DATA SHEET

SODIUM CHLORIDE INJECTION®

Sodium chloride
Solution for Injection 0.9% B.P and Solution for Infusion 0.9% B.P

PRESENTATION

Sodium chloride is a white, crystalline powder or colourless crystals, freely soluble in water and practically insoluble in ethanol.

Sodium Chloride Injection is sterile, isotonic, preservative-free solutions containing Sodium Chloride BP 0.9% in Water for Injections BP.

USES

Actions
Sodium is the major cation of extracellular fluid and functions principally in the control of water distribution, fluid and electrolyte balance and osmotic pressure of body fluids. Chloride, the major extracellular anion, closely follows the physiological disposition of the sodium cation in maintenance of acid-base balance, isotonicity and electrodynamic characteristics of cells.

Pharmacokinetics
As the Sodium Chloride Intravenous preparations are directly administered to the circulation, the bioavailability of the components is 100%. Excess sodium is predominantly excreted by the kidneys, with small amounts lost in faeces and sweat.

INDICATIONS

For the restoration and maintenance of salt and extracellular fluid levels or as a vehicle for the administration of parenteral drugs.

DOSAGE AND ADMINISTRATION

To be used as directed by a physician.
Parenteral drug products should be inspected prior to administration for particulate matter and discolouration.

Dosage is dependant on the age, weight, clinical and fluid/electrolyte condition of the patient. Adult requirements are usually fulfilled by daily IV infusion of 1L 0.9% Sodium Chloride solution.

Sodium Chloride Injection 0.9% provides a source of sodium ions (154 mmol/L), chloride ions (154 mmol/L) and water.

**CONTRAINDICATIONS**

- congestive heart failure
- severe renal impairment
- conditions of sodium retention and oedema
- liver cirrhosis
- irrigation during electrosurgical procedures

**WARNINGS AND PRECAUTIONS**

- Solutions containing sodium chloride should be used cautiously in patients with cardiovascular diseases such as congestive heart failure, hypertension, impaired renal function or renal disease such as urinary tract obstruction, pregnancy associated hypertension, pulmonary or peripheral oedema, hypoproteinaemia, those receiving corticosteroids or corticotrophin or any condition associated with sodium retention. Congestive heart failure and pulmonary oedema may be precipitated, particularly in patients with cardiovascular disease or those receiving corticosteroids, corticotrophin or other drugs that may give rise to sodium retention.
- Sodium chloride solutions should be used with caution in geriatric patients and infants.
- Excessive administration of sodium chloride solution may result in hypokalaemia and acidosis resulting in dehydration of internal organs. Monitoring of fluid, electrolyte and acid-base balance may be necessary.
- When used as a vehicle for intravenous drug delivery, the Data Sheet of such drugs should be checked prior to use to ensure compatibility with the sodium chloride solution. Reconstitution instructions should be read carefully.
- Do not use unless the solution is clear. The entire contents of the vial or ampoule should be used promptly.
- Intravenous infusion during or immediately after surgery may result in sodium retention.
**Pregnancy and Lactation**

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

Safety in lactation has not yet been established. Use of this product whilst breastfeeding is recommended only when potential benefits outweigh potential risks to the newborn.

**Effects on ability to drive and use machinery**

Presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

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**ADVERSE EFFECTS**

- Thrombophlebitis may occur at the injection site during prolonged infusions.
- Excess IV administration may cause hypernatraemia, hypokalaemia, or acidosis.
- If any adverse reactions are observed during administration, discontinue treatment and institute appropriate supportive treatment.
- Hypernatraemia rarely occurs with therapeutic doses of sodium chloride, but may occur in excessive administration. A serious complication of this is dehydration of the brain causing somnolence and confusion, which may progress to convulsions, coma and ultimately respiratory failure and death. Other symptoms include thirst, reduced salivation and lachrymation, fever, tachycardia, hypertension, headache, dizziness, restlessness, weakness and irritability.

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**INTERACTIONS**

- Additives may be incompatible with sodium chloride.
- Do not store solutions containing additives unless compatibility has been proven.
- Do not administer such preparations unless the solution is clear.
- Co-administration of drugs inducing sodium retention may exacerbate any systemic effects.

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**OVERDOSAGE**

**Symptoms**

Excess Sodium Chloride within the body may produce the following general gastrointestinal effects: nausea, vomiting, diarrhoea and cramps.

Salivation and lacrimation are reduced, whilst thirst and swelling are increased.
Possible other symptoms include hypotension, tachycardia, renal failure, peripheral and pulmonary oedema and respiratory arrest.

Symptoms of the CNS include headache, dizziness, irritability, restlessness, weakness, muscle twitching or rigidity, convulsions, coma and death.

**Treatment**

Normal plasma sodium concentrations should be restored at no more than 10 – 15 mmol/day with IV hypotonic saline. Dialysis may be required if there is renal impairment, if plasma sodium levels are greater than 200 mmol/L or if the patient is moribund. Convulsions should be treated with diazepam

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**PHARMACEUTICAL PRECAUTIONS**

**Instructions for Use/Handling**

Use once only and discard any remaining portion.

**Shelf life**

2 years

Sodium Chloride Injection BP 0.9% 5mL Steriluer® ampoule (50s).

Sodium Chloride Injection BP 0.9% 10mL Steriluer® ampoule (50s) & (600s).

3 years

Sodium Chloride Injection BP 0.9% 20mL Steriamp® ampoule (30s).

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**MEDICINE CLASSIFICATION**

General Sales Medicine.

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**PACKAGE QUANTITIES**

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Sodium Chloride Injection BP 0.9% 20mL Steriamp® ampoule (30s).
FURTHER INFORMATION

*Molecular Formula*
NaCl

*Molecular Weight*
58.44

*CAS Number*
7647-14-5

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15 August 2012