

# Slow-K® Product Licence

**Product Number:** 80040226

**Brand Name:** Slow-K

**Issued on February 21, 2013 to:**

**Name of licensee:**

Novartis Pharmaceuticals Canada Inc.  
385 Bouchard Blvd  
Dorval, Quebec, H9S 1A9  
Canada

Revised Date of Licence: March 31, 2016

## **Authorized for the following:**

**Dosage form:** Sugar-coated tablet

**Recommended route of administration:** Oral

**Recommended dose:**

Adults:

Take 2-6 tablets, once a day. Consult a health care practitioner to determine the proper dosage or if you are taking diuretics. 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. It is recommended not to exceed 12 tablets daily. If the daily requirement exceeds 20 mEq K+ (3-12 tablets), it should be taken in divided doses, so that not more than 20 mEq K+ (3 tablets) 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.

Adults:

Prevention of hypokalemia: Take 2-3 tablets, once a day (16 to 24 mEq is usually sufficient). Requirement will depend on the patient's individual needs and health care practitioner decision. Consult a health care practitioner to determine the proper dosage or if you are taking diuretics. 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. It is recommended not to exceed 12 tablets daily. If the daily requirement exceeds 20 mEq K+ (3-12 tablets), it should be taken in divided doses, so that not more than 20 mEq K+ (3 tablets) 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.

Adults:

Treatment of potassium depletion or metabolic alkalosis: Take 5-12 tablets, once a day (40-96 mEq/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. Consult a health care practitioner to determine the proper dosage or if you are taking diuretics. 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. It is recommended not to exceed 12 tablets daily. If the daily requirement exceeds 20 mEq K+ (3-12 tablets), it should be taken in divided doses, so that not more than 20 mEq K+ (3 tablets) 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.

**Recommended duration of use:**

N/A

**Recommended use or purpose:**

Treatment of potassium depletion in patients with hypokalemia and metabolic alkalosis. Helps to prevent potassium deficiency due to low dietary intake. Helps to prevent potassium deficiency (hypokalemia) not resulting from a dietary deficiency.

**Risk Information:****Cautions and Warnings**

To be taken only on the advice of a physician. Consult a health care practitioner prior to use if you have a kidney or heart condition. Do not use if you have adrenal insufficiency or uncontrolled diabetes mellitus. Do not use if you are taking medications which increase serum potassium such as potassium-sparing diuretics or angiotensin converting enzyme (ACE) inhibitors. Do not use with other potassium-containing supplements or with potassium-containing salt-substitutes. Do not use if you have a gastrointestinal ulceration or obstruction. Do not use if you have trouble swallowing (dysphagia) or if you are at a high risk for potassium chloride-induced gastric lesions (e.g. due to recent gastric surgery). Consult a health care practitioner prior to use if you are pregnant or breastfeeding. Discontinue use and consult a health care practitioner immediately if you experience numbness of the extremities, muscle weakness, paralysis, cardiac arrhythmias, low blood pressure, or confusion.

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. 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 sucraseisomaltase 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. 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<sup>+</sup> content of human milk is approximately 13mEq/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.

### 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. In case of moderate/severe hyperkalemia, standard treatment should be initiated with monitoring of the serum potassium levels. Rare cases of pharmacobezoar have been reported in association with large overdose of Slow-K tablets.

### **Contra-indications**

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. 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). 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.

### **Known Adverse Reactions**

#### 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. 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.

Electrolytes

One of the most severe adverse effects is hyperkalemia

Skin

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

**Medicinal Ingredients**

<b>Proper Name</b>	<b>Common Name</b>	<b>Quantitiy per Dosage Unit</b>	<b>Extract</b>	<b>Potency</b>	<b>Source Material</b>
Potassium Chloride	Potassium Chloride	600 mg	N/A	312.0 mg Potassium Ion	Synthetic