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1.3	Product Information
1.3.1	Summary Product Characteristics (SPC)

Summary Product Characteristics (SPC)

1. Name of the medicinal product

1.1 (Invented) name of the medicinal product

Normal Saline Intravenous Infusion BP 0.9g/100 ml

1.2 Strength

Sodium chloride 0.9g/100 ml

1.3 Pharmaceutical form

Infusion.

2. Qualitative and quantitative composition

Each 100 ml contains:

Sodium Chloride BP….....0.9 g

Water for injection BP…Q.S to 100 ml

3. Pharmaceutical form

Intravenous Infusion

4. Clinical particulars

4.1 Therapeutic indications

Sodium chloride is used in the management of deficiencies of sodium and chloride ions in salt-losing conditions. Sodium chloride solutions are used as a source of sodium chloride and water for hydration.

The concentration and dosage of sodium chloride solutions for intravenous use is determined by several factors including the age, weight and clinical condition of the patient and in particular the patient's hydration state. Serum-electrolyte concentrations should be carefully monitored.

4.2 Posology and method of administration

Method of administration: This product is an intravenous Injection.

In severe sodium depletion 2 to 3 liters of sodium chloride 0.9% (isotonic, iso-osmotic) may be given over 2 to 3 hours and thereafter at a slower rate.

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Posology:

Carcinogenesis and Mutagenesis and Impairment of Fertility

Studies with Sodium Chloride (sodium chloride (sodium chloride injection) injection) Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy :Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP. It is also not known whether Sodium Chloride (sodium chloride (sodium chloride injection) injection) Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride (sodium chloride (sodium chloride injection) injection) Injection, USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Studies have not been conducted to evaluate the effects of Sodium Chloride (sodium chloride (sodium chloride injection) injection) Injection, USP on labor and delivery. Caution should be exercised when administering this drug during labor and delivery.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Chloride (sodium chloride (sodium chloride injection) injection) Injection, USP is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Sodium Chloride (sodium chloride (sodium chloride injection) injection) Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of sodium chloride (sodium chloride (sodium chloride injection) injection) solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population.

Geriatric Use

Clinical studies of Sodium Chloride (sodium chloride (sodium chloride injection) injection) Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in the responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low

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end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or drug therapy.
This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

4.3 Contraindications

Sodium Chloride is contra-indicated in patients having acidosis, hypertonic dehydation, hypernatraemia and hyperkalemia.

The product should be administered with caution in patients with hypertension, heart failure, peripheral and pulmonary edema, impaired renal function, pre-eclampsia or other conditions associated with sodium retention.

4.4 Special warnings and precautions for use

Sodium Chloride Injection, BP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

In patients with diminished renal function, administration of Sodium Chloride (sodium chloride (sodium chloride injection) BP may result in sodium retention.

Do not connect flexible plastic containers of intravenous solutions in series connections. Such use could result in air embolism due to residual air being drawn from one container before administration of the fluid from a secondary container is completed. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

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4.5 Interaction with other medicinal products and other forms of interaction

Lithium Carbonate:

Sodium chloride may increase the excretion rate of Lithium carbonate which could result in a lower serum level and potentially a reduction in efficacy

Tolvaptan:

Risk or severity of adverse effects can be increased when Sodium chloride is combined with Tolvaptan.

Laboratory tests: Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

4.6 Pregnancy and lactation

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP. It is also not known whether Sodium Chloride (sodium chloride (sodium chloride injection) injection) Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride (sodium chloride (sodium chloride injection) injection) Injection, USP should be given to a pregnant woman only if clearly needed.

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5. Pharmacological properties

5.1 Indication

This intravenous solution is indicated for use in adults and pediatric patients as a source of electrolytes and water for hydration. Also, designed for use as a diluent and delivery system for intermittent intravenous administration of compatible drug additives.

Associated Conditions

- Corneal Edema
- Dehydration
- Hyponatremias
- Nasal irritation
- Skin Irritation
- Hypochloremic state

Associated Therapies

- Wound irrigation therapy
- Parenteral drug administration

Pharmacodynamics

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

Mechanism of action

Sodium and chloride — major electrolytes of the fluid compartment outside of cells (i.e., extracellular) — work together to control extracellular volume and blood pressure. Disturbances in sodium concentrations in the extracellular fluid are associated with disorders of water balance.

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Absorption

Absorption of sodium in the small intestine plays an important role in the absorption of chloride, amino acids, glucose, and water. Chloride, in the form of hydrochloric acid (HCl), is also an important component of gastric juice, which aids the digestion and absorption of many nutrients.

Volume of distribution

The volume of distribution is 0.64 L/kg.

Protein binding

Sodium is not bound by plasma proteins.

Metabolism

Route of elimination

Substantially excreted by the kidneys. (drugs.com)

Half life

17 minutes.

Clearance

Not Available

Toxicity

The rare inadvertent intravascular administration or rapid intravascular absorption of hypertonic sodium chloride can cause a shift of tissue fluids into the vascular bed, resulting in hypervolemia, electrolyte disturbances, circulatory failure, pulmonary embolism, or augmented hypertension. (toxnet)

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6. Pharmaceutical particulars

6.1 List of excipients

Sodium Chloride BP, Water for Injections BP.

6.2 Incompatibilities

Do not use equipment containing aluminum (e.g., needles, cannulae) that would come in contact with the drug solution as precipitates may form.

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Store below 30 degree celcius.

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6.5 Nature and contents of container

Flexible Poly vinyl chloride pouches filled with intravenous infusion and stoppered and overwrapped with low density polyethylene nylon material, the pouch size is 500 ml & 1000 ml packed inside a 5 ply corrugated cartons.

6.6 Special precautions for disposal

Use only if the solution is clear, without visible particles and if the Pouch is undamaged.
The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
Using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of Pyrogens. In the case of adverse reaction, infusion must be stopped immediately.
Additives:
The product should be used immediately after opening. Discard after single use.
Discard any unused portion.
Do not reconnect partially used bags.
1. Opening
a. Remove the Pouch from the overwrapped nylons just before use.
b. Check for minute leaks by squeezing firmly. If leaks are found, discard solution, as sterility may be impaired.
c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.
2. Preparation for administration
3. Use an aseptic method to set up the infusion

7. Registrant

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