PRODUCT MONOGRAPH

SLOW-K*

Slow-Release Potassium Chloride Tablets

600 mg (8 mEq K^+)

NOVARTIS Standard

Potassium Supplement

Novartis Pharmaceuticals Canada Inc.
Dorval, Quebec
H9S 1A9

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SLOW-K*

(Slow-Release Potassium Chloride)

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Oral	600 mg sugar-coated tablet	Cetostearyl alcohol, gelatine, magnesium stearate *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

SLOW-K* is indicated for:

- treatment of potassium depletion in patients with hypokalemia and metabolic alkalosis.
- prevention of potassium depletion when the dietary intake of potassium is inadequate for this purpose. The prophylactic administration of potassium ion may be indicated in patients receiving digitalis and/or diuretics for the treatment of congestive heart failure, and hepatic cirrhosis with ascites. SLOW-K* may be indicated in selected patients with hypertension on long-term diuretic therapy, hyperaldosteronism states with normal renal function, the nephrotic syndrome, and certain diarrheal states.

Potassium ions participate in a number of essential physiological processes (see PHARMACOLOGY). Depletion may occur whenever the rate of potassium loss through renal excretion and/or loss from the gastrointestinal tract exceeds the rate of potassium intake. Although there is no uniform correlation between plasma concentrations of potassium and total body stores, clinical signs of potassium deficiency are usually observed whenever the plasma potassium concentration falls below 3.5 mEq/Litre (hypokalemia).

Hypokalemia can be prevented and/or corrected by giving supplementary potassium. Administration of potassium salts is an alternative to increasing dietary intake of potassium-rich foods, which may not always be practical. In view of the frequency with which deficits of K+ and Cl- coexist, potassium chloride is the preferred salt for most of the clinical conditions associated with hypokalemia (see WARNINGS).

SLOW-K* (slow-release potassium chloride) is a sugar-coated (not enteric-coated) tablet containing 600 mg potassium chloride in a wax matrix. This formulation is intended to provide a

controlled release of potassium chloride from the matrix, thereby minimizing the likelihood of producing high localized concentration of potassium within the gastrointestinal tract. The release of potassium chloride is largely pH- independent and occurs at a rate sufficient to permit complete absorption during its transit through the gastrointestinal tract.

Geriatrics :
As renal function, and hence the potential for maintaining potassium balance may decrease with age, serum potassium levels should be monitored regularly and dosage adjusted as appropriate. As gastrointestinal motility may also be affected by age, elderly patients should be reminded to swallow solid oral potassium salts with adequate amounts of fluid. (see WARNINGS AND PRECAUTIONS-Special Population section)

Pediatrics:
Safety and effectiveness in children have not been established. SLOW-K* is therefore not recommended for pediatric use (see WARNINGS AND PRECAUTIONS-Special Population section)

CONTRAINDICATIONS

- Hypersensitivity to potassium administration, e.g., in adynamia episodica hereditaria or congenital paramyotonia or patients who are hypersensitive to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the product monograph.
- Hyperkalemia of any etiology, since a further increase in the serum potassium concentration in such patients can produce cardiac arrhythmia and cardiac arrest. Hyperkalemia may complicate any of the following conditions: marked renal failure, untreated Addison's disease, hyperadrenalism associated with adrenogenital syndrome, hyporeninemic hypoaldosteronism, extensive tissue breakdown (as in severe burns, trauma, massive hemolysis, rhabdomyolysis, tumour lysis), acute dehydration, heat cramps, metabolic acidosis.
- Renal impairment with oliguria or azotemia.
- Concomitant administration of SLOW-K* and potassium-sparing diuretics (e.g. spironolactone, triamterene or amiloride) (See DRUG INTERACTIONS section)
- Patients in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. These states include:
    - Partial or complete esophageal obstruction, for example by carcinomas (esophageal, post-cricoidal, thyroidal), aortic aneurysm, left-atrial enlargement, inflammatory stricture due to reflux esophagitis, and esophageal displacement due to cardiac surgery (e.g. valve replacement).
    - Stenosis or atony in any part of the gastrointestinal tract (e.g. pyloric stenosis, intestinal strictures).

