SCHEDULING STATUS: S2

PROPRIETARY NAME AND DOSAGE FORM:

SANDOZ K-600 (tablets)

COMPOSITION:

Active ingredient:

Each Sandoz K-600 coated tablet contains 600 mg potassium chloride equivalent to approximately 315 mg potassium or 8 mmol K^+ in slow release form.

Inactive ingredients:

Acacia spray dried, cetostearyl alcohol, dispersed buff 18016 (iron oxide red, iron oxide yellow, titanium dioxide), gelatin, magnesium stearate, polyethylene glycol (PEG) 8000, sucrose, talc purified, titanium dioxide.

Contains sugar (sucrose 97 mg per tablet).

PHARMACOLOGICAL CLASSIFICATION:

A 24 Mineral substitutes, electrolytes and trace elements

PHARMACOLOGICAL ACTION:

Release of the potassium chloride in the gastrointestinal tract is prolonged.
The insoluble wax matrix is excreted in a softened form in the faeces.
This medicine contains potassium chloride. It has not been proven that this dosage will necessarily prevent a significant potassium loss or correct an existing deficiency of potassium.

Pharmacokinetic properties:

When SANDOZ K-600 is given in a single dose of 5 or 6 coated tablets (40 or 48 mmol K^+ respectively) the potassium chloride is gradually released over a period of approximately 4 hours during its passage through the gastrointestinal tract. The pattern of its absorption is such that renal excretion of the potassium occurs 30 to 60 minutes later than when the same dose is

given in the form of a KCl solution. In the presence of a normal potassium balance and normal renal function, approximately 90 % of the potassium supplied by SANDOZ K-600 is excreted via the kidneys within 7 hours and more than 98 % within 24 hours.

INDICATIONS:

For potassium supplementation in the following conditions:

- During diuretic therapy if serum potassium falls below 3 mmol/ℓ.
- If potassium falls below 3,2 mmol/ℓ during digitalis therapy or when symptoms of or ECG changes indicative of hypokalaemia occur. (In acute potassium loss, which may be life threatening, potassium must be administered intravenously.)

Note:

The need for prolonged SANDOZ K-600 therapy should be reassessed after 4 to 8 weeks (see "WARNINGS AND SPECIAL PRECAUTIONS") by determination of the serum potassium levels, as with continued diuretic therapy potassium levels usually return to the approximate normal value.

CONTRAINDICATIONS:

Hypersensitivity to potassium administration, as found, for example, in adynamia episodica hereditaria and congenital paramyotonia.

All forms of hyperkalaemia as encountered in renal failure, in conditions involving extensive cell destruction (e.g. severe burns, crush syndrome, massive haemolysis, rhabdomyolysis, tumour lysis), in untreated Addison's disease, hyporeninaemic hypoaldosteronism as well as in metabolic acidosis and acute dehydration.

Renal failure and oliguria even where it is not yet accompanied by manifest hyperkalaemia.

All states in which passage through the digestive tract is retarded or obstructed (e.g. owing to diverticula or compression of the oesophagus by an enlarged atrium, to stenosis or atony in various gastrointestinal segments).

Owing to the possible risk of hyperkalaemia occurring, potassium salts should not be given concomitantly with potassium-sparing diuretics (aldosterone antagonists, triamterene, amiloride)

or ACE inhibitors (see “INTERACTIONS”). SANDOZ K-600 should not be administered concomitantly with intravenous potassium

WARNINGS AND SPECIAL PRECAUTIONS:

Warnings:

Hyperkalaemia:

In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalaemia and cardiac arrest. This arises most commonly in patients given potassium by the intravenous route but it may also occur in patients receiving SANDOZ K-600 orally. Potentially fatal hyperkalaemia can develop rapidly and may be asymptomatic.

Gastrointestinal lesions:

If a patient treated with SANDOZ K-600 develops pronounced nausea, severe vomiting, severe abdominal pains or flatulence, diarrhoea or gastrointestinal haemorrhage, the preparation should be withdrawn at once because these signs and symptoms may point to the presence of ulceration or perforation in the gastrointestinal tract caused by SANDOZ K-600 tablets. Such risks may be increased in patients with oesophageal stasis, known peptic and/or gastric ulcers, delayed intestinal transit, or intestinal ischaemia due to generalised atherosclerotic vascular disease.

ACE inhibitors:

ACE inhibitors produce potassium retention by inhibiting aldosterone production. In patients receiving ACE inhibitors, therefore, potassium supplements should only be given under very close monitoring of serum potassium levels.

Special precautions:

Regular monitoring of the serum electrolytes is indicated particularly in patients receiving potassium substitution therapy over prolonged periods and/or in high doses, especially in those with impaired renal function or heart disease.

In patients with impaired renal function and in elderly individuals, special care should be exercised when prescribing potassium salts in view of the risk of their producing hyperkalaemia.

When blood samples are taken for analysis of plasma potassium, it is important to bear in mind that artificial elevations can occur after an improper venipuncture technique or as a result of *in vitro* haemolysis of the sample.

Careful attention should be paid to any pointers to gastrointestinal intolerance when prescribing SANDOZ K-600.

Thus, for example, before administering the tablets, one should preclude the possibility that the patient may be suffering from active ulceration in the gastrointestinal tract or from a condition in which passage through the tract may be obstructed to such an extent as to compromise the transit of substances given by the oral route.
Caution should be exercised when prescribing solid oral potassium preparations, particularly in high dosages, in patients concurrently receiving anticholinergics because of their potential to slow gastrointestinal motility (see “INTERACTIONS”).

SANDOZ K-600 should be prescribed with particular caution in patients with a history of peptic ulcer because of the possibility of their causing gastrointestinal ulceration.

