SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Slow Sodium
Sodium Chloride ALTURiX 600 mg Prolonged-release Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains 600mg of sodium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet.
White, round, biconvex tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment and prophylaxis of sodium chloride deficiency.

4.2 Posology and method of administration

Posology

Adults: For prophylaxis 4-8 tablets per day. For treatment dosage should be adjusted to individual needs up to a maximum of 20 tablets per day in cases of severe salt depletion. For control of muscle cramps during routine maintenance haemodialysis usually 10-16 tablets per dialysis. In some cases of chronic renal salt-wasting up to 20 tablets per day may be required with appropriate fluid intake.

Children: Dosage should be adjusted to individual needs.

Elderly: No special dosage adjustment.

Method of administration
It is important that the tablets should be swallowed whole with water (approx. 70ml per tablet where kidney function is normal to avoid hypernatraemia), and not chewed.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Any situation where salt retention is undesirable, such as oedema, heart disease, cardiac decompensation and primary or secondary aldosteronism; or where therapy is being given to produce salt and water loss.

4.4 Special warnings and precautions for use

Warnings: None

Precautions: Administration of sodium chloride without adequate water supplementation can produce hypernatraemia.

The matrix (ghost) is often eliminated intact and owing to the risk of obstruction, Slow Sodium / Sodium Chloride ALTURiX should not be given to patients suffering from Crohn's disease or any other intestinal condition where strictures or diverticula may form.

4.5 Interaction with other medicinal products and other forms of interaction

In hypertensive patients with chronic renal failure, sodium chloride may tend to impair the efficacy of antihypertensive drugs.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

This medicinal product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

No side effects have been reported with Slow Sodium / Sodium Chloride ALTURiX at the recommended dosage.

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 Website: www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

4.9 Overdose

Signs and symptoms

Excessive intake of sodium chloride can result in hypernatraemia. Symptoms of hypernatraemia include restlessness, weakness, thirst, reduced salivation and lachrymation, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypertension, tachycardia, delirium, hyperpnoea and respiratory arrest.

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 eg 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

Pharmacotherapeutic group: Other mineral supplements, sodium, ATC Code: A12 CA01

Mechanism 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.

Slow Sodium / Sodium Chloride ALTURiX 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.

Elimination
The amount of sodium lost (as sweat) is normally small. Osmotic balance is maintained by excretion of surplus amounts in the urine.

5.3 Preclinical safety data

There is no relevant preclinical data for evaluation of safety beyond those already considered in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Cetostearyl alcohol
Gelatin

Magnesium stearate

Tablet coating
Hypromellose
Hydroxypropyl cellulose
Talc
Titanium dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Five years.

6.4 Special precautions for storage

Store below 30°C. Keep the container tightly closed in order to protect from moisture.

6.5 Nature and contents of container

High density polyethylene (HDPE) container with a low density polyethylene (LDPE) cap containing 100 tablets.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

ALTURiX Limited
287 Upper Fourth Street
Milton Keynes
MK9 1EH

8 MARKETING AUTHORISATION NUMBER(S)

PL 44490/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 April 1998

10 DATE OF REVISION OF THE TEXT

10/09/2024