Sodium Chloride Injection 20%
PRODUCT INFORMATION

NAME OF THE DRUG

Chemical Name: Sodium chloride
Empirical Formula: NaCl
Molecular Weight: 58.44
CAS registry number: 7647-14-5
Structure:

Na⁻Cl

DESCRIPTION

Sodium Chloride Injection 20% is a sterile hypertonic solution of sodium chloride in Water for Injections, pH 4.5 to 7.0, containing no preservatives.

INDICATIONS

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

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 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, **hypoproteinaemia*, impaired renal function, **urinary tract obstruction*, 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 whilst breastfeeding is recommended only when potential benefits outweigh potential risks to the newborn.

***Interactions with other drugs**
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.

ADVERSE REACTIONS

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*.

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% 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.

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 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.

PRESENTATION

Polyamp DuoFit®: 20% w/v, 10 mL x 50

STORAGE

Store below 30°C.

POISONS SCHEDULE

Unscheduled

NAME AND ADDRESS OF THE SPONSOR

AstraZeneca Pty Ltd
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Alma Road North Ryde
NSW 2113 Australia

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

19 February 1993
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* *Please note changes in Product Information*