In these instances, potassium supplementation should be with a liquid preparation.

WARNINGS AND PRECAUTIONS

Cardiovascular

Potassium supplements should be used with caution in diseases associated with heart block since increased serum potassium may increase the degree of block.

Endocrine and Metabolism

In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

SLOW-K* should be used with caution in patients receiving any drug known to have a potential for hyperkalemia, such as ACE inhibitors, angiotensin-II-receptor-antagonists, NSAIDs (e.g. indomethacin), beta-blockers, heparin, digoxin and cyclosporine. (see DRUG INTERACTIONS section)

Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium acetate, potassium bicarbonate or potassium citrate.

Clinical signs of hypokalemia (plasma potassium concentrations less than 3.5 mEq/Litre) include impaired neuromuscular function, which may vary from minimal weakness to frank paralysis; intestinal dilatation and ileus; and, more frequently, abnormalities of myocardial function with disturbed ECG patterns characterized by an exaggerated U wave, a broad and flat T wave, and a depressed ST segment.

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

Gastrointestinal

Since anticholinergic agents have the potential to reduce gastrointestinal motility, they should be prescribed with caution when given concomitantly with solid oral potassium preparations, particularly in high doses.

A probable association exists between the use of coated tablets containing potassium salts, with or without thiazide diuretics, and the incidence of serious small bowel ulceration. Such preparations should be used only when adequate dietary supplementation is not practical, and should be discontinued if abdominal pain, distention, nausea, vomiting or gastrointestinal bleeding occurs.

SLOW-K* is a wax matrix tablet formulated to provide a controlled rate of release of potassium

chloride and thus to minimize the possibility of a high local concentration of potassium near the bowel wall. While the reported frequency of small bowel lesions is very much less with wax matrix tablets (less than one per 100,000 patient years) than with enteric-coated potassium chloride tablets (40-50 per 100,000 patient years), a few cases associated with wax matrix tablets have been reported.

SLOW-K* should be discontinued immediately and the possibility of bowel obstruction or perforation considered if pronounced nausea, severe vomiting, diarrhea, abdominal pain, distention or gastrointestinal bleeding occurs.

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

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

Sensitivity/Resistance

SLOW-K* contains sucrose (=saccharose). Patients with rare hereditary disorders like fructose-intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not use this medicine.

Special Populations

Pregnant Women: For SLOW-K*, no clinical data on exposed pregnancies are available. There is no indication in animal studies of direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see PART II-TOXICOLOGY section).

In general, no drug should be taken during the first trimester, and the benefits and risks of drug administration should be carefully considered throughout pregnancy.

Pregnancy is associated with gastrointestinal hypomotility. Solid oral potassium supplements should therefore only be given to pregnant women if such therapy is considered essential.

Nursing Women: The excretion of potassium in milk has not been studied in animals or human The normal K+ content of human milk is approximately 13 mEq/Litre. Since oral potassium becomes part of the body's potassium pool, provided the body potassium is not excessive, the contribution of SLOW-K* can be expected to have little or no effect on the potassium level in human milk.

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

Pediatrics: Safety and effectiveness in children have not been established. SLOW-K* is therefore not recommended for pediatric use.

Geriatrics: As renal function, and hence the potential for maintaining potassium balance may decrease with age, serum potassium levels should be monitored regularly and dosage adjusted as appropriate. As gastrointestinal motility may also be affected by age, elderly patients should be reminded to swallow solid oral potassium salts with adequate amounts of fluid.

Monitoring and Laboratory Tests

Periodic serum potassium determinations are recommended during long-term potassium supplementation. When blood samples are taken for the analysis of plasma potassium, it is important to remember that artifactual elevations can occur after an improper venipuncture technique or as a result of in-vitro hemolysis of the sample.

