PRODUCT INFORMATION

SODIUM CHLORIDE INJECTION 0.9% BP
SODIUM CHLORIDE INTRAVENOUS INFUSION 0.9% BP (sodium chloride)

NAME OF THE MEDICINE

Sodium Chloride

The molecular formula is NaCl and the molecular weight is 58.44.

CAS Number: 7647-14-5

DESCRIPTION

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

Sodium Chloride Injection and Sodium Chloride Intravenous Infusion are sterile, isotonic, preservative-free solutions containing Sodium Chloride 0.9% in Water for Injections.

PHARMACOLOGY

Pharmacodynamics

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.

CONTRAINDICATIONS

- congestive heart failure
- severe renal impairment
- conditions of sodium retention and oedema
- liver cirrhosis

- irrigation during electrosurgical procedures

PRECAUTIONS

- Solutions containing sodium chloride should be used cautiously in patients with cardiovascular diseases such as congestive heart failure, hypertension, impaired renal function or other 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 Product Information document 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.

Use in Pregnancy:

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

Use in Lactation

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.

Genotoxicity

The active ingredients sodium and chloride are not mutagenic.

Carcinogenicity

The active ingredients sodium and chloride are not carcinogenic. They are basic cellular components.

INTERACTIONS WITH OTHER MEDICINES

- 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.

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.

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 1 L 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.

OVERDOSAGE

Symptoms:

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

Salivation and lacrimination 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 200mmol/L or if the patient is moribund. Convulsions should be treated with diazepam.

PRESENTATION AND STORAGE CONDITIONS

Presentation

Sodium Chloride Injection BP 0.9% 5 mL Steriluer® ampoule (50s), AUST R 49272

Sodium Chloride Injection BP 0.9% 10 mL Steriluer® ampoule (50s), AUST R 49278

Sodium Chloride Injection BP 0.9% 10 mL Steriluer® ampoule (5s, 600s), AUST R 49278 (Available in Australia only)

Sodium Chloride Injection BP 0.9% 20 mL Steriamp® ampoule (30s), AUST R 49279

Sodium Chloride Intravenous Infusion BP 0.9% 50 mL Plastic Vial (10s). (Available in Australia only), AUST R 10804

Sodium Chloride Intravenous Infusion BP 0.9% 100 mL Plastic Vial (10s), AUST R 49280

Storage

Store below 25°C.

Use once only and discard any remaining portion.

The expiry date (month/year) is stated on the package after EXP.

NAME AND ADDRESS OF THE SPONSOR

Sponsor

Pfizer Australia Pty Ltd
A.B.N. 5000 8422 348
38-42 Wharf Road
WEST RYDE NSW 2114

Manufacturer

Pfizer (Perth) Pty Limited
ABN 32 051 824 956
15 Brodie Hall Drive,
Bentley WA 6102 Australia

POISON SCHEDULE OF THE MEDICINE

Unscheduled (Australia)

DATE OF APPROVAL

3rd July 2000

DATE OF MOST RECENT AMENDMENT

27 June 2012