NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Sodium Chloride Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium chloride 0.9% B.P

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for Injection and Infusion

Sodium Chloride Injection is a sterile, isotonic, preservative-free solution.

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 is dependent 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.

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

Instructions for Use/Handling

Use once only and discard any remaining portion.

- 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 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 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 ampoule should be used promptly.
- Intravenous infusion during or immediately after surgery may result in sodium retention.

4.5 Interaction with other medicines and other forms of interaction

- 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

Fertility

No data available.

Pregnancy

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

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 machinery

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

4.8 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 of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

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 advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

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.

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.

Reproductive and developmental toxicity

No data available.

6. PHARMACEUTICAL PARTICUALRS

6.1 List of excipients

Water for Injections BP

6.2 Incompatibilities

No data available.

6.3 Shelf life

2 years

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

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

3 years

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

6.4 Special precautions for storage

Store at or below 25°C.

6.5 Nature and contents of container

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

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

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

6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

General Sale Medicine.

8. SPONSOR

LumaCina New Zealand
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9. DATE OF FIRST APPROVAL

13 October 1988

10. DATE OF REVISION OF THE TEXT

18 September 2023

Summary table of changes

Section changed	Summary of new information

6.3, 6.5	Minor editorial updates
8	Update sponsor’s details