Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium chloride 5 mmol/ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of oral solution contains 5mmol (292.2mg) of sodium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium chloride is indicated for the treatment of sodium chloride deficiency.

4.2 Posology and method of administration

Posology
The recommended dosing regimen has been empirically derived. It is therefore important that dosage selection should be adjusted according to the age, weight, the extent of sodium deficit and clinical condition of the patient.

Adults (including the elderly):
A typical oral replacement dose of sodium chloride in chronic salt-losing conditions is about 40-80 mmol (8ml-16ml) of sodium daily, given as divided doses. Serum sodium concentration in patients should be raised by not more than 10 mmol/L to 12mmol/L of body water during the first 24 hours of treatment or 18 mmol/L/48 hours should be observed.

Paediatric population
Dosage in children (1 month to 18 years) should be adjusted to individual's need.
Typically, children should receive 1-2mmol/kg (0.2-0.4ml/kg) in divided doses over a 24 hour period.
Neonates
Treatment with Sodium Chloride 5mmol/ml Oral Solution should only be initiated under the supervision of specialist paediatric physicians. Dosage should be adjusted if necessary according to clinical need and after plasma sodium monitoring.
3 to 5 mmol per kg daily in divided doses. Dosages can be adjusted according to patient requirements. Example dilutions are 2 mmol diluted in 100ml formula feed, or 3 to 4 mmol diluted in 100 ml breast milk.
Always ensure the product is added and thoroughly mixed into the drink, breast milk or formula feed immediately before administration.

Renal impairment
Dose adjustment may be necessary depending on the clinical condition of the patient and close monitoring of serum sodium levels.

Method of administration
For oral administration.
The oral solution may be diluted in a glass of water or baby's bottle.
Sodium chloride solutions should **not** be used to induce emesis as there is a danger of induction of hypernatraemia.

4.3 Contraindications

Sodium chloride is contraindicated in any situation where salt retention is undesirable, such as oedema, heart disease, cardiac decompensation and primary or secondary aldosteronism; or if you are taking medication that causes salt and water loss from the body.

4.4 Special warnings and precautions for use

Sodium Chloride should be administered with caution to patients with hypertension, heart failure, peripheral and pulmonary oedema, renal impairment, pre-eclampsia, if you are on a low salt diet or other conditions associated with sodium retention. Patients with the above mentioned conditions should be monitored frequently during the period of medication with Sodium chloride oral solution. In addition, care is also required when administering this solution to very young or elderly patients.

4.5 Interaction with other medicinal products and other forms of interaction

Lithium: Patients on salt-restricted diets who also receive lithium carbonate are prone todevelopment of lithium toxicity as the excretion of lithium appears to beproportional to the intake of sodium chloride. Lithium can interfere with the regulation of sodium and water levels in the body, and can cause dehydration. Conversely, increased sodiumintake can reduce both therapeutic response to lithium as well as its side effects.

Calcium: Urinary calcium excretion increases as dietary sodium chloride increases.

Drugs that decrease renal acid secretion by inhibiting carbonic anhydrase willincrease sodium excretion.

Atrial Natriuretic Peptide (ANP) causes an increase in glomerular filtration rate and a decrease in tubular reabsorption, leading to an increased renal excretion of sodium.

Insulin increases the activity of Na^+-K^+ ATPase so that more sodium is removed from cells into the ECF.

Aldosterone facilitates sodium transport from the intestine into the blood and increases the reabsorption of sodium from urine, sweat, saliva and gastric juices, leading to an increase in sodium concentration in the extracellular fluid.

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Sodium chloride is not expected to have an adverse effect on fertility, pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Injudicious saline therapy (e.g. post-operatively and in patients with impaired cardiac or renal function) may cause hypernatraemia. The most serious effects of hypernatraemia is caused by osmotically induced water shifts that decrease intracellular volume, resulting in dehydration of internal organs, especially the brain. Dehydration of the brain may cause somnolence and confusion, progressing to convulsions, coma, respiratory failure, and death.

