interaction

Concomitant administration of other sodium salts may contribute to the sodium load.
Additives may be incompatible with sodium chloride.
Co medication of drugs inducing sodium retention may exacerbate any systemic effects.
Only use as a pharmaceutical diluent where indicated in the manufacturer's literature.

4.7 Effects on ability to drive and use machines

None

4.8 Side 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.

Generally, 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

Pharmacotherapeutic Group – Electrolyte Solution

ATC Code: B05XA03

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. In addition chloride is the major anion in extracellular fluid and in involved in maintaining the acid-base balance. Solutions of sodium chloride resemble extracellular fluid. 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.

6. Pharmaceutical particulars

6.1 List of excipients

- Water For Injections BP.

6.2 Incompatibilities

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

6.3 Shelf life

36 months .

Use immediately after first opening.

6.4 Special precautions for storage

Do not store above 30^{0}C and do not freeze.

6.5 Nature and contents of container

Pack sizes: 250mL, and 500 mL.

The bottles are made from Low Density Polyethylene plastic; the bottles are then overwrapped with a protective plastic pouch.

6.6 Special precautions for disposal and other handling

For I.V. Injection

Use as directed by the physician.

Keep out of reach of children.

Do not use unless solution is clear and the container is undamaged.

Any contents of the product remaining after use should be discarded.

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7. Marketing authorisation holder

Abacus Parenteral Drugs Limited

Block 191, Plot no.114, Kinga Mukono

P.O.Box 31376, Kampala, Uganda.

8. Marketing authorisation number

7206/26/10

9. Date of first authorisation/renewal of the authorisation

10/1/2010

10. Date of revision of the text

20/06/2016

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