AUSTRALIAN PRODUCT INFORMATION

SODIUM CHLORIDE INJECTION 20%
(SODIUM CHLORIDE)

1 NAME OF THE MEDICINE
Sodium chloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
10 mL of clear, colourless, sterile, hypertonic solution for injection of pH 4.5 to 7.0 containing 2 g of sodium chloride.

Excipient with known effect: sodium hydroxide.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM
Injection concentrated. Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
As an additive to parenteral fluids in patients who have specific electrolyte needs.

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 The correct volume of sodium chloride 20% is then aseptically withdrawn and diluted to the required concentration by addition to an appropriate IV solution such as 5% dextrose. 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.

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 Injection 20% is hypertonic and must be diluted before use.
Do not use unless the solution is clear. The entire contents of the ampoule should be used promptly. 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, 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, hypoproteinæmia, impaired renal function, urinary tract obstruction, pre-eclampsia and very young or elderly patients.

**Use in renal impairment**
Sodium chloride should be administered with care to patients with impaired renal function.

**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 Injection 20% 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 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 hypertonic saline as an additive to parenteral fluids for electrolyte replacement is unlikely to result in adverse effects. Inadvertent administration of hypertonic sodium chloride
solutions may result in sudden hypernatraemia and potential complications such as cardiovascular shock, CNS disorders, extensive haemolysis and cortical necrosis of kidney.

A serious complication of hypernatraemia 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.

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

**Reporting of suspected adverse reactions**


### 4.9 Overdose

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

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 IV 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 are to be treated with IV diazepam.

### 5 PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

**Mechanism of action**

No data available.

**Clinical trials**

No data available.

#### 5.2 Pharmacokinetic properties

No data available.

#### 5.3 Preclinical safety data

**Genotoxicity**

No data available.
Carcinogenicity
No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Water for injection.
Sodium hydroxide and/or hydrochloric acid for pH adjustment.

6.2 Incompatibilities
Sodium Chloride Injection 20% 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.

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 30°C.

6.5 Nature and contents of container
10 mL polyethylene ampoules (Polyamp DuoFit®) in packs of 50.

6.6 Special precautions for disposal
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 Physicochemical properties
Chemical structure
NaCl
CAS number: 7647-14-5
Molecular weight: 58.44

7 MEDICINE SCHEDULE (POISONS STANDARD)
Unscheduled.

8 SPONSOR
AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone: 1800 805 342
9 DATE OF FIRST APPROVAL

13 AUG 1991

10 DATE OF REVISION

13 AUG 2018

Summary table of changes

<table>
<thead>
<tr>
<th>Section changed</th>
<th>Summary of new information</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>Conversion to new PI form. Change to Sponsor address.</td>
</tr>
</tbody>
</table>

Polyamp DuoFit® is a trade mark of the AstraZeneca group of companies.

© AstraZeneca 2018