SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

SANDO-K®
Potassium Chloride / Potassium Bicarbonate ALTURiX 600 mg / 400 mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 600 mg potassium chloride and 400 mg potassium bicarbonate.

Excipient with known effect
Each tablet contains 521.5 mg sucrose.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Effervescent Tablet
Flat, round, white effervescent tablet with a slightly rough surface, weighing 2.4 g and 22 mm in diameter and 4.25 mm thick.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of hypokalaemic states such as those associated with:

i) Use of drugs which can induce potassium depletion e.g. frusemide, thiazide diuretics, corticosteroids, carbenoxolone and cardiac glycosides, especially in combination with diuretics

ii) Potassium loss resulting from severe diarrhoea, vomiting or fistulas;

iii) Acid-base disturbances e.g. alkalosis, renal tubular acidosis, states in which there is aldosterone excess, Cushing syndrome;

iv) Decreased intake of potassium e.g. malnutrition, alcoholism, some elderly patients with deficient diets;

v) Since this medicinal product contains chloride ions (Cl^-), it may be used in the treatment of hypokalaemia associated with hypochloraemic alkalosis.

4.2 Posology and method of administration

Posology

Adults and children

Dosage is dependent upon the clinical conditions and diet of the patient, however the administration of 2 to 4 tablets daily (24 to 48 mmol K+) is likely to provide an adequate prophylactic or therapeutic dose in most patients. Large doses may be indicated in more severe hypokalaemic conditions when the dose should be regulated by the patient's response
as determined by serum electrolyte levels and acid-base studies.

Dosage guidelines
A drop in serum potassium level of 1 mmol/l represents a loss of about 100-200 mmol of potassium from body stores.

While serum potassium levels below 2 mmol/l may warrant intravenous replacement therapy, following are approximate guidelines in less severe potassium depletion:

For serum levels between 2-3 mmol/l, a maximum daily dose of 100-200 mmol K+ (8-16 tablets) and for serum levels between 3-4 mmol/l, a maximum daily dose of 50-100 mmol K+ (4-8 tablets) should be considered.

Elderly

No evidence exists that elderly patients require different dosages or show different side- effects than younger patients.

However, such patients should be carefully supervised as factors sometimes associated with ageing, such as poor diet or impaired renal function, may indirectly affect the dosage or tolerability.

Method of administration
Oral administration, after dissolution of the tablet in water. May be taken with food if preferred.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Severe renal impairment with oliguria
- Inadequately treated Addison's disease
- Hyperkalaemia from any cause
- Crush injuries
- Acute dehydration

4.4 Special warnings and precautions for use

Periodic evaluation of the patient's clinical status, serum electrolytes and the ECG should be carried out when replacement therapy is undertaken. This is particularly important in patients with cardiac disease and in those receiving digitalis. Care should be taken to avoid dosage in excess of requirements for patients with impaired renal function.

Caution is also necessary in patients receiving potassium-sparing diuretics and ACE-inhibitors, and in patients with myotonia congenita or severe haemolysis. In patients with acidosis, the acid-base balance should be monitored. In patients with hypertension, it should be remembered that correction of hypokalaemia may lower blood pressure.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

If co-administered with potassium-sparing diuretics and ACE-inhibitors, the risk of hyperkalaemia must be considered.

4.6 Fertility, pregnancy and lactation

No clinical problems have been encountered during pregnancy and lactation. Nevertheless, the benefit of treatment should be considered in relation to the risks before this medicinal product is given to pregnant or nursing women.

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

Abdominal discomfort, diarrhoea, nausea and vomiting may occur.

If there are any signs of gastric irritation, this medicinal product, in common with all other potassium salts, should be given with or after food. Gastric irritation has occurred but this is rare since the tablets dissolve in water and are taken in solution, thus preventing high local concentrations. A moderate hyperkalaemia may be asymptomatic; if suspected reference to the section on overdosage is recommended.

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

Hyperkalaemia. Poisoning is usually minimal below 6.5 mmol per litre but may be severe above 8 mmol per litre. However, comparatively low doses may cause adverse effects when excretion is delayed as in renal insufficiency. The absolute toxicity is dependent on other electrolytes and acid-base levels.

Hyperkalaemic symptoms include paraesthesia of the extremities, listlessness, mental confusion, weakness, paralysis, hypotension, cardiac arrhythmias, heart block and cardiac arrest.

Hyperkalaemia is often asymptomatic. However, increasing serum potassium levels can be detected by changes in the ECG; initially the appearance of tall, peaked T waves, followed by a widening of the QRS complex bending into the abnormal T waves. P-wave voltage decreases and the PR interval is prolonged.

Severe cardiac toxicity may be treated with calcium gluconate (10-20ml of a 10% injection given over 1-5 minutes with ECG monitoring). The effect may be transient and the injection may need to be repeated.

Raised serum potassium levels respond to administration of dextrose (300-500ml/hr of 10 or 25% solution), dextrose and insulin (as for dextrose with 10 units of insulin per 20g dextrose), or sodium bicarbonate solution.

Cation exchange resins may be used, or in severe cases peritoneal dialysis or haemodialysis may be necessary.

Caution should be exercised in patients who are digitalised and who may experience acute digitalis intoxication in the course of potassium removal.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Potassium (different salts in combination), ATC Code: A12 BA30

Mechanism of action:
The potassium ion is essential to the maintenance of body function, being involved in the synthesis of protein, metabolism of carbohydrate and storage of energy reserves. It interacts with sodium in the operation of the transmembrane pump and at the site of exchange in the kidney, exchanges with sodium ion to maintain body homeostasis. A close relationship between potassium ion and magnesium ion has also been noted; a deficit in one ion has been associated with low levels of the other.

The diet of a healthy adult will provide an adequate intake of potassium (considered to be 20.5 to 33.3 mmol potassium daily) from a total intake of 60-100 mmol potassium. Total body potassium in an adult is about 3,500 mmol depending on the non-fat body tissues. A deficient intake or failure to conserve potassium leads to symptoms of hypokalaemia.

5.2 Pharmacokinetic properties

Unless a deficiency is present, requiring a supplement, sufficient potassium is taken into the body through the daily diet.

Absorption
The chloride salt of potassium is readily absorbed from the gastro-intestinal tract.

Distribution
Potassium enters the intracellular fluid to maintain a concentration of about 150 mEq/l and the normal range of concentration of potassium in the plasma is considered to be 3.5 - 5 mEq/l.

Elimination
Excretion of potassium is mainly by the distal tubules of the kidney, by the faeces (5 to 10 mmol/day) and a smaller amount in perspiration.

Metabolic, drug induced, or dietary deficiencies in potassium intake may require administration of a supplement.

5.3 Preclinical safety data

This medicinal product contains potassium chloride and potassium bicarbonate. The physiological, pharmacological and clinical toxicity of potassium salts are well documented and limited animal data are therefore available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dioctyle sodium sulfosuccinate
Silica, colloidal anhydrous
Talc (acid washed)
Saccharin sodium
Icing sugar
Pulverised sugar
Citric acid anhydrous
Polyethylene glycol 4000

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original tube. Keep the tube tightly closed in order to protect from moisture.

6.5 Nature and contents of container

High density polypropylene tube with polyethylene bellowed stopper containing integral silica gel desiccant capsule.

Pack size: 100 effervescent tablets (5 tubes x 20 effervescent 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 44490/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 April 1998.

10 DATE OF REVISION OF THE TEXT

22/05/2024