The correction of hypokalemia, particularly in the presence of cardiac disease, renal disease or acidosis requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram and the clinical status of the patient.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Gastrointestinal
The most common adverse reactions to oral potassium salts are nausea, vomiting, flatulence, abdominal discomfort and diarrhea.

There have also been reports of esophageal and gastrointestinal obstruction, haemorrhage ulceration with or without perforation of the upper or lower gastrointestinal tract (see WARNINGS). Small bowel lesions have been reported following the administration of SLOW-K* (slow-release potassium chloride). The incidence is much lower than that reported for enteric-coated potassium chloride tablets (see WARNINGS AND PRECAUTIONS section).

Electrolytes
One of the most severe adverse effects is hyperkalemia (see WARNINGS AND PRECAUTIONS section).

Skin
Pruritus and/or skin rash, as well as urticaria, have been reported rarely.

DRUG INTERACTIONS

Overview
Concomitant treatment with potassium sparing diuretics (spironolactone, triamterene, amiloride)

is contraindicated.

SLOW-K* should be used with caution in patients receiving agents known to have a potential for hyperkalemia, such as ACE inhibitors (e.g. captopril, enalapril; see WARNINGS), angiotensin-II receptor antagonists, NSAID's (e.g. indomethacin), beta-blockers, heparin, digoxin and cyclosporine.

Since anticholinergic agents have the potential to reduce gastrointestinal motility, they should be prescribed with caution when given concomitantly with solid oral potassium preparations, particularly in high doses.

Drug-Drug Interactions

Table 1 Established or Potential Drug-Drug Interactions

SLOW-K*	Ref	Clinical comment
ACE inhibitors	T	increase risk of hyperkalemia
Angiotensin-II receptor antagonists	T	increase risk of hyperkalemia
NSAID's	T	increase risk of hyperkalemia
beta-blockers	T	increase risk of hyperkalemia
Heparin	T	increase risk of hyperkalemia
Digoxin	T	increase risk of hyperkalemia
Cyclosporine	T	increase risk of hyperkalemia
Anticholinergic agents	T	Reduce gastrointestinal motility

Legend: C = Case Study; CT = Clinical Trial; T = Theoretical

Drug-Food Interactions
The interaction of SLOW-K* has not been studied with regards to food.

Drug-Herb Interactions
The interaction of SLOW-K* with herbal medications on supplements has not been studied.

Drug-Laboratory Interactions
Specific drug laboratory interaction studies have not been conducted with SLOW-K*.

Drug-Lifestyle Interactions
Specific drug lifestyle interaction studies have not been conducted with SLOW-K*.

DOSAGE AND ADMINISTRATION

Dosing Considerations
The usual dietary intake of potassium by the average adult is 50 to 100 mEq per day. Potassium

depletion sufficient to cause hypokalemia usually requires the loss of 200 or more mEq of potassium from the total body store.

Recommended Dose and Dosage Adjustment

Dosage must be adjusted to the individual needs of each patient, and to the cause and degree of the manifest or potential hypokalemic state. Where intermittent diuretic therapy is being used, SLOW-K* (slow-release potassium chloride) should preferably be given on days other than those on which diuretic is administered.

- *Prevention of hypokalemia*: Typically in the range of 20 mEq per day.

- *Correction of hypokalemia*: Typically in the range of 40 to a maximum of 100 mEq per day, depending on initial plasma K+ concentrations. The response to treatment should preferably be monitored by repeated plasma K+ determinations, and SLOW-K* continued until the hypokalemia has been corrected.

The usual dosage range is 2 to 6 SLOW-K* tablets daily. It is recommended not to exceed 12 tablets daily. If the daily requirement exceeds 20 mEq K+, it should be taken in divided doses, so that not more than 20 mEq K+ is given in a single dose.

SLOW-K* is preferably administered after meals. The tablets must not be crushed, chewed or sucked but should be swallowed whole with fluids while the patient is upright.

