SODIUM CHLORIDE 20% AND 23.4%

(SODIUM CHLORIDE) CONCENTRATED INJECTION FOR INFUSION

1 NAME OF THE MEDICINE

Sodium chloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of Sodium Chloride 20% contains 200 mg of sodium chloride which is equivalent to 3.4 mmol of sodium ions and 3.4 mmol of chloride ions.

Each mL of Sodium Chloride 23.4% contains 234 mg of sodium chloride which is equivalent to 4.0 mmol of sodium ions and 4.0 mmol of chloride ions.

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

3 PHARMACEUTICAL FORM

Sodium Chloride 20% and 23.4% are hypertonic concentrated injections for infusion. pH 4.5 to 7.0. Dilute before use.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

As an additive to parenteral fluids in patients who have specific electrolyte needs for sodium or chloride ions.

As a sclerosing agent for small symptomatic varicose veins.

4.2 DOSE AND METHOD OF ADMINISTRATION

The dosage of sodium chloride as an additive in intravenous fluids must be calculated after consideration of clinical and laboratory data. The correct volume of sodium chloride 20% or 23.4% is then aseptically withdrawn and diluted to the required concentration by addition to an appropriate intravenous solution such as 5% glucose. The final solution should be administered within 4 hours.

Sclerotherapy

Inject required volume and concentration of hypertonic sodium chloride 20% or 23.4% into the affected vein and apply a compression bandage.

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.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Sodium Chloride 20% and 23.4% are hypertonic (concentrated) and **must be diluted before 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.

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.

Use in hepatic impairment

See Section 4.2 Contraindications.

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 to elderly patients.

Paediatric use

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

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Sodium Chloride 20% and 23.4% may be incompatible with other solutions and drugs. The product information document of each solution or drug should be checked prior to use to ensure compatibility with the sodium chloride solution.

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)

Proper use of hypertonic (concentrated) saline as an additive to parenteral fluids for electrolyte replacement is unlikely to result in adverse effects. Inadvertent administration of concentrated sodium chloride solutions may result in sudden hypernatraemia and potential complications such as somnolence, and confusion progressing to convulsions, cardiovascular shock, CNS disorders, extensive haemolysis, respiratory failure and cortical necrosis of the kidney.

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

Mild hypernatraemia: symptoms include thirst, reduced salivation and lachrymation, fever, tachycardia, hypertension, headache, dizziness, restlessness, irritability and weakness.

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 and 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

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 chloride is well absorbed through the gastrointestinal tract (this is enhanced in the presence of glucose). Excess sodium is predominantly excreted by the kidney and small amounts are lost in the faeces and sweat.

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

No data available.

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

About one third is found in the skeleton and approximately half is present in the 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 antimicrobial preservative.

6.2 INCOMPATIBILITIES

See Section 4.5 Interactions with Other Medicines and Other Forms of Interactions.

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 23.4% (AUST R 23119) - store below 30°C.

Sodium Chloride 20% (AUST R 23180) - store below 25°C.

Sodium Chloride 20% (AUST R 48630) - store below 30°C.

6.5 NATURE AND CONTENTS OF CONTAINER

- Sodium Chloride 23.4% is supplied in a 10 mL vial in a carton containing 10 vials.

  Phebra Product Code - INJ027.

- Sodium Chloride 20% (AUST R 23180) is presented in 10 mL vials.

  Phebra Product Code - INJ025.

- Sodium Chloride 20% (AUST R 48630) is presented in 50 mL vials.

  Phebra Product Code - INJ026.

Not all presentations may be marketed.

The vial stopper is not made with natural rubber latex.

[1] AUST R 23119; AUST R 23180; AUST R 48630;

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

The molecular weight of the compound is 58.44. The molecular formula is NaCl.

CAS number

7647-14-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled

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 23.4% (AUST R 23119): 14 October 1991

Sodium Chloride 20% 10 mL vials (AUST R 23180): 14 October 1991

Sodium Chloride 20% 50 mL vials (AUST R 48630): 09 June 1994

10 DATE OF REVISION

29 Jun 2021

[2] Phebra and the Phi symbol are both trademarks of Phebra Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.

PRODUCT INFORMATION
Sodium Chloride 20% and 23.4% concentrated injection for infusion

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
Title, header, and footer	Dosage form has been updated from '' concentrated injection'' to 'concentrated injection for infusion''.
2	Minor editorial update
3	Minor editorial update. **Dilute before use** has been added.
4.2	Minor editorial update
4.4	Minor editorial update
4.5	Minor editorial update
6.1	Updated as per ARTG records. Minor editorial update.
6.4	Minor editorial update
6.5	Minor editorial update
9	Minor editorial update