



POTASSIUM CITRATE POWDER MONODOSES

Expanded Under Prescription

Made in Argentina

Formulation: Each monodose contains: Potassium Citrate 3,000 g. Inactive ingredients: Aspartamo 0,025 g, Orange peel flavour 0,070 g, Tricalcium phosphate 0,015 g, Silicon dioxide 0,004 g.

Therapeutic actions: Treatment and prevention of renal lithiasis.

Indications: Calcic, uric and combined lithiasis.

Pharmacological action: The oral administration of potassium citrate produces an alkaline charge which increases urinary pH. It also increases urinary citrate, not due to an increased filter charge of citrate but because it alters the renal handling of citrate. Citrate delays the crystallization of calcium salts which form stones through two mechanisms: 1º) it forms complexes with calcium and reduces the concentration of ionic calcium, thus reducing urinary saturation of oxalate, which is the moving force of the crystallization of said salts, 2º) citrate directly inhibits oxalate crystallization. Potassium citrate does not alter the saturation of calcium phosphate salts, because the beneficial effect that the formation of calcium citrate complexes may have is lost due to the pH increase which increases phosphate dissociation. Calcium phosphate stones are more stable in an alkaline medium. Citrate has been shown to inhibit the spontaneous precipitation of calcium oxalate and it delays the agglutination of preformed calcium oxalate crystals.

Pharmacokinetics: Under normal conditions, most of the potassium citrate orally administrated is absorbed. Almost all the citrate which is absorbed is oxidized under normal conditions, while the potassium ion remains free, thus generating an alkaline charge. This alkaline charge increases the pH and the urinary citrate. There is evidence that shows that a small amount of the absorbed citrate is not oxidized and appears in the urine. The citraturic action of potassium citrate contributes in a smaller degree. About 75% of the renally filtered citrate is reabsorbed, while the remaining 25% is eliminated in the urine. In case of hypokalemia, the potassium ion per se may increase urinary excretion of citrate when attempting to correct intracellular acidosis.

Dosage: Hypocitraturic calcic lithiasis: Mild to moderate hypocitraturia: 2 monodoses per day. Severe hypocitraturia (e.g. associated to chronic diarrheic syndrome or total tubular renal acidosis): up to 4 monodoses daily. Hyper-uricosuric calcic lithiasis: 1 to 2 monodoses daily. Non-hyperuricosuric calcic lithiasis: in all patients treated with thiazides it's recommended one monodose per day. Uric lithiasis: 1 to 2 monodoses daily. One daily monodose should always be divided in two times.

Contraindications: Renal insufficiency. Urinary infections. Urinary tract obstruction. Hyponatremia. Adrenocortical insufficiency. Hypokalemia. Hypochlorhydria. Metabolic or respiratory alkalosis. Active peptic ulcer. Intestinal obstruction. Patients under anticholinergic therapy. Heart disease which can be aggravated by potassium.

Warnings: In patients with alterations in the potassium excretion mechanisms, such as renal insufficiency, there is risk of life-threatening hyponatremia.

Precautions: It is recommended to determine the plasmatic electrolytes (sodium, potassium and chloride), the creatinine and the hemogram every four months. Patients under treatment with UROKIT are encouraged to go on a salt-free diet and to increase the consumption of liquids.

Drug Interactions: Urine alkalization, through a mechanism of ion trapping, may favor urinary excretion of weak acids such as salicylates and phenobarbital. On the other hand, it decreases the elimination of certain sympathomimetic and stimulating drugs (such as amphetamines). It should be administered with caution to patients who are taking other drugs which may increase natriuremia, such as potassium sparing diuretics, ACE inhibitors, cyclosporine, potassium penicillin. Drugs with antimuscarinic effect (antispasmodic, etc.) delay the gastric emptying and may increase gastrointestinal toxicity of potassium salts.

Adverse reactions: Mild gastrointestinal disorders such as abdominal discomfort, nausea, vomiting and diarrhea may occur. They may be reduced by administering this drug with food.

Overdose: Long-term administration to patients with potassium excretion disorders may produce hyponatremia which, in advanced stages, may cause muscular paralysis and cardiovascular collapse. Excessive doses of citrate have laxative effects.

Recommended initial treatment: In patients with hyponatremia, the administration of i.v. 10% dextrose solution containing 10-20 units of insulin/1000ml is recommended. The correction of the probable acidosis will be carried out with i.v. sodium bicarbonate and peritoneal dialysis

Storage:

- Do not store above 30°C. Protect from moisture and light.
- Keep away from the reach of the children.

How Supplied: Containers with 20 and 60 monodoses.

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