SLOW-K®

(potassium chloride)

DESCRIPTION

Potassium Chloride B.P. 600 mg (approximately 8 mEq) in a slow-release wax core.

Excipients: Cetostearyl alcohol, gelatin, magnesium stearate, acacia, titanium dioxide (E171), talc purified, sucrose, red iron oxide (E172), yellow iron oxide (E172) and Carnauba Wax

PHARMACOLOGY

The potassium chloride in Slow-K is gradually released from the insoluble neutral wax core during transit through the alimentary tract, and is completely absorbed. The wax core is excreted in a softened form in the faeces, but its presence there is not indicative of incomplete

absorption of the active ingredient.

The characteristic slow release, sustained over a period of 3 to 4 hours, virtually precludes high concentrations of potassium chloride accumulating in localised areas of the gut, which otherwise might irritate, or damage, the mucosa. The release of potassium is largely independent of pH.

Hyperkalaemia is rarely encountered because any excess of potassium is normally rapidly excreted via the kidneys. The pattern of absorption of potassium from Slow-K is such that renal excretion occurs 30 to 60 minutes later than when a dose of the same size is given in solution.

In the presence of a normal potassium balance, approximately 90% of the potassium supplied by Slow-K is excreted via the kidneys within 7 hours, and more than 98% within 24 hours.

The chloride salt is usually preferable to the bicarbonate, citrate or tartrate as potassium and chloride loss are often associated. A potassium supplement which does not contain the chloride ion may be largely excreted in the urine.

Slow-K does not taste unpleasant and is readily acceptable to patients.

INDICATIONS

For the treatment and specific prevention of hypokalaemia:

- during protracted or intensive diuretic medication for hypertension, massive oedema, or congestive heart failure (potassium supplementation is of particular importance in patients under concomitant digitalisation, because hypokalaemia increases the toxicity of digitalis)
- in liver cirrhosis, especially during diuretic therapy
- in renal diseases associated with increased potassium excretion (e.g. salt wasting nephropathies, hereditary tubular disorders)
- in gastro-intestinal disorders which induce potassium loss (e.g. severe or chronic diarrhoea, vomiting, fistula drainage, enterostomy or abuse of laxatives)
- in hypochloraemic alkalosis or in patients receiving a low salt diet or a diet deficient in potassium
- during prolonged or intensive treatment with corticosteroids, ACTH, carbenoxolone or high doses of carbenicillin or benzylpenicillin
- in Cushing's syndrome or hyperaldosteronism
- in megaloblastic anaemia during the early stages of treatment

In these conditions, Slow-K is particularly indicated if a diet rich in potassium cannot be guaranteed.

CONTRAINDICATIONS

- Hypersensitivity to potassium administration (e.g. adynamia episodica hereditaria, congenital paramyotonia) or hypersensitivity to any of the excipients (see Description).
- All forms of hyperkalaemia, as encountered in marked renal failure, in conditions
 involving extensive cell destruction (e.g. trauma, severe burns, crush syndrome, massive
 haemolysis, rhabdomyolysis, tumour lysis), in untreated Addison's disease, in
 hyporeninemic hypoaldosteronism, or in decompensated cases of metabolic acidosis and
 acute dehydration.
- Hyperkalaemic periodic paralysis (an inherited autosomal dominant disorder affecting sodium channels in muscle cells and the ability to regulate potassium levels in the blood).
- Marked renal failure, even where hyperkalaemia is not yet manifest.
- All conditions in which passage through the digestive tract is retarded or obstructed (e.g. diverticula, compression of the oesophagus, gastro-intestinal stenosis or atony).
- Concomitant treatment with potassium-sparing diuretics (aldosterone antagonists, triamterene, amiloride) (see Precautions and Interactions with Other Medicines).
- Patients in whom there is cause for arrest or delay in tablet passage through the
 gastrointestinal tract, such as partial or complete oesophageal obstruction (e.g. by
 oesophageal, postcricoidal or thyroidal carcinomas, aortic aneurysm, left-atrial
 enlargement, inflammatory stricture due to reflux oesophagitis, oesophageal displacement
 due to cardiac surgery), stenosis or atony in any part of the gastrointestinal tract.