The insoluble wax matrix is excreted in a softened form and may be found in the feces

OVERDOSAGE

Overdosage from therapeutic doses of solid oral potassium salts in persons with normal excretory mechanisms rarely occurs. However, if excretory mechanisms are impaired, potentially fatal hyperkalemia may occur. Acute (accidental or intentional) overdosages of solid oral potassium salts have resulted in severe and/or fatal hyperkalemia.

Symptoms

Overdosage with potassium is characterized chiefly by cardiovascular, neuromuscular and gastrointestinal disturbances.

Cardiovascular:	ECG changes, hypotension and shock, bundle-branch block, ventricular arrhythmias, ventricular fibrillation leading, possibly, to cardiac arrest.
Neuromuscular:	Paresthesia, areflexia, convulsions, flaccid paralysis of striated muscle leading possibly to respiratory paralysis.
Gastrointestinal:	Nausea, vomiting, diarrhea and abdominal cramp.

It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic

changes which include increased amplitude and peaking of the T-wave, and flattening or absence of P-wave. As hyperkalemia worsens prolongation of the P-R interval, widening of the QRS complex with ST segment depression, and arrhythmias may develop.

Widening of the QRS complex is one of the most ominous signs and indicates the need for aggressive treatment.

Treatment
The plasma concentration and electrocardiogram must be monitored in every case of potassium overdosage, as well as serum electrolytes, BUN, glucose and arterial blood gases.

Electrocardiographic signs of hyperkalemia (tall peaked T waves, P-R prolongation, disappearance of P waves, QRS widening, heart block) are indications for immediate treatment.

In severe hyperkalemia (plasma potassium exceeds 8 mEq/L or ECG abnormalities include absence of P wave, presence of widened QRS complex or ventricular arrhythmia):

- Administer intravenously 300 to 500 mL/hour of 10% dextrose solution containing 10-20 units of insulin per 1,000 mL.
- Correct acidosis, if present, with intravenous sodium bicarbonate (44 to 132 mEq per Litre of glucose solution).
- Administer 10 to 30 mL of 10% calcium gluconate intravenously over 1 to 5 minutes under continuous ECG monitoring.
- Administer cation exchange resin by high retention enema. 30 to 50 g sodium polystyrene sulfonate suspended in 100 mL warm aqueous sorbitol solution should be kept in the sigmoid colon for several hours, if possible. The colon is then irrigated with a non-sodium containing solution to remove the resin. Repeated enemas can be administered, or the resin given repeatedly by mouth to maintain a physiologic potassium concentration.
- Hemodialysis or peritoneal dialysis may be of use, particularly in patients with renal failure.

In moderately severe hyperkalemia (plasma potassium between 6.5 and 8 mEq/L or ECG peaking of T wave):

- Administer intravenously 300 to 500 mL/hour of 10% dextrose solution containing 10-20 units of insulin per 1,000 mL.
- Correct acidosis, if present, with intravenous sodium bicarbonate (44 to 132 mEq per Litre of glucose solution).
- Correct hyponatremia and hypovolemia, if present.

Once the patient's cardiac state has been stabilized, in the case of a recent acute ingestion of SLOW-K* (slow-release potassium chloride), consideration should be given to the evacuation of the stomach. When overdosage is the result of chronic therapeutic ingestion, SLOW-K* should be discontinued immediately as well as potassium containing foods and medications and also potassium-sparing diuretics.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, lowering the serum potassium concentration too rapidly can produce digitalis toxicity.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Potassium ion is the principal intracellular ion of most body tissues. Potassium ions are involved in a number of essential physiological processes, including the maintenance of intracellular tonicity, the transmission of nerve impulses, the contraction of cardiac, skeletal, and smooth muscle, the maintenance of normal renal function and the regulation of the acid-base balance.

Pharmacokinetics

Absorption: Concentrations of potassium ions range in intracellular fluid from 130 - 150 up to 160 mEq/Litre and in plasma from 3.5 to 5.0 mEq/Litre.

KCl is gradually released from SLOW-K* over a period of approximately 4 hours during its transit through the gastrointestinal tract. Absorption of potassium from the bowel is complete.

