AUSTRALIAN PRODUCT INFORMATION – SODIUM CHLORIDE 0.9% (SODIUM CHLORIDE) INJECTION BP
SODIUM CHLORIDE 0.9% (SODIUM CHLORIDE) INTRAVEOUS INFUSION BP

1. NAME OF THE MEDICINE

Sodium chloride

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride Injection BP 0.9% 5 mL ampoule contains sodium chloride 45 mg per 5 mL.

Sodium Chloride Injection BP 0.9% 10 mL ampoule contains sodium chloride 90 mg per 10 mL.

Sodium Chloride Injection BP 0.9% 20 mL ampoule contains sodium chloride 180 mg per 20 mL.

Sodium Chloride Intravenous Infusion BP 0.9% 50 mL vial contains sodium chloride 450 mg per 50 mL.

Sodium Chloride Intravenous Infusion BP 0.9% 100 mL vial contains sodium chloride 900 mg per 100 mL.

For the full list of excipients, see Section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Sodium Chloride Injection: Solution for injection.

Sodium Chloride Intravenous Infusion: Injection for intravenous infusion.

Sodium Chloride Injection and Sodium Chloride Intravenous Infusion are sterile, isotonic, preservative-free solutions.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Dose and method of administration

To be used as directed by a physician.

Parenteral drug products should be inspected prior to administration for particulate matter and discolouration.

Dosage

Dosage is dependent 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.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

- 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 hypernatraemia, 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 hepatic impairment

See section 4.3 Contraindications and section 4.4 Special warnings and precautions for use.

Use in renal impairment

See section 4.3 Contraindications and section 4.4 Special warnings and precautions for use.

Use in the elderly

Sodium chloride solutions should be used with caution in geriatric patients.

Paediatric use

Sodium chloride solutions should be used with caution in infants.

Effects on laboratory tests

No data available.

4.5 Interactions with other medicines and other forms of 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.

4.6 Fertility, pregnancy and lactation

Effects on fertility

No data available.

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.

4.7 Effects on ability to drive and use machines

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Adverse effects (undesirable 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.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 Overdose

Symptoms of overdose:

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 of overdose:

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.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

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.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

Genotoxicity

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

Carcinogenicity

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

See section 4.4 Special warnings and precautions for use, and section 4.5 Interactions with other medicines and other forms of interactions.

6.3 Shelf life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 Special precautions for storage

Store below 25°C.

Use once only and discard any remaining portion.

6.5 Nature and contents of container

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

Sodium Chloride Injection BP 0.9% 10 mL Steriluer® ampoule (5s, 50s, 600s), AUST R 49278

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), AUST R 10804

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

Not all presentations may be available.

6.6 Special precautions for disposal

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 Physicochemical properties

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

Chemical structure

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

CAS number

7647-14-5

7. MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

8. SPONSOR

Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000
Toll Free Number: 1800 675 229
www.pfizer.com.au

9. DATE OF FIRST APPROVAL

03 July 2000

10. DATE OF REVISION

17 August 2021

Summary Table of Changes

Section changed	Summary of new information
3, 4.2, 4.3, 4.9, 5.2, 5.3, 6.3, 6.5, 7, 9	Minor editorial changes.

4.4	Addition of hypernatraemia following excessive administration of sodium chloride solution.