# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 30% w/v Concentrate for Solution for Infusion.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium chloride 300 mg per mL (5.13 mmol per mL)
The product is available as:
Sodium chloride 3 g /10 mL ampoules
Sodium chloride 15 g /50 mL vials.
Sodium chloride 30 g /100 mL vials.

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

Concentrate for solution for infusion.

The product is a sterile clear, colourless solution.

# 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 per hour.

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.

Sodium Chloride 30% w/v Concentrate for Solution for Infusion should be diluted sufficiently to obtain an isotonic (0.9% w/v) solution. An isotonic solution can be prepared by diluting 30 mL Sodium Chloride 30% w/v Concentrate for Solution for Infusion to 1 litre with a non-electrolyte solution or water for injections.

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

## 4.3 Contraindications

Caution: Sodium Chloride 30% w/v Concentrate for Solution for Infusion is a hypertonic solution, and should be diluted 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 may result in hypokalaemia and should be avoided.

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 condition has been reported in patients with diabetes mellitus. False reading 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, in order to avoid unnecessary, and possibly dangerous, treatment with sodium chloride.

Only use the solution if it is particle free.

## 4.5 Interaction with other medicinal products and other forms of interaction

See section 6.2. for streptomycin incompatibility.

## 4.6 Fertility, 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

The following general adverse effects may occur due to excess sodium chloride in the body: 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 such as 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 10-15 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

Pharmacotherapeutic group (ATC code): Electrolyte solutions B05X A03
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 – 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 – 154 mmol per litre. The intracellular sodium concentration is about 5 - 10mmol per litre.

There are between 0.1 - 1.0% chloride irons 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.

## 6.2 Incompatibilities

Streptomycin sulfate is stated to be incompatible with sodium chloride.
The addition of sodium chloride to mannitol 20 – 25% may cause precipitation of the mannitol.
As with all parental concentrate solutions, incompatibility of diluting fluids with the concentrate should be assessed before addition. In the absence of compatibility studies, this concentrate must not be mixed with other medicinal products.

## 6.3 Shelf life

3 years
Discard any unused solution immediately after first use.
From a microbiological point of view, the product should be used immediately. If not used immediately in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions.

## 6.4 Special precautions for storage

Store below 25°C.

### 6.5 Nature and contents of container

Colourless type 1 glass ampoules containing 10mL and colourless type 1 glass vials containing 50 mL and 100 mL of solution. Vials are closed with bromobutyl rubber stoppers and sealed with aluminium tamper-proof flip-top seals. The product is packed into cartons containing 10 ampoules, 1 vial or 10 vials. Both pack sizes of vials may not be available at the same time.

### 6.6 Special precautions for disposal

Sodium Chloride 30% w/v Concentrate for Solution for Infusion is a concentrate.

Once opened the product should be used immediately and any unused drug discarded.

This product must be diluted before administration (see section 4.2.).

## 7 MARKETING AUTHORISATION HOLDER

Torbay Pharmaceuticals Limited,
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## 8 MARKETING AUTHORISATION NUMBER(S)

PL 56021/0007

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd October 2004

## 10 DATE OF REVISION OF THE TEXT

24/10/2023