Excretion: Normally any amount given in excess of intracellular requirements is rapidly eliminated with approximately 90% excreted via the kidneys within 8 hours, and more than 98% within 24 hours.

Special Populations and Conditions

Pediatrics: Safety and effectiveness in children have not been established. SLOW-K* is therefore not recommended for pediatric use. (see WARNINGS AND PRECAUTIONS-Special Population section)

Geriatrics: As renal function, and hence the potential for maintaining potassium balance may decrease with age, serum potassium levels should be monitored regularly and dosage adjusted as appropriate. As gastrointestinal motility may also be affected by age, elderly patients should be reminded to swallow solid oral potassium salts with adequate amounts of fluid. (see WARNINGS AND PRECAUTIONS-Special Population section)

STORAGE AND STABILITY

Protect tablets from heat (i.e. store below 30°C) and humidity.

Keep out of reach of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

SLOW-K*: Light-orange, round, biconvex, sugar-coated tablets. Each tablet contains 600 mg of potassium chloride (equivalent to 8 mEq) in a slow-release wax matrix core and the following non-medicinal ingredients: cetostearyl alcohol, gelatin, magnesium stearate. The coating contains: carnauba wax, gelatin, spray dried Acacia, purified talc, sucrose (granulated), red iron oxide, titanium dioxide and yellow iron oxide.

Available in bottles of 100 and 500 tablets.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: potassium chloride

Molecular formula and molecular mass:
KCl-K 52.44%, Cl 47.56% Molecular Weight: 74.55

Physicochemical properties: Potassium chloride is a colourless crystals or white crystalline powder, hygroscopic. Freely soluble in water. Practically insoluble in ethanol.

TOXICOLOGY

Preclinical safety data

The acute and repeated-dose oral toxicity of potassium chloride (KCl) in animals is low. Gastrointestinal irritant effects have been observed in rhesus monkeys at high oral dosages of SLOW-K*. Some positive results in *in vitro* genotoxicity assays were attributed to very high concentrations of KCl. Carcinogenicity studies in rats administered KCl in-feed were negative. Limited information from developmental studies in rodents indicates there is no ill effect on offspring. There is no evidence from animal experiments that KCl exerts any teratogenic effects or reproductive toxicity which would be relevant to man.

Studies to evaluate the effects of potassium chloride in slow-release tablets in comparison with enteric-coated potassium chloride tablets were conducted in baboons and rhesus monkeys.

Baboon Studies:

Two tablets each of enteric-coated thiazide plus KCl (572 mg per tablet) or thiazide plus KCl in slow-release formulation (identical to SLOW-K* wax matrix) were given to male and female olive baboons (1 of each per group), twice daily for 5 days. In the animals which received enteric-coated potassium chloride, necropsy and macroscopic examination of the whole gastrointestinal tract revealed numerous inflammatory lesions in the jejunum and ileum, with hyperemia, swelling and necrosis of the mucosa. Baboons receiving potassium chloride in the slow-release formulation showed no lesions of the gastrointestinal tract in either macroscopic examination or under low-power magnification.

In a second study, the same regimen of thiazide plus KCl in slow-release formulation in 4 baboons confirmed the absence of gastrointestinal lesions.

Rhesus Monkey Study:
Five groups of 6 (3 female and 3 male) Rhesus monkeys designated as Groups II, III, IV, V and VI were intubated twice daily for 4½ days in a comparative ulcerogenic study, with 1200 mg 20% Kaochlor (Warren-Teed), 1000 mg enteric-coated KCl (Truxton), 1200 mg SLOW-K*, 2400 mg SLOW-K* and 3600 mg SLOW-K* respectively. A sixth group (Group I) served as control but was exposed to the same stresses of daily restraint and passage of the stomach tube. Results obtained are summarized in Table 3.

Table 3: Incidence of gross gastrointestinal erosion/ulcers in Rhesus monkeys treated with SLOW-K* and two commercial potassium chloride preparations.