PRECAUTIONS

Gastrointestinal disorders

If a patient receiving Slow-K 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 indicate ulceration or perforation in the gastro-intestinal tract (see Adverse Effects).

Such risks may be increased in patients with oesophageal statis, known peptic and/or gastric ulcers, delayed intestinal transit, or intestinal ischemia due to generalised atherosclerotic vascular disease.

Caution should be exercised when prescribing solid oral potassium preparations, particularly in high dosage, patients concurrently receiving anticholinergic agents because of their potential to reduce gastrointestinal motility (see Interactions with other medicines).

Because of the possibility of their causing gastrointestinal irritation, oral potassium preparations should be prescribed with particular caution in patients with a history of peptic ulcer.

Patients with ostomies may have an altered intestinal transit time and are better treated with other forms of potassium salts.

Hyperkalaemia

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

Slow-K is contraindicated in patients with marked renal failure (see Contraindications). In patients with mild to moderately impaired renal function, special care should be exercised when prescribing potassium salts in view of the risk of their producing hyperkalaemia and cardiac arrest. This arises most commonly in patients given potassium by the intravenous route, but it may also occur in patients receiving potassium orally. Potentially fatal hyperkalaemia can develop rapidly and may be asymptomatic.

Slow-K should be used with caution in patients receiving any drug known to have a potential for hyperkalaemia (see Interactions with other medicines). Particularly careful monitoring of serum electrolytes and appropriate dosage adjustments is indicated in cases of protracted therapy with large doses of potassium, and must invariably be carried out in patients with impaired renal function or heart disease.

Metabolic acidosis

Hypokalaemia occurring in cases of metabolic acidosis should be treated, not with potassium chloride, but with the potassium salt of a weak acid (e.g. potassium bicarbonate).

Patients with Hepatic Impairment

No studies have been performed in hepatically impaired patients. However, Slow-K should be given with caution dues to increased likelihood of electrolyte disturbances in patients with hepatic impairment.

Treatment Monitoring

Periodic serum potassium determinations are recommended during long-term potassium supplementation, especially in clinical conditions which carry a risk of hyperkalaemia (e.g. impairment of renal function, heart disease).

In addition, careful attention should be paid to the acid-base balance, to other serum electrolyte levels (e.g. magnesium), to the ECG, and to the clinical status of the patient.

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

Other

In some patients, diuretic-induced magnesium deficiency will prevent the restoration of intracellular deficits of potassium, so that hypomagnesia should be corrected at the same time as hypokalaemia.

Slow-K contains sucrose. Patients with rare hereditary disorders like fructose intolerance, glucose-galactose maladsorption, or sucrase-isomaltase insufficiency should not use this medicine.

Use in Pregnancy

Oral potassium preparations in solid dosage forms should be given to pregnant women only if clearly needed, because the gastro-intestinal hypomotility associated with pregnancy increases the possibility of adverse reactions.

Use in Lactation

The excretion of potassium in milk has not been studied in animals or human.

Slow-K should only be given during breast-feeding when the expected benefit to the mother outweighs the potential risk to the baby.

Paediatric Use

Keep out of reach of children. Safety and effectiveness of Slow-K for use in children have not been established. Slow-K is only suitable for use in adults and should not be used in children.

Use in the Elderly

Slow-K should be given with caution and with frequent serum potassium monitoring due to increased risk of hyperkalaemia.

INTERACTIONS WITH OTHER MEDICINES

Potassium-sparing diuretics

Drugs which interfere with potassium excretion may promote hyperkalaemia when given together with Slow-K.

Concomitant treatment with potassium-sparing diuretics (aldosterone antagonists such as spironolactone, triamterene, amiloride) is contraindicated (see Contraindications).

Drugs causing hyperkalaemia

Slow-K should be used with caution in patients receiving any drug known to have a potential for hyperkalaemia, such as ACE inhibitors, angiotensin-II-receptor-antagonists, NSAIDs (e.g. indomethacin), beta-blockers, heparin, digoxin and ciclosporin (see Precautions).

