NAME OF THE MEDICINE

Sodium chloride

The molecular weight of the compound is 58.44 and the CAS registry number is 7647-14-5. The molecular formula is NaCl.

DESCRIPTION
Sterile hypertonic solution of sodium chloride BP in water for injections BP.

The injections contain no preservatives. pH 4.5 to 7.0.

Each mL of Sodium Chloride Concentrated Injection 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 Concentrated Injection 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.

PHARMACOLOGY
The human body contains about 4 moles of sodium (about 92g). 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.

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.

CONTRAINDICATIONS
- Congestive heart failure.
- Severe renal impairment.
- Conditions of sodium retention and oedema.
- Liver cirrhosis.

PRECAUTIONS
Sodium Chloride Concentrated Injections 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.

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

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 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.

**INTERACTIONS WITH OTHER MEDICINES**
Sodium Chloride Concentrated Injection 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.

**ADVERSE 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.

**DOSAGE AND 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% solution 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 solution 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.

**OVERDOSAGE**
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.

**PRESENTATION AND STORAGE CONDITIONS**

SODIUM CHLORIDE CONCENTRATED INJECTION 23.4% is presented in a 10 mL vial in a carton of 10.

Phebra Product Code: INJ027

AUST R 23119

*SODIUM CHLORIDE CONCENTRATED INJECTION 20% is presented in 10 mL vials (AUST R 23180), 50 mL vials (AUST R 48630) and 10 mL ampoules (AUST R 78930).

†Currently not marketed

SODIUM CHLORIDE CONCENTRATED INJECTION 23.4% (AUST R 23119) – store below 30°C

SODIUM CHLORIDE CONCENTRATED INJECTION 20% (AUST R 23180) - store below 25°C

SODIUM CHLORIDE CONCENTRATED INJECTION 20% (AUST R 48630) - store below 30°C

**NAME AND ADDRESS OF THE SPONSOR**

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**POISON SCHEDULE OF THE MEDICINE**

Not scheduled

_Date of first inclusion in the Australian Register of Therapeutic Goods (the ARTG)_

SODIUM CHLORIDE CONCENTRATED INJECTION 23.4% (AUST R 23119): 14 October 1991

SODIUM CHLORIDE CONCENTRATED INJECTION 20% 10 mL vials (AUST R 23180): 2 July 2001

SODIUM CHLORIDE CONCENTRATED INJECTION 20% 50 mL vials (AUST R 48630): 9 June 1994

SODIUM CHLORIDE CONCENTRATED INJECTION 20% 10 mL ampoules (AUST R 78930): 14 October 1991

_Date of most recent amendment:_ 17 May 2013

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