The main safety concern associated with the treatment of hyponatraemia concerns over rapid and over correction of sodium serum levels. In such cases, there is an osmotic shift of water out of the body's cells, in the case of the brain leading to the uncommon but potentially life-threatening condition known as *osmotic demyelination syndrome* in which axonal damage occurring in characteristic pontine areas can give rise to features such as quadriparesis and cognitive changes. This syndrome is a serious, sometimes fatal demyelinating disorder of the central nervous system that all forms of sodium chloride: hypertonic saline, isotonic saline, sodium chloride given orally, and even water restriction alone, have been causally associated with it.

General adverse effects of sodium chloride excess in the body are as follows.

MedDRA System Organ Class	Frequency	Adverse Reaction
Gastrointestinal disorders	Not known*	Swollen tongue, nausea, vomiting, diarrhoea, abdominal cramps, thirst, and reduced salivation

Nervous system disorders	Not known*	Irritability, headache, dizziness, weakness, convulsions and coma
Eye disorders	Not known*	Reduced lacrimation
Cardiac disorders	Not known*	Tachycardia, cardiac failure
Vascular disorders	Not known*	Hypertension, hypotension
General disorders and administration site conditions	Not known*	Fever, sweating, restlessness, irritability, weakness, muscular twitching and rigidity

*Frequency cannot be estimated from the available data

Administration of large doses may give rise to sodium accumulation, oedema, and hyperchloraemic acidosis.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Signs and symptoms
Retention of excess sodium in the body usually occurs when there is defective renal sodium excretion. This leads to the accumulation of extracellular fluid to maintain normal plasma osmolality, which may result in pulmonary and peripheral oedema and their sequelae. Hypernatraemia (a rise in plasma osmolality) rarely occurs after therapeutic doses of sodium chloride, but may occur after inappropriate/injudicious administration of hypertonic saline. The most serious effect of hypernatraemia is dehydration of the brain which causes somnolence and confusion progressing to convulsions, coma, respiratory failure and death. Other symptoms include thirst, reduced salivation and lacrimation, fever, tachycardia, hypertension or hypotension, headache, dizziness, restlessness, irritability, weakness and muscular twitching and rigidity.

Treatment.
Treatment requires the use of sodium-free liquids and the cessation of excessive sodium intake. In the event of a significant overdose serum sodium levels should be evaluated as soon as possible and appropriate steps taken to correct any abnormalities. The use of a loop diuretic e.g. frusemide (with potassium supplementation as required) may be appropriate in severe cases of hypernatraemia. Levels should be monitored until they return to normal.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaceutical group: Other mineral supplements, sodium.
ATC Code: A12CA01

Mode of action: Sodium chloride is the principle salt involved in maintaining the osmotic tension of blood and tissues. Changes in osmotic tension influence the movement of fluids and diffusion of salts in cellular tissue.

Sodium chloride 5mmol/ml oral solution provides a source of sodium (in the form of sodium chloride) where a deficiency exists.

5.2 Pharmacokinetic properties

Absorption
Sodium chloride is readily absorbed from the gastro-intestinal tract.

Distribution
It is present in all body fluids but specially in the extracellular fluid.

Metabolism
Sodium chloride is not significantly metabolised.

Elimination
Excess sodium is mainly excreted by the kidney, and small amounts are excreted in the faeces and sweat.

Linearity/non-linearity
Osmotic balance is maintained by excretion of surplus amounts in the urine.

5.3 Preclinical safety data

No further relevant information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

12 months
Discard 07 days after first opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Bottle: Amber PET bottles

Closure: Tamper-evident, child-resistant plastic cap consists of polypropylene inner, polyethylene outer and expanded polyethylene (EPE) liner.

Pack size: 100ml

Dosing Device:
100ml bottle containing 1ml polypropylene oral syringe with 0.01ml graduation marks and an adaptor for the syringe.

100ml bottle containing 4ml oral pipette with 01ml graduation marks.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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1 WML
1 Windmill Lane
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8 MARKETING AUTHORISATION NUMBER

PA22697/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th November 2018
Date of last renewal: 29th September 2023

10 DATE OF REVISION OF THE TEXT

April 2023