NEW ZEALAND DATA SHEET

1 SODIUM CHLORIDE 0.9% FREEFLEX

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Sterile isotonic solution of sodium chloride 9g/L in Water for Injections, containing no preservatives (normal saline).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Infusion for solution

4 CLINICAL PARTICULARS
4.1 Therapeutic Indications
Normal saline 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
The dosage of sodium chloride as a vehicle for parenteral drugs and as an electrolyte replenisher must be calculated after consideration of clinical and laboratory data.

For use in one patient, on one occasion only. It does not contain antimicrobials. Any unused portion should be discarded. Care should be taken with intravenous technique to avoid injection site reactions and infections

4.3 Contraindications
Sodium Chloride 0.9% is contraindicated in patients with congestive heart failure, severe renal impairment, conditions of sodium retention, oedema, liver cirrhosis and irrigation during electrosurgical procedures.

4.4 Special Warnings and Precautions for Use
Do not use unless the solution is clear. The entire contents of the bag should be used promptly.

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.

Excessive administration of sodium chloride causes hypernatraemia, resulting in dehydration of internal organs, hypokalaemia and acidosis. Monitoring of fluid, electrolyte and acid/base balance may be necessary. 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 should be administered with care to patients with congestive heart failure, hypertension, peripheral or pulmonary oedema, hypoproteinaemia, impaired renal function, urinary tract obstruction, pre-eclampsia and very young or elderly patients. Intravenous infusion during or immediately after surgery

may result in sodium retention. Given that there is a possibility of systemic absorption of irrigation solutions, the same precautions apply.

Paediatric Use
In paediatric use, the dose should be calculated for each patient based on clinical condition, including body weight and laboratory data.

Use in Elderly
For use in elderly, the dose should be based on individual patient assessment, including weight, fluid and electrolyte status and renal and cardiac function.

4.5 Interaction with other medicines and other forms of interaction

Additives may be incompatible with sodium chloride.
Co-medication of drugs inducing sodium retention may exacerbate any systemic effects.

4.6 Fertility, pregnancy and lactation

Fertility
There is no fertility data presented.

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 while breastfeeding is recommended only when potential benefits outweigh potential risks to the newborn infant.

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

Excessive amounts of sodium chloride may cause hypernatraemia, hypokalaemia and acidosis. Proper use of normal saline as a vehicle for parenteral drugs or as an electrolyte replacement therapy is unlikely to result in adverse effects.

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. Pulmonary embolism or pneumonia may also result. Other symptoms include thirst, reduced salivation and lacrimation, fever, tachycardia, hypertension, headache, dizziness, restlessness, weakness and irritability.

Infusion of excess sodium chloride 0.9% solution may cause fluid overload or electrolyte imbalance. Intravenous administration of solutions may cause local reactions including pain, vein irritation and thrombophlebitis. Extravasation of solution may cause tissue injury.

If any adverse effects are observed during administration, discontinue infusion, evaluate the patient and institute appropriate supportive treatment.

Displaced catheters or drainage tubes can lead to irrigation or infiltration of unintended structures or cavities. Excessive volume or pressure during irrigation of closed cavities may result in distension or disruption of tissues. Inadvertent contamination from careless technique may transmit infection. Adverse effects resulting from irrigation of body cavities, tissues or indwelling catheters and tubes are usually avoidable when appropriate procedures are followed.

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
Infusion of excess intravenous fluid may cause hypervolaemia and electrolyte imbalances. Excess sodium chloride in the body produces general gastrointestinal effects of nausea, vomiting, diarrhoea and cramps. Salivation and lacrimation are reduced, while thirst and sweating are increased. Hypotension, tachycardia, renal failure, peripheral and pulmonary oedema and respiratory arrest may occur. CNS symptoms include headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. If any adverse effects are observed during administration, discontinue infusion, evaluate the patient and institute appropriate supportive treatment.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia) or 0800 764 766 (New Zealand).

Treatment
Normal plasma sodium concentrations should be carefully restored at a rate not greater than 10-15 mmol/day using I.V. hypotonic saline. Dialysis may be necessary if there is significant renal impairment, the patient is moribund or plasma sodium levels are greater than 200 mmol/L. Convulsions may require diazepam or other appropriate treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group:
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, IV SOLUTION ADDITIVES, ELECTROLYTE SOLUTIONS
ATC Code: B05XA03
Sodium Chloride Injection 0.9% provides a source of sodium ions (154 mmol/L), chloride ions (154 mmol/L) and water.

5.2 Pharmacokinetic properties
As 0.9% Sodium Chloride infusion solutions are directly administered to the systemic circulation by infusion, the bioavailability (absorption) of the active components is complete (100%).

5.3 Preclinical safety data
Studies with sodium chloride have not been performed to evaluate carcinogenic or mutagenic potential.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water of injection, q.s

6.2 Incompatibilities

Additives may be incompatible with sodium chloride.

6.3 Shelf life

Package	Contents	Shelf Life
Bag, plastic, Polyolefin freeflex Bag	**50 mL**	**24 months**
Bag, plastic, Polyolefin freeflex Bag	**100 mL**	**24 months**
Bag, plastic, Polyolefin freeflex Bag	**250 mL**	**36 months**
Bag, plastic, Polyolefin freeflex Bag	**500 mL**	**36 months**
Bag, plastic, Polyolefin freeflex Bag	**1000 mL**	**36 months**

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Freeflex bags -
50mL AUST R 144596
100mL AUST R 144609
250mL AUST R 144632
500mL AUST R 29745
1000mL AUST R 47400
*not all pack sizes may be marketed

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: Nil
New Zealand: General Sales Medicine

8 SPONSOR

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Australia
Telephone: (61-2) 9391 5555

Fresenius Kabi New Zealand Limited

60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892

9 DATE OF FIRST APPROVAL

10/9/2009

10 DATE OF REVISION OF THE TEXT

21/03/2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
	New Data Sheet format