SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sterile Sodium Chloride Concentrate BP 30% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains 300 mg Sodium Chloride BP.

3. PHARMACEUTICAL FORM

Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The product is used for rehydration only when diluted. Before administration, the concentrate must be diluted and thoroughly mixed with a larger volume of fluid.

4.2 Posology and method of administration

When concentrations of 3 and 5% w/v are indicated, the solution should be administered into a large vein, at a rate not exceeding 100 ml/hr.

Adults, children and the elderly

Concentration and sodium chloride dosage for intravenous use are determined by several factors including age, weight and clinical condition of the patient. The usual sodium and chloride requirements for adults can be satisfied by infusion of the equivalent of 1 litre of sodium chloride 0.9% w/v daily.

Sterile Sodium Chloride Concentrate BP 30% w/v should be sufficiently diluted to produce an isotonic (0.9% w/v) solution. An isotonic solution can

be prepared by the addition of 150mEq (60ml of a 2.5mEq/ml solution) to 925ml of non-electrolyte solution or water for injections.

Sodium Chloride 0.9% injections are often used as diluents for the infusion of drug additives, and 0.9% solutions of sodium chloride are widely used for sterile irrigation and dilution purposes.

4.3 Contraindications

Caution hypertonic solution, dilute before use.

4.4 Special warnings and precautions for use

Sodium chloride should be administered with caution to patients with congestive heart failure, peripheral or pulmonary oedema, impaired renal function, or pre-eclampsia. Care should also be taken when administering sodium chloride intravenously to very young or elderly patients. Excessive administration should be avoided as this may result in hypokalaemia.

Pseudohyponatraemia, a condition where spuriously low concentrations of sodium are found, occurs when a high concentration of solid matter (such as lipids and protein) are present in the plasma. This has been reported in patients with diabetes mellitus. False readings for plasma concentrations may be obtained as sodium is present only in the aqueous phase of plasma. Correct values are obtained by referring the concentration to plasma water, thus avoiding unnecessary, and possibly dangerous, treatment with sodium chloride.

Reject if solid particles are present.

4.5 Interactions with other medicinal products and other forms of interaction

Streptomycin sulphate is stated to be incompatible with sodium chloride.

4.6 Pregnancy and lactation

It is safe to use in pregnancy and lactation after risk assessment.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

General adverse effects of excess sodium chloride in the body include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lachrymation, sweating, fever, hypotension, tachycardia, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.

Infants may appear not to be severely dehydrated, but coma and convulsions may persist due to vascular injury. They may show respiratory distress with tachypnoea and flaring nostrils.

Intra-amniotic injection of hypertonic solutions of sodium chloride can lead to serious adverse effects including disseminated intravascular coagulation, renal necrosis, cervical and uterine lesions, haemorrhage, pulmonary embolism, pneumonia and death.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Excessive administration of sodium chloride causes hypernatraemia, the most serious effect of which is dehydration of internal organs, especially the brain, which may lead to thrombosis and haemorrhage.

Normal serum - sodium concentrations should be carefully restored at a rate not exceeding 10 to 15 mmol per day by administration of hypotonic saline solutions intravenously.

Dialysis may be necessary if there is a significant renal impairment, the patient is moribund, or if the serum - sodium concentration is greater than 200 mmol per litre. Serum electrolyte levels need to be monitored and any imbalance corrected.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium is the principal cation in the extracellular fluid and is the main osmotic component in the control of blood volume.

5.2 Pharmacokinetic properties

The body contains 40 to 60 mmol of sodium per kg body weight, approximately 40% of which is found in the skeleton. The normal concentration range for extracellular fluid is 135 to 154 mmol per litre. The intracellular sodium concentration is about 5 to 10 mmol per litre. There are between 0.1 to 1.0% chloride ions in the body, contained in extracellular fluid surrounding the nerve cell and in gastric juices. 0.6% is found in the urine.

5.3 Preclinical safety data

There are no additional data of significance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections BP
May contain hydrochloric acid or sodium hydroxide.

6.2 Incompatibilities

The addition of sodium chloride to mannitol 20 to 25% may cause precipitation of the mannitol.

6.3 Shelf life

3 years (36 month)

6.4 Special precautions for storage

Store at a temperature not exceeding 25°C.

6.5 Nature and contents of container

Glass ampoules containing 2 ml or 10 ml of solution. 10 ampoules are packed in a carton.

6.6 Instructions for use, handling and disposal

Caution hypertonic solution, dilute before use
Reject if solid particles are present

7 MARKETING AUTHORISATION HOLDER

Macarthys Laboratories Ltd.
T/A Martindale Pharmaceuticals
Bampton Road, Romford RM3 8UG.

8. MARKETING AUTHORISATION NUMBER

PL 01883/6158

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorised:	25 August 1988
Last renewed:	June 2004

10 DATE OF REVISION OF THE TEXT

10/02/2022