# 1 NAME OF THE MEDICINAL PRODUCT

Sterile Sodium Chloride 30% w/v Concentrate for solution for infusion.

# 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 300mg per ml

15 g in 50ml.

The solution is equivalent to approximately 5.13 mmol/ml of sodium ions.

The solution is equivalent to approximately 5.13 mmol/ml of chloride ions.

Excipients with known effect:

Sodium: This solution contains 118.15mg/ml of sodium

For the full list of excipients, see section 6.1.

# 3 PHARMACEUTICAL FORM

Concentrate for Solution for Infusion

Clear Colourless Solution

# 4 CLINICAL PARTICULARS

## 4.1 Therapeutic indications

Concentrated sodium chloride Infusion is used for rehydration only when diluted. Before administration, the concentrated sodium chloride infusion must be diluted and thoroughly mixed with a larger volume of fluid.

## 4.2 Posology and method of administration

Posology

When a concentration of 3 or 5% are indicated, the solutions should be administered into a large vein, at a rate not exceeding 100ml/hr.

Adults, Children and the elderly:

The infusion rate and volume depend on the age, weight, clinical condition (e.g. burns, surgery, head-injury, infections), and concomitant therapy should be determined by the consulting physician experienced in paediatric intravenous fluid therapy (see sections 4.4. and 4.8)

The concentration and dosage of sodium chloride solutions for intravenous use is determined by several factors including the age, weight and clinical condition of the patient.

The usual sodium chloride requirements for adults can be satisfied by infusion of the equivalent of 1L of sodium chloride 0.9% 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% 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.

Fluid balance, serum electrolytes and acid-base balance may need to be monitored before and during administration, with particular attention to serum sodium in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs, due to the risk of hospital acquired hyponatraemia (see sections 4.4, 4.5 and 4.8).

Method of administration

For intravenous use

For instructions on the dilution of the medicinal product before administration, see section 6.2.

## 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Caution hypertonic solution, dilute before use.

## 4.4 Special warnings and precautions for use

Caution hypertonic solution, dilute before use.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia (see below).

Hyponatraemia

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, cerebral contusion and brain oedema) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

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.

This medicinal product contains 118.15mg per ml equivalent to 5.9% of the WHO recommended maximum daily intake of 2g sodium for an adult.

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

Sodium-retaining drugs e.g. corticosteroids or carbenoxolone should not be given with this product

Drugs leading to an increased vasopressin effect

The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).

- Drugs stimulating vasopressin release include: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action include: Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues include: Desmopressin, oxytocin, vasopressin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

## 4.6 Fertility, pregnancy and lactation

Sterile sodium chloride 30% w/v concentrate for solution for infusion should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin (see section 4.4, 4.5 and 4.8).

Considerable caution must be exercised if used in pre-eclampsia.

## 4.7 Effects on ability to drive and use machines

Not applicable.

## 4.8 Undesirable effects

Excessive amounts of sodium may produce hypernatraemia i.e. an abnormally high sodium concentration in the blood, causing dehydration of the brain which causes somnolence and confusion progressing to convulsions, respiratory failure, coma and death.

Other symptoms may include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lachrymation, sweating, fever, tachycardia, hypertension, hypotension and also possible loss of bicarbonate with an acidifying effect on the body, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma, and death.

Also, excessive amounts of sodium may produce without hypernatraemia an increase in the total sodium and water content of the body associated with the expansion of the extra cellular fluid compartment (oedema) which may affect the cerebral, pulmonary or peripheral systems.

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 solution 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.

| Tabulated list of adverse reactions | | |
|---|---|---|
| System Organ Class | Adverse reaction (MedDRA term) | Frequency |
| Metabolism and nutrition disorders | Hospital acquired hyponatraemia* | Not known |
| Nervous system disorders | Acute hyponatraemic encephalopathy* | Not known |

*Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4)

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

Overdose can result from excessive intravenous administration or accidental ingestion of contents and 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.In the event of recent acute ingestion of sodium chloride, induction of emesis or gastric lavage should be carried out along with general symptomatic and supportive treatment.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

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.

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.

## 5.2 Pharmacokinetic properties

Sodium Chloride is well absorbed from the gastrointestinal tract. Sodium is predominately excreted by the kidney, but there is extensive renal reabsorption. Small amounts of sodium are lost in the faeces and sweat.

## 5.3 Preclinical safety data

No further data is available additional to that included in previous sections of the SPC.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Water for Injections.

## 6.2 Incompatibilities

The compatibility of Sodium Chloride with potential diluents should be confirmed before use.

Streptomycin sulfate is stated to be incompatible with sodium chloride.

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

As with all parenteral 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

24 months.

The contents of the vial should be used immediately after first opening.

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

Not Applicable

## 6.5. Nature and contents of container

50ml TYPE 1 CLEAR GLASS VIAL with A HALOBUTYL ELASTOMER RUBBER STOPPER and ALUMINIUM OVERSEAL

## 6.6 Special precautions for disposal

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

Solutions containing visible solid particles should not be used. Once opened the product should be used immediately and any unused drug discarded.

Do not use the product if the packaging is damaged.

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

## 7. MARKETING AUTHORISATION HOLDER

Aurum Pharmaceuticals Ltd

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RM3 8UG

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## 8. MARKETING AUTHORISATION NUMBER

PL 12064/0021

# 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/07/2000

Date of latest renewal: 11/10/2006

## 10 DATE OF REVISION OF THE TEXT

23/04/2021