

AUSTRALIAN PRODUCT INFORMATION – SODIUM CHLORIDE 0.9% IRRIGATION SOLUTION (SODIUM CHLORIDE)

1. NAME OF THE MEDICINE

Sodium chloride

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL of Sodium Chloride 0.9% contains 9 mg of sodium chloride.

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

3. PHARMACEUTICAL FORM

Solution, irrigation

Sodium Chloride 0.9% Irrigation Solution is a clear, colourless, sterile, isotonic, and preservative-free solution for irrigation.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- during surgical procedures where an isotonic irrigation is required e.g. irrigation of body cavities, tissues or wounds, indwelling urethral catheters and surgical drainage tubes.
- dilution of medications prior to use in accordance with the product information for the medication being diluted e.g. to dilute inhalation solutions prior to nebulisation

4.2 Dose and method of administration

Sodium Chloride Irrigation Solution must not be administered by parenteral injection. The use of aseptic technique is essential when the irrigation solution is used for irrigation of body cavities, wounds and urethral catheters.

Dosage

Dosage of Sodium Chloride Irrigation Solution depends on the capacity or surface area of the structure to be irrigated and the nature of the procedure. When it is used as a diluent or vehicle for other drugs, the manufacturer's recommendations should be followed. Specialised references should be consulted for specific information on the compatibility of additives.

4.3 Contraindications

Sodium Chloride 0.9% Irrigation Solution should not be used for irrigation during electrosurgical procedures.

Sodium Chloride 0.9% Irrigation Solution should not be used for intravenous injection or injection by other usual parenteral routes.

Do not use unless the solution is clear and the seal is intact.

4.4 Special warnings and precautions for use

For external use only. Not for injection, for irrigation only.

Sodium Chloride 0.9% Irrigation Solution should generally not be used in conditions in which systemic absorption is likely to result. It is possible that an amount may enter the systemic circulation depending on the nature of the surgical procedure.

Systemic absorption of irrigation solutions may cause fluid and/or solute overload resulting in dilution of serum electrolytes, overhydration, congestive conditions or pulmonary oedema.

The risk of dilutional conditions is inversely proportional to the electrolyte concentration administered and the risk of solute overload and resultant congestive conditions with peripheral and/or pulmonary oedema is directly proportional to the electrolyte concentration administered.

Given the possibility of systemic absorption of irrigation solutions, Sodium Chloride 0.9% Irrigation Solution should be used with caution in patients with congestive heart failure, renal impairment, liver cirrhosis, or any condition characterised by sodium retention and oedema.

If adverse effects, overhydration or solute overload occurs with Sodium Chloride 0.9% Irrigation Solution, it should be discontinued, the patient closely evaluated and appropriate corrective therapy instituted, if necessary.

The contents of an opened container should be used promptly to minimise a possibility of bacterial growth or pyrogen formation. Discard the unused portion of irrigating solution, since no antibacterial agent has been added.

Use in hepatic impairment

Given the possibility of systemic absorption of irrigation solutions, Sodium Chloride 0.9% Irrigation Solution should be used with caution in patients with liver cirrhosis.

Use in renal impairment

Given the possibility of systemic absorption of irrigation solutions, Sodium Chloride 0.9% Irrigation Solution should be used with caution in patients with renal impairment.

Use in the elderly

No data available.

Paediatric use

No data available.

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 0.9% Irrigation Solution
- Product Information documents of intended medications for mixing should be checked beforehand to avoid incompatibility.
- Do not store Sodium Chloride 0.9% Irrigation Solution after mixing with any additives.
- Co-medication of drugs inducing sodium retention may exacerbate any systemic effects caused by this irrigation solution.

4.6 Fertility, pregnancy and lactation

Effects on fertility

No data available.

Use in pregnancy – Pregnancy Category A

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

Use in lactation

Safety in lactation has not been established. Use of this product whilst breast feeding is recommended only when potential benefits outweigh potential risks to the newborn.

Depending on the surgical procedure during which this product is used for irrigation, various amounts of sodium chloride may enter the systemic circulation. It is likely that the proportion of the systemically absorbed sodium and chloride ions would be subsequently excreted into milk.

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)

- 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.

- If a large quantity of Sodium Chloride 0.9% Irrigation Solution is absorbed during a surgical procedure, fluid overload and electrolyte disturbance may result. See Section 4.4 Special warnings and precautions for use and Section 4.9 Overdose.
- If an adverse reaction does occur, discontinue the administration of the irrigating solution, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

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

If poisoning occurs, contact a doctor or Poisons Information Centre.

Symptoms

While systemic overdose would be extremely rare when used as directed, excess sodium chloride in the body may produce gastrointestinal side-effects such as nausea, vomiting, diarrhoea and cramps. Salivation and lacrimation are reduced, whilst thirst is increased. Other possible symptoms include hypotension, tachycardia, headache, dizziness, weakness, muscle twitching or rigidity, peripheral and pulmonary oedema and respiratory arrest.

Treatment

Normal plasma sodium concentrations should be restored at a rate of no more than 10-15mmol/day using IV hypotonic saline. Dialysis may be required if there is renal impairment, if plasma sodium levels are greater than 200mmol/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 Chloride 0.9% Irrigation Solution exerts a mechanical cleansing action for sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters and surgical drainage tubes. It also acts as diluent or vehicle for other pharmaceutical preparations.

Sodium is the major cation of the 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 the maintenance of acid-base balance, isotonicity and electrodynamic characteristics of cells.

Clinical trials

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Genotoxicity

The active ingredients sodium and chloride are not mutagenic.

Carcinogenicity

The active ingredients sodium and chloride are not carcinogenic.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid

Sodium hydroxide

Water for injections

6.2 Incompatibilities

- Additives may be incompatible with Sodium Chloride 0.9% Irrigation Solution
- Product Information documents of intended medications for mixing should be checked beforehand to avoid incompatibility.
- Do not store Sodium Chloride 0.9% Irrigation Solution after mixing with any additives

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.

Single use only. Discard unused portion.

6.5 Nature and contents of container

Sodium Chloride 0.9% Irrigation Solution (sterile) is presented in 30 mL Steritube[®], pack of 30's. AUST R 11290

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

21 August 2001.

10. DATE OF REVISION

02 March 2020

Summary Table of Changes

Section changed	Summary of new information
All	All sections reformatted in line with the new form.

1; 2; 3; 4; 5; 6; & 8	Editorial
6.1	Excipients added
8	Sponsor details updated