GROUP NO.	TREATMENT	FORM OF MEDICATION	DAILY DOSE (mg/day)	GASTROINTESTINAL LESIONS EROSION/ULCERS	IRRITATION
I	Control	Sham treatment (passage of stomach tube)	None	0/6	0/6
II	KAOCHLOR (Warren-Teed)	20% solution	2400	6/6	3/6
III	Enteric- coated KCl (Truxton)	Tablets (1000 mg)	2000	4/6	5/6
IV	SLOW-K (CIBA-GEIGY)	Tablets (600 mg)	2400	0/6	3/6
V	SLOW-K (CIBA-GEIGY)	Tablets (600 mg)	4800	1/6	3/6
VI	SLOW-K (CIBA-GEIGY)	Tablets (600 mg)	7200	3/6	6/6

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PART III: CONSUMER INFORMATION

SLOW-K*
(potassium chloride)

This leaflet is part III of a three-part "Product Monograph" published when SLOW-K* was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SLOW-K*. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

SLOW-K* is an oral potassium supplement used to replace potassium losses and prevent potassium deficiency which may be caused by:

- certain drugs such as digitalis and or diuretics (water pills)
- certain diseases such as kidney disease or gastrointestinal disease with diarrhea, vomiting.

SLOW-K* is indicated in those patients who cannot tolerate or refuse to take liquid or effervescent potassium chloride.

What it does:

SLOW-K* is a sustained-release formulation containing potassium chloride (KCl). This formulation controls the release of KCl so that adequate amounts of KCl are available in your body throughout the day. Potassium is fundamentally involved in many body processes, such as fluid balance, acid-alkali balance, protein synthesis, nerve conduction, energy production, muscle contraction, synthesis of DNA and control of heartbeat and kidney function.

When it should not be used:

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

SLOW-K* should not be used in case of:

- an allergic reaction to potassium chloride or any other ingredients of SLOW-K* listed in "*What the important nonmedicinal ingredients are*" section.
- hyperkalemia (occurs when there is too much potassium in the blood) which may result from a number of conditions such as:
    - Addison's (adrenal gland) disease
    - severe injury or burns, anemia , tumors, rhabdomyolysis, a breakdown of muscle fibres caused by the use of certain drug
    - metabolic acidosis (disturbance of the body's acid-base balance that results in excessive acidity of the blood)
    - Excessive loss of body water which may be caused by severe vomiting or diarrhea
- Insufficient kidney function
- If you are now taking certain drugs used to treat high blood pressure or certain heart diseases (potassium-sparing diuretics e.g. spironolactone, triamterene, amiloride).
- If you have blockage of the gastro-intestinal tract (e.g. esophagus, stomach or intestine).

If this applies to you, tell your doctor without taking SLOW-K*. If you think you may be allergic to SLOW-K*, ask your doctor for advice.

What the medicinal ingredient is:
potassium chloride

What the important nonmedicinal ingredients are:
cetostearyl alcohol, gelatin, magnesium stearate. The coating contains: carnauba wax, gelatin, spray dried Acacia, purified talc, sucrose (granulated), red iron oxide, titanium dioxide and yellow iron oxide.

What dosage forms it comes in:
SLOW-K* is available as 600 mg sugar-coated tablets containing potassium chloride.

WARNINGS AND PRECAUTIONS

BEFORE you use SLOW-K* talk to your doctor or pharmacist ~~if~~:

- If you are pregnant or breast feeding
- If you have heart disease
- If you have undergone any surgery of the intestine (e.g. colostomy, ileostomy or urostomy).
- If you were told by your doctor that your body has difficulty in eliminating potassium (e.g. because of kidney problems).
- If you have been told by your doctor that you have an intolerance to some sugars.

If this applies to you, tell your doctor.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, vitamins, herbals or a salt substitute as many salt substitutes contain potassium. It may be necessary to change the dose or in some cases to stop one of these medicines.

