NEW ZEALAND DATA SHEET

1 SODIUM CHLORIDE INJECTION BP 0.9%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Sodium Chloride Injection BP 0.9% is a sterile, preservative-free solution, pH 4.5-7.0 containing sodium chloride 0.9% in Water for Injections.

For full list of excipients see section 6.2

3 PHARMACEUTICAL FORM

Solution for Injection

4 CLINICAL PARTICULARS

4.1 THERAPUTIC INDICATIONS

Sodium Chloride Injection BP 0.9% can be used as the vehicle for many parenteral drugs and as an electrolyte replenisher for maintenance or replacement of deficits of extracellular fluid. It can also be used as a sterile irrigation medium.

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. Sodium Chloride Injection BP 0.9% does not contain any antimicrobial preservatives. Care should be taken with intravenous technique to avoid injection site reactions and infections.

Dosage is dependant on the age, weight, clinical and fluid/electrolyte condition of the patient.

4.3 CONTRAINDICATIONS

Congestive heart failure
Severe renal impairment
Conditions of sodium retention and oedema
Liver cirrhosis

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Solutions containing sodium chloride should be used cautiously in patients with cardiovascular or renal disease, pregnancy associated hypertension, pulmonary or peripheral oedema, those receiving corticosteroids or corticotrophin or any condition associated with 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, resulting in dehydration of internal organs, hypokalaemia and acidosis. 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.

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-medication of drugs inducing sodium retention may exacerbate any systemic effects.

4.6 FERTILITY, PREGNANCY AND LACTATION

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.

Carcinogenicity, mutagenicity, impairment of fertility
The active ingredients sodium and chloride are not carcinogenic or mutagenic. They are basic cellular components.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

There is no information on the effects of 0.9% Sodium Chloride on the ability to operate an automobile or other heavy machinery.

4.8 UNDESIRABLE EFFECTS

Proper use of normal saline as a vehicle for parenteral drugs or as an electrolyte replacement therapy is unlikely to result in adverse effects.
If any adverse reactions are observed during administration, discontinue treatment and institute appropriate supportive treatment.
Thrombophlebitis may occur at the injection site during prolonged infusions.
Excess intravenous administration of sodium chloride may cause hypernatraemia, hypokalaemia and acidosis.
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 OVERDOSGE

Symptoms of overdosage:

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 of overdosage:

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 131126 (Australia) or 0800 764 766 (New Zealand).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Sodium Chloride Injection BP 0.9% provides a source of sodium ions (154 mmol/L), chloride ions (154 mmol/L) and water. With an osmolarity of approx. 308 mosmol/L, the product is isotonic, and therefore designated as physiological sodium chloride solution.

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 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

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

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injection

6.2 INCOMPATIBILITIES
Additives may be incompatible with sodium chloride.

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

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store below 25°C. For use in one patient on one occasion only. Discard any remaining portion.

6.5 NATURE AND CONTENTS OF CONTAINER
AUST R 197200 Sodium Chloride Injection BP 0.9% 5 mL ampoule (20's)
AUST R 197198 Sodium Chloride Injection BP 0.9% 10 mL ampoule (20's, 50's)
AUST R 197199 Sodium Chloride Injection BP 0.9% 20 mL ampoule (20's)

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE
Australia: Unscheduled
New Zealand: General Sale Medicine

8 SPONSOR
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9 DATE OF FIRST APPROVAL
18/9/2014

10 DATE OF REVISION OF TEXT
21/03/2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
	New Data Sheet format