SANDOZ K-600 should be used with caution in patients receiving any medicine known to cause hyperkalaemia, i.e. other potassium chloride supplements, potassium sparing diuretics, NSAIDS (e.g. indomethacin), ACE inhibitors, lithium, beta-blockers, heparin and digoxin (see “INTERACTIONS”).

Patients with ostomies may have an altered intestinal transit time and the use of SANDOZ K-600 is not advised in these patients.

SANDOZ K-600 should be used with caution in patients treated with medicines which may cause hypomagnesaemia. Plasma magnesium levels should be determined and corrected if necessary in these patients.

Sucrose:

SANDOZ K-600 contains sucrose (see “COMPOSITION”). Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take SANDOZ K-600.

SANDOZ K-600 contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS:

Potassium supplements should be used with caution in patients receiving medication that increase serum-potassium concentrations. These include potassium sparing diuretics, such as spironolactone, amiloride and triamterene, ACE inhibitors, and ciclosporin, and medicines that contain potassium such as potassium salts of penicillin.

Similarly, the concomitant use of potassium containing salt substitutes for flavouring food should be avoided.

Antimuscarinics delay gastric emptying and consequently may increase the risk of gastrointestinal adverse effects in patients receiving solid oral dosage forms of potassium.

The use of non-steroidal anti-inflammatory drugs (NSAIDs) in combination with SANDOZ K-600 may increase the risk of gastrointestinal side effects.

SANDOZ K-600 tablets are not recommended for concurrent use with digitalis glycosides in the presence of heart block. If SANDOZ K-600 must be used to prevent or correct hypokalaemia in digitalised patients, careful monitoring of serum potassium is extremely important.

There is an increased risk of hyperkalaemia when a potassium-wasting diuretic, such as thiazide diuretics, is discontinued after concurrent use with SANDOZ K-600.

Chronic use of laxatives may reduce serum potassium concentrations.

PREGNANCY AND LACTATION:

Pregnancy:

SANDOZ K-600 should be used with caution during pregnancy.

SANDOZ K-600 should be given to pregnant women only if clearly needed because of gastrointestinal hypomotility associated with pregnancy.

Children:
Safety and effectiveness in children have not been established.

Lactation:
Safety of use in lactating mothers has not been established.

Effects on ability to drive and use machines:
You should drive your motor vehicle or operate dangerous machinery with caution until you know how SANDOZ K-600 affects you.

DOSAGE AND DIRECTIONS FOR USE:
The dosage should be adapted to the cause and degree of the manifest hypokalaemic state.

Provided no signs of intolerance occur, the medication should be continued until the hypokalaemia has been corrected.

Depending on the patient's individual requirements, a daily dosage of 6 to 12 tablets, in several fractional doses should be given. Not more than 20 mmol K^+ (2 tablets) should be given in a single dose.

The tablets should be swallowed whole with fluid during meals while the patient is in an upright position. Adequate fluid intake during treatment with SANDOZ K-600 is essential.
The adequacy of oral potassium replacement in hypokalaemia states must be assessed by periodic monitoring of serum potassium levels.

In acute potassium loss, which may be life threatening, potassium must be administered intravenously.

SIDE EFFECTS:

Blood and lymphatic system disorders:
Less frequent: Hyperkalaemia.

Gastrointestinal disorders:
Frequent: Local irritation of the mucosa provoking nausea, flatulence, vomiting, abdominal pains, diarrhoea or gastrointestinal bleeding, perforation and obstruction.

Ulceration with serious consequences may occur.

Skin and subcutaneous disorders:
Less frequent: Pruritus and/or skin rash, as well as urticaria, have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Signs and symptoms:
Mainly cardiovascular (hypotension, shock, ventricular arrhythmias, bundle- branch block, ventricular fibrillation leading to cardiac arrest) and neuromuscular (paraesthesiae, convulsions, areflexia, flaccid paralysis of striated muscle leading possibly to respiratory paralysis) and mental confusion.

Besides elevation of the serum potassium concentration, typical ECG changes are also encountered (increased amplitude and peaking of T-wave, disappearance of P-wave, widening of QRS complex, and ST depression).

Treatment:
Treatment is symptomatic and supportive.

In mild hyperkalaemia that has developed on long-term treatment, discontinuation of SANDOZ K-600 and other medicines that may increase plasma-potassium concentrations, and avoidance of foods with high potassium content may be sufficient to correct the hyperkalaemia.

In cases of acute oral overdosage of potassium supplements, the stomach should be emptied by gastric lavage.

When treating hyperkalaemia, it should be borne in mind that, lowering the serum potassium concentration too rapidly can produce digitalis toxicity in patients who have been stabilised on digitalis.

IDENTIFICATION:

Brownish orange, biconvex, round, polished, sugar-coated tablets. Diameter approximately 11,5 to 12,5 mm. Thickness approximately 6,5 to 8,1 mm.

PRESENTATION:

Packs of 30, 100 or 500 tablets in white, polypropylene or high density polyethylene securitainers or blisters.

STORAGE INSTRUCTIONS:

Store at or below 25 °C and protect from light and moisture.
Do not remove the product from the container before use.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:

36/24/0177

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

SANDOZ SA (Pty) Ltd[1]
Waterfall 5-lr
Magwa Crescent West
Jukskei View
Gauteng, 2090

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

Date of registration: 05 September 2003

Date of most recent approval of professional information: 30 November 2016

Additional country registration details:

Country	*Product name*	*Scheduling status (or Category of distribution)*	*Registration number*
Namibia	Sandoz K-600	NS1	12/24/0074

Name and address of manufacturer:

Kiara Health
72 Steel Rd
Spartan
Kempton Park, 1619
South Africa

[1]Company Reg. No.: 1990/001979/07