It is particularly important to tell your doctor or pharmacist if you are taking any of the following medicines:

- Potassium-sparing diuretics (e.g. spironolactone, triamterene, amiloride) used in the treatment of high blood pressure or certain heart diseases.
- ACE inhibitors (e.g. lisinopril, captopril) used in the treatment of high blood pressure.
- Angiotensin-II-receptor-antagonists (e.g. valsartan, losartan etc.) used in the treatment of high blood pressure.
- NSAIDs (e.g. indomethacin) used to relieve pain and inflammation.
- Beta-blockers (e.g. atenolol, bopindolol etc.) used in the treatment of high blood pressure.
- Anticholinergics (drugs which block the actions of the nerve transmitter, acetylcholine, and are used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, poisoning with certain toxic compounds, and as an aid to anaesthesia).
- Heparin used to prevent blood clotting.
- Digoxin used in the treatment of heart beat disorders.

- Cyclosporine used to control your body's immune system in order to prevent rejection of transplanted organs.

PROPER USE OF THIS MEDICATION

Usual dose:
Take this medicine only as instructed by your doctor.
The usual daily dose for adults at the start of the treatment is 2 to 3 sugar-coated tablets for prevention and 5 to 12 sugar-coated tablets for correction of potassium deficiency.
Your doctor will tell you exactly how many tablets of SLOW-K* to take.
Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

When to take SLOW-K*:
Taking SLOW-K* at the same time each day will help you remember when to take your medicine.
Do not take more of it, do not take it more often, and do not take it for a longer period of time than your doctor has directed. This is especially important if you are also taking diuretics and digitalis medicines for your heart.

How to take SLOW-K*:
Swallow the tablets whole with a full glass of water or other liquid during meals while sitting upright. Do not crush, chew, or suck the tablet.
If you have trouble swallowing tablets, or if they seem to stick in your throat, consult your doctor, because this could cause irritation that might lead to ulcers.

How long to take SLOW-K*:
SLOW-K* should be continued until potassium deficiency has been corrected.
Continue taking SLOW-K* as your doctor tells you.
If you have questions about how long to take SLOW-K*, talk to your doctor or your pharmacist.

Overdose:
If you have taken too much SLOW-K*, or if someone else accidentally takes your medicine, contact a doctor or hospital or your local poison control center for advice straight away. Show the pack of SLOW-K*. Medical treatment may be necessary.

Missed Dose:
If you forget to take a dose of this medicine, but remember to do so within 2 hours, take the missed dose right away with a full glass of water or other liquid. Then go back to your regular dosing schedule. However, if you do not remember until later, skip the missed dose and then go back to your regular dosing schedule. Do not double the doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, SLOW-K* can cause side effects, although not everybody gets them.
Some side effects are rare which include:

- Marked nausea or vomiting; pronounced flatulence; pain in the abdomen; diarrhea; stomach or intestinal problems such as obstruction, bleeding and ulceration; itchy skin rash.

Another side effect observed is increase in levels of potassium which may further aggravate kidney problems and lead to heart problems.
If any of these affects you severely, tell your doctor.
If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Monitoring during your treatment with SLOW-K*:
Your doctor will periodically monitor your blood potassium levels if you are taking SLOW-K* for a longer duration and/or are suffering from a heart or kidney disease. In addition, you should undergo cardiac examination and monitoring of blood pH and serum levels of other electrolytes (e.g. magnesium).

If you have any questions about how SLOW-K* works or why this medicine has been prescribed for you, ask your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Marked nausea or vomiting; pronounced flatulence; pain in the abdomen; diarrhea;		✓	✓
Rare	Stomach or intestinal problems such as obstruction, bleeding and ulceration; itchy skin rash		✓	

This is not a complete list of side effects. For any unexpected effects while taking SLOW-K* contact your doctor or pharmacist.

HOW TO STORE IT

- Do not use after the expiry date shown on the box.
- Store away from heat and moisture.
- Store in the original package.
- Keep out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through Canada Vigilance Program collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance by:

toll-free telephone: 866-234-2345
toll-free fax 866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca
By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.novartis.ca or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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