

AUSTRALIAN PRODUCT INFORMATION – SODIUM CHLORIDE 0.9 % FREEFLEX (SODIUM CHLORIDE)

1 NAME OF THE MEDICINE

Sodium chloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

3 PHARMACEUTICAL FORM

Solution for Injection.

Clear, colourless liquid

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 and 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.

Use in the 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.

Paediatric use

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

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.

Co-medication 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 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

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)

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 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

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.

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.

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

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 sodium chloride intravenous preparations are directly administered to the circulation, the bioavailability of the components is 100 %.

Excretion

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 as well as hydrochloric acid and sodium chloride for pH adjustment.

6.2 Incompatibilities

Additives may be incompatible with sodium chloride.

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.

6.5 Nature and contents of container

Supplied in composite plastic laminate Freeflex bags and are available in packs of:

AUST R 144596 (40,60,65 and 70) x 50 mL bags

AUST R 144609 (40,50,55 and 60) x 100 mL bags

AUST R 144632 (20,30,35 and 40) x 250 mL bags

AUST R 29745 1 x 500 mL bag

AUST R 47400 1 x 1000 mL bag

*Not all pack sizes/ volumes may be marketed.

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

Chemical Structure

Molecular formula: NaCl

Molecular weight: 58.44

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

CAS number

7647-14-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Australia: Unscheduled

New Zealand: General Sales Medicine

8 SPONSOR

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080
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Telephone: (02) 9391 5555

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9 DATE OF FIRST APPROVAL

9 May 2005

10 DATE OF REVISION

18th October 2019

Summary table of changes

Section Changed	Summary of new information
All	New Format
5.1	Pharmacodynamic properties updated
5.3	Pre-clinical safety data updated