SODIUM CHLORIDE 0.9%

(SODIUM CHLORIDE) SOLUTION FOR INJECTION

1 NAME OF THE MEDICINE

Sodium chloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains 9 mg sodium chloride equivalent to 0.15 mmol sodium ions and 0.15 mmol chloride ions.

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

3 PHARMACEUTICAL FORM

Sodium Chloride 0.9% is an isotonic solution for injection. pH 4.5 to 8.0. Osmolality of 296 mOsm/L.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Prophylaxis of heat prostration or muscle cramps, chloride deficiency due to diuresis or salt restriction, prevention or treatment of extracellular volume depletion.

Parenteral

Sodium Chloride 0.9% (isotonic) is used to restore sodium chloride losses; to dilute or dissolve drugs for intravenous (IV), intramuscular (IM), or subcutaneous (SC) use; flushing of IV catheters; extracellular fluid replacement; priming solution for haemodialysis; initiate and terminate blood transfusions so red blood cells will not haemolyse; metabolic alkalosis when there is fluid loss and mild sodium depletion.

Topical or irrigation

Relief of inflamed, dry, or crusted nasal membranes or as a topical irrigating or flush solution.

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.

Use in one patient on one occasion only and discard. Contains no antimicrobial preservative. Solutions containing visible, solid particles must not be used.

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

Do not use unless the solution is clear. The entire contents of the vial should be used immediately on opening. Do not store opened vials. Do not re-sterilise. Do not use on more than one patient.

Any solution remaining should be discarded.

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 or other drugs that may give rise to sodium retention.

Sodium chloride should be administered with care to patients with congestive heart failure, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia and very young or elderly patients.

Special concerns

Use with caution in CV, cirrhotic, or renal disease; in presence of hypoproteinaemia, hypervolemia, urinary tract obstruction, and CHF; in those with concurrent oedema and sodium retention and in patients receiving corticosteroids or corticotropin; and during lactation.

Use with caution in geriatric or postoperative clients with renal or CV insufficiency with or without CHF.

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 hepatic impairment

Use with caution in cirrhotic disease.

Use in renal impairment

Care should be taken in administering sodium chloride solutions to patients with renal impairment.

Use in the elderly

Sodium chloride should be administered with care in elderly patients.

Paediatric use

Sodium chloride should be administered with care in very young patients.

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

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)

Proper use of Normal Saline (0.9%) as a vehicle for parenteral drugs or as an electrolyte replacement is unlikely to result in adverse effects.

Mild Hypernatraemia. Symptoms include, thirst, reduced salvation and lachrymation, fever, tachycardia, hypertension, headache, dizziness, restlessness, irritability and weakness.

Hypernatremia. Excessive sodium chloride may lead to hypokalaemia and acidosis. Fluid and solute overload leading to dilution of serum electrolyte levels, CHF, over hydration, acute pulmonary oedema (especially in patients with cardiovascular disease or in those receiving corticosteroids or other drugs that cause sodium retention). Too rapid administration may cause local pain and venous irritation.

Postoperative intolerance of sodium chloride. Cellular dehydration, weakness, asthenia, disorientation, anorexia, nausea, oliguria, increased BUN levels, dissention, deep respiration.

Symptoms due to solution or administration technique. Fever, abscess, tissue necrosis, infection at injection site, venous thrombosis or phlebitis extending from injection site, local tenderness, extravasation, hypervolemia.

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.

Excessive administration of chloride ions can lead to a loss of bicarbonate with an acidifying effect.

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

Reporting suspected adverse reactions

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 http://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

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.

Treatment

Normal plasma sodium concentrations should be carefully restored at a rate not greater than 10-15 mmol/day using intravenous hypotonic saline. In mild cases, oral administration of water and restriction of sodium intake is sufficient. In more severe cases, 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 are to be treated with intravenous diazepam.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

The human body contains about 4 moles of sodium (about 92 g). About one third is found in the skeleton and approximately half is present in the extracellular fluid.

Sodium is the major cation of the body's extracellular fluid. It plays a crucial role in maintaining the fluid and electrolyte balance. Excess retention of sodium results in over hydration (oedema, hypervolemia), which is often treated with diuretics.

Abnormally low levels of sodium result in dehydration. The average daily requirement of salt is approximately 5 g.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Sodium chloride is well absorbed through the gastrointestinal tract (this is enhanced in the presence of glucose).

Distribution

Sodium is the major cation of the body's extracellular fluid.

Metabolism

No data available.

Excretion

Excess sodium is predominantly excreted by the kidney and small amounts are lost in the faeces and sweat.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Water for injections.

Hydrochloric acid and/or sodium hydroxide are used for pH adjustment.

The injection does not contain - preservative.

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).[1] The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

- Sodium Chloride 0.9% 10 mL ampoule (AUST R 78928) - Store below 30ºC.
- Sodium Chloride 0.9% 50 mL vial (AUST R 11975) - Store below 25°C.
- Sodium Chloride 0.9% 100 mL vial (AUST R 48349) - Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

- Sodium Chloride 0.9% 50 mL glass vial is supplied in a carton containing 10 vials.
  Phebra product code - INJ069

- Sodium Chloride 0.9%** 100 mL glass vial is supplied in a carton containing 10 vials.
  Phebra product code - INJ072

- Sodium Chloride 0.9% 10 mL ampoule is supplied in a carton containing 10 ampoules.
  Phebra product code - INJ061

Not all presentations may be marketed.

The vial stopper is not made with natural rubber latex.

** Injection/Irrigation solutions have a flip off/tear off top on the sterile vial.

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

Structural Formula*:* NaCl.

The molecular weight of the compound is 58.44

CAS number

7647-14-5.

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled

[1] AUST R 78928, AUST R 11975, AUST R 48349.

8 SPONSOR

Phebra[2] Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.
Telephone: 1800 720 020

9 DATE OF FIRST APPROVAL

Sodium Chloride 0.9% 10 mL ampoule (AUST R 78928): 02 Jul 2001
Sodium Chloride 0.9% 50 mL vial (AUST R 11975): 13 Aug 1991
Sodium Chloride 0.9% 100 mL vial (AUST R 48349): 23 May 1994

10 DATE OF REVISION

29 Jun 2021

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
Title, header, and footer	Update dosage form to 'solution for Injection'.
3	Minor editorial change for better readability. pH range has been updated from 4.5-7.0 to 4.5-8.0 based on stability data. Osmolality added in alignment with the TGO 91 guideline.
4.1	Minor editorial change for better readability.
5.3	Bold 'Carcinogenicity' subtitle.
6.1	Updated as per ARTG records. Minor editorial change.
6.4	Minor editorial change for better readability.
6.5	Minor editorial change for better readability.
9	Minor editorial change for better readability.

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