Other drugs such as direct renin inhibitors (e.g. aliskerin) and proton pump inhibitors can cause hyperkalaemia when used concomitantly with Slow-K. Thus, concomitant used should be exercised with caution.

Anticholinergics

Since anticholinergic drugs may reduce gastrointestinal motility, they should be prescribed with great care when given concomitantly with solid oral potassium preparations, particularly in high dosage (see Precautions).

ADVERSE EFFECTS

Oral potassium preparations, particularly if their passage through the gastrointestinal tract is retarded or obstructed, may cause local irritation of the mucosa and thus provoke gastrointestinal disturbances (nausea, flatulence, vomiting, abdominal pains, diarrhoea or gastrointestinal bleeding).

Such unwanted effects, however, are encountered only occasionally if Slow-K is employed in its proper indications. Though very rare, the possibility of ulceration with serious consequences cannot be completely excluded (see Precautions).

Post-marketing experience

The following adverse reactions have been reported during post-marketing of Slow-K. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency which is therefore categorised as not known.

Adverse reactions are listed according to system organ classes in MedDRA. Within each system organ class, adverse reactions are presented in order of decreasing seriousness.

Gastrointestinal disorders

Gastrointestinal obstruction, gastrointestinal haemorrhage, gastrointestinal ulcer with or without perforation of the upper or lower GIT, delayed intestinal transit or obstruction in the GIT, nausea, flatulence, vomiting, abdominal pain, diarrhoea.

Skin and subcutaneous tissue disorders Urticaria, rash, pruritus.

Metabolism and nutrition disorders

Hyperkalaemia – either with renal potassium excretion or with internal disposal.

DOSAGE AND ADMINISTRATION

The dosage of Slow-K should be adjusted to suit the cause and extent of the potassium deficiency in each case. Depending on the patient's individual requirements, 2 to 6 tablets daily, given in several fractional doses, will generally suffice. In severe potassium deficiency, however, it may be necessary for a patient to take 9 to 12 tablets daily. When Slow-K is administered in conjunction with an oral diuretic agent, 1 or 2 tablets daily may be sufficient.

The tablets should be swallowed whole with fluid during meals. Medication with Slow-K should be continued until the potassium deficiency has been corrected.

<u>OVERDOSAGE</u>

Signs and symptoms:

Cardiovascular: hypotension, shock, ventricular arrhythmia, bundle-branch block, ventricular fibrillation leading possibly to cardiac arrest.

Neuromuscular: paraesthesiae, convulsions, areflexia, flaccid paralysis of striated muscle leading possibly to respiratory paralysis.

Elevation of the serum potassium concentration.

ECG changes: increased amplitude and peaking of T waves, disappearance of P wave, widening of QRS complex, and S-T depression.

Treatment:

Gastric lavage, administration of cation-exchange agents, infusion of glucose + insulin, forced diuresis and possibly peritoneal dialysis or haemodialysis.

Contact the Poison Information Centre on 131 126 for advice on management.

PRESENTATION AND STORAGE CONDITIONS

Tablet 600 mg; containers of 100 tablets.

Information to be given to the patient:

Please note that the tablets should be swallowed whole with fluid at mealtimes. If you notice any of the following signs while under treatment with Slow-K, i.e. marked nausea or vomiting, pronounced flatulence, pain in the abdomen, diarrhoea with black or blood-stained stools, you should stop taking the medicine at once and notify your doctor without delay.

Storage:

Store below 30°C.

NAME AND ADDRESS OF THE SPONSOR

NOVARTIS Pharmaceuticals Australia Pty. Limited ABN 18 004 244 160 54 Waterloo Road NORTH RYDE NSW 2113

POISON SCHEDULE OF THE MEDICINE

Schedule 4 – Prescription Only Medicine

DATE OF FIRST INCLUSION IN THE ARTG

13 November 2000

DATE OF MOST RECENT AMENDMENT

9 March 2012