

PRESCRIBING INFORMATION

POLYCITRA-K*

potassium citrate and citric acid oral solution, USP

398 mg potassium/5 mL

Potassium Supplement

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CLINICAL PHARMACOLOGY

POLYCITRA-K (potassium citrate and citric acid) oral solution is a pleasant-tasting, sugar-free, oral potassium supplement.

INDICATIONS

POLYCITRA-K (potassium citrate and citric acid) is indicated for the treatment or prevention of hypokalemia, treatment of digitalis intoxication, and for the treatment of potassium replacement and electrolyte recharge.

CONTRAINDICATIONS

POLYCITRA-K (potassium citrate and citric acid) is contraindicated in patients with ventricular fibrillation, hyperkalemia of various etiologies in association with Addison's disease, suprarenal hyperplasia associated with a loss of salt, extensive tissue deterioration such as severe burns, acute dehydration and heat cramps.

POLYCITRA-K is contraindicated in patients with severe renal impairment with oliguria or azotemia.

POLYCITRA-K is contraindicated in patients with increased hypersensitivity to potassium (e.g. paramyotonia congenita or adynamia episodica hereditaria).

WARNINGS

The administration of potassium salts to patients with disturbed potassium elimination (e.g. patients with chronic nephropathy) may cause hyperkalemia and cardiac arrest. This phenomenon is more frequent with intravenous potassium administration while it may occur with oral treatment. Severe or even fatal hyperkalemia may appear rapidly, without any particular prodrome. Therefore, use of potassium salts requires a particular monitoring of kalemia with frequent evaluations and dosage adjustments.

Concurrent administration with potassium-sparing diuretics (spironolactone, triamterene, amiloride) might induce hyperkalemia. In the presence of renal impairment, the administration of potassium supplements must be closely monitored.

PRECAUTIONS

The therapeutic use of potassium in potassium-depletion cases requires a particular monitoring of the acid-base equilibrium, especially in the presence of cardiac disease, renal disease or acidosis. Regular verifications of the serous electrolytes rate of ECG and of the clinical state of the patient should take place. Potassium must be used cautiously in case of disease associated with heart block, as the increase in potassium serous concentration may increase the blockage degree.

ADVERSE REACTIONS

The adverse events that resulted from potassium salt administration were nausea, vomiting, diarrhea and abdominal discomfort. In order to decrease the incidence of gastrointestinal irritation associated with the oral ingestion of concentrated potassium-salt preparations, patients must be instructed to:

- completely dissolve each dose in the indicated quantity of water,
- increase the hydrous intake, if possible,
- and take the product after a meal.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Potassium concentrations above 4 mEq/L and above 2 g/day in the blood and urine respectively may cause hyperkalemia in the normal effort conditions.

Overdosage may cause paresthesia of the extremities, apragmatism, mental confusion, tiredness, paralysis, hypotension, cardiac arrhythmias, cardiac block and arrest.

ECG alterations are characterized by the amplitude and the increase of T waves, the lowering of the ST segment, the decrease in R wave amplitude, the widening of the QRS complex, the extension of the PR interval and the disappearance of the P wave. Widening of the QRS complex is one of the major symptoms and must alert to the importance of rigorous measures.

Hyperkalemia is often asymptomatic and only manifested by elevated serous concentration and the above-mentioned electrocardiographic alterations.

Treatment

- Deletion of the potassium-containing food and drugs, and of the potassium-sparing diuretics.
- Intravenous administration of 300 to 500 mL/hour of a 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1,000 mL.
- Use of the ion-exchange resins, hemodialysis or peritoneal dialysis.
- In the presence of threatening cardiac arrhythmias, administration of 10 to 50 mL of a 10 % solution of calcium gluconate intravenously during 1 to 5 minutes to interfere with the cardiac toxicity.
- It is essential to keep the patient under ECG telecontrol.

The fast decrease in serum concentrations, during the treatment of hyperkalemia in digitalis-stabilized patients, may cause digitalis intoxication.

DOSAGE AND ADMINISTRATION

In adults, the recommended dose of POLYCITRA-K (potassium citrate and citric acid) is 1 to 2 teaspoonfuls (5 to 10 mL providing 10 to 20 mEq) three times daily, after meals, diluted in 250 mL of cold water or juice.

For prevention of hypokalemia: Take 2 to 4 teaspoons (10 to 20 mL providing 20 to 40 mEq) per day after meals, in 2 to 4 divided doses, diluted in 250 mL of cold water or juice.

To be taken immediately after meals or with food, to reduce the possibility of upset stomach or laxative effect.

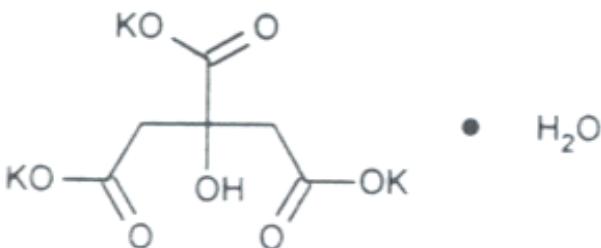
PHARMACEUTICAL INFORMATION**Drug Substance**

Proper Name: potassium citrate monohydrate

Chemical Name: 1,2,3-propane tricarboxylic acid, 2-hydroxy-, tripotassium salt, monohydrate

Tripotassium citrate monohydrate

Structural Formula:



Molecular Formula: $C_6H_5K_3O_7 \cdot H_2O$

Molecular Weight: 324.41

Description: Potassium citrate is an odorless transparent crystal, or white granular powder.

Composition

Each teaspoon (5 mL) of POLYCITRA-K (potassium citrate and citric acid) contains 398 mg of potassium (from 1100 mg potassium citrate monohydrate), providing 10 mEq potassium, equivalent to 10 mEq bicarbonate (HCO_3).

The inactive ingredients are: citric acid, purified water, sodium saccharin, sodium carboxymethyl cellulose, butylparaben, purified siliceous earth, glycerin, vanillin, FD&C Red No. 40, folded orange oil, and loganberry flavour.

Stability and Storage Recommendations

POLYCITRA-K (potassium citrate and citric acid) oral solution should be stored at controlled room temperature ($15^\circ\text{C} - 30^\circ\text{C}$). Protect from freezing.

AVAILABILITY OF DOSAGE FORMS

POLYCITRA-K (potassium citrate and citric acid) oral solution is supplied in bottles of 475 mL with a plastic child-resistant closure.