Sodium Chloride 1 mmol/ml Oral Solution

Summary of Product Characteristics Updated 23-Jun 2015 | Viridian Pharma Ltd

1. NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 1 mmol/ml Oral Solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains 1 mmol (58.44 mg) of sodium chloride.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Solution
Clear and colourless

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Correction of mild to moderate hyponatraemia in infants.

4.2. Posology and Method of Administration

Warning: This product must be diluted in drinks, breast milk or formula feed before administration.

Treatment with Sodium Chloride 1 mmol/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.

Infants:

3 to 5 mmol (3 to 5 ml of Sodium Chloride 1mmol/ml Oral Solution) per kg daily in divided doses. Dosages can be adjusted according to patient requirements. Example dilutions are 2 mmol (2 ml) diluted in 100ml formula feed, or 3 to 4 mmol (3 to 4 ml) 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.

4.3. Contraindications

Hypersensitivity to sodium chloride or to any of the excipients listed in section 6.1.

Sodium Chloride 1 mmol/ml Oral Solution is contraindicated in any situation where salt retention is undesirable, such as oedema, heart failure and

aldosteronism. Sodium Chloride 1 mmol/ml Oral Solution should not be administered to patients with intestinal obstruction.

During the first few days after birth, there is a physiological reduction of extracellular fluid volume as the infant adjusts to extra-uterine life. Hyponatraemia in this situation may reflect water retention rather than sodium deficiency, and treatment should be undertaken by monitoring and adjustment of water balance rather than administration of sodium chloride.

4.4. Special Warnings and Precautions for Use

For oral or enteral administration only.

Warning: This product must be diluted in drinks, breast milk or formula feed before administration.

Care should be taken when administering in conditions where normal electrolyte balance may be disturbed. These include co-existing hepatic or renal impairment, additional sodium loss through diuretic therapy, or additional sodium intake through other sources e.g. medication or intravenous fluids.

4.5 Interactions with other Medicinal Products and other forms of Interaction

None stated.

4.6. Fertility, Pregnancy and Lactation

Pregnancy: No adverse effects during pregnancy are anticipated.
Breast-feeding: No adverse effects during breast feeding are anticipated.
Fertility: Sodium chloride is not expected to have an adverse effect on fertility.

4.7. Effects on Ability to Drive and Use Machines

Sodium Chloride 1 mmol/ml Oral Solution would not be expected to affect the ability to drive or use machines.

4.8. Undesirable Effects

Paediatric population

Hypernatremia is an adverse outcome associated with excessive sodium chloride intake. A major symptom of hypernatremia is thirst, which is not always obvious in young infants. Other clinical manifestations are neurologic, due to an osmotic shift of water out of brain cells. Patients may exhibit lethargy, weakness, irritability, confusion, or neuromuscular excitability. In more extreme cases this can lead to seizures and coma.

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.yellowcard.mhra.gov.uk

4.9 Overdose

In the event of significant overdose, serum electrolytes should be evaluated as soon as possible, appropriate steps taken to correct any abnormalities and levels monitored until return to normal levels is established.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Mineral supplements, ATC Code: A12CA

Sodium chloride maintains the osmotic tension of the blood and tissues.

5.2. Pharmacokinetic Properties

Oral or enteral sodium chloride is actively transported across gastro-intestinal membranes. It is widely distributed in extracellular and intracellular fluids. In infancy, it is mainly eliminated in the urine.

5.3. Preclinical Safety Data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Potassium sorbate (E202)
Citric acid (E330)
Purified water

6.2. Incompatibilities

None known

6.3. Shelf Life

2 years.

The product may be used for up to 1 month from first opening.

6.4. Special Precautions for Storage

Keep bottle in outer carton.

6.5. Nature and Contents of Container

Amber glass bottle with polypropylene screw cap and LDPE liner. The bottle is packed in a cardboard carton containing a 5ml oral syringe with an adaptor together with the patient information leaflet.

Pack Size: 100 ml

6.6. Special Precautions for Disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Viridian Pharma Ltd, Yew Tree House, Hendrew Lane, Llandevaud, Newport, Gwent NP18 2AB

8. MARKETING AUTHORISATION NUMBER

PL 20346/0008

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18th February 2015

10. DATE OF REVISION OF THE TEXT

23nd June 2015

COMPANY CONTACT DETAILS

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