POTASSIUM CITRATE

ACITRATE

1080 mg Extended-Release Tablet

ANTIUROLITHIC

℞

FORMULATION:
Each extended-release tablet contains:
Potassium Citrate USP (10 mEq).....1080 mg

PRODUCT DESCRIPTION:
White to off white colour elongated biconvex extended-release tablets having scored on one side.

PHARMACODYNAMICS:
Metabolism of absorbed Potassium Citrate produces an alkaline load, raising urinary pH and increasing urinary citrate by augmenting citrate clearance. Thus, Potassium Citrate therapy appears to increase urinary citrate mainly by changing the renal handling of citrate. Increased urinary citrate and pH, decreases calcium ion activity by increasing calcium complexation to dissociated anions. Thus, decreasing the saturation of calcium oxalate.
Potassium Citrate also inhibits the crystallization and spontaneous nucleation of calcium oxalate and calcium phosphate in hypocitraturic calcium nephrolithiasis. However, Potassium Citrate does not alter the urinary saturation of calcium phosphate, because the effect of increased citrate complexation of calcium is antagonized by the rise in pH-dependent dissociation of phosphate. Calcium phosphate stones are more stable in alkaline urine.

MECHANISM OF ACTION:
Potassium Citrate, which works by restoring naturally occurring chemicals in the urine that stop crystals from forming and also inhibits the formation of the 2 most common types of kidney stones, calcium oxalate and uric acid stones. In numerous studies, patients treated with Potassium Citrate have demonstrated significantly lower rates of kidney stone formation. In many patients, new stones do not form at all.

PHARMACOKINETICS:
Potassium citrate is administered orally. Potassium first enters the extracellular fluid and is then actively transported into cells. Skeletal muscle accounts for the bulk of the intracellular store of potassium. Renal excretion of potassium normally is equal to the amount being absorbed in the diet. Potassium is freely filtered at the glomerulus and almost completely reabsorbed in the proximal tubule. Tubular secretion occurs in the late distal convoluted tubule and collecting duct, and accounts for the potassium excreted in the urine, which is about 10% of the amount filtered. Fecal elimination of potassium is minimal and plays no significant role in potassium homeostasis.
When Potassium Citrate is used to alkalinize the urine, urinary citrate and urinary pH values are important. In the setting of normal renal function, the rise in urinary citrate following a single dose of extended-release Potassium Citrate begins by the first hour and lasts for 12 hours.
With multiple doses, the rise in citrate excretion reaches its peak by the third day and averts the normally wide circadian fluctuation in urinary citrate, thus maintaining urinary citrate at a higher, more constant level throughout the day. The rise in citrate excretion is directly dependent on the Potassium Citrate dosage.
When the treatment is withdrawn, urinary citrate begins to decline toward the pre-treatment level on the first day.
Following long-term treatment, Potassium Citrate at a dosage of 60 mEq/day raises urinary citrate by approximately 400 mg/day and increases urinary pH by approximately 0.7 units.
In patients with severe renal tubular acidosis or chronic diarrhea syndrome where urinary citrate may be very low (<100 mg/day), Potassium Citrate may be relatively ineffective in raising urinary citrate. A higher dose of Potassium Citrate may therefore be required to produce a satisfactory citraturic response. In patients with renal tubular acidosis in whom urinary pH may be high, Potassium Citrate produces a relatively small rise in urinary pH.
In addition to raising urinary pH and citrate, Potassium Citrate increases urinary potassium by approximately the amount contained in the medication. In some patients, Potassium Citrate causes a transient reduction in urinary calcium.

INDICATIONS:
Potassium Citrate is indicated for the management of renal tubular acidosis (RTA) with calcium stones, hypocitraturic calcium oxalate nephrolithiasis of any etiology, and uric acid lithiasis with or without calcium stones.

DOSAGE AND ADMINISTRATION:
In patients with severe hypocitraturia (urinary citrate of less than 150 mg/day), therapy should be initiated at a dosage of 60 mEq/day (20 mEq three times/day or 15 mEq four times/day with meals or within 30 minutes after meals or bedtime snack). In patients with mild-moderate hypocitraturia (>150 mg/day), Potassium Citrate tablet should be initiated at a dosage of 30 mEq/day (10 mEq three times/day with meals).
Twenty-four hour urinary citrate and/or urinary pH measurements should be used to determine the adequacy of the initial dosage and to evaluate the effectiveness of any dosage change. In addition, urinary citrate and/or pH should be measured every four months.
Or as prescribed by the physician.

CONTRAINDICATIONS:
Potassium Citrate tablet is contraindicated in patients with hyperkalemia (or who have conditions predisposing them to hyperkalemia), as a further rise in serum potassium concentration may produce cardiac arrest. Such conditions include: chronic renal failure, uncontrolled diabetes mellitus, acute dehydration, strenuous physical exercise in unconditioned individuals, adrenal insufficiency, extensive tissue breakdown, or the administration of a potassium-sparing diuretics (such as triamterene, spironolactone or amiloride). Potassium Citrate tablet is contraindicated in patients in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract, such as those suffering from delayed gastric emptying, esophageal compression, intestinal obstruction or stricture or those taking anticholinergic medication. Because of its ulcerogenic potential, Potassium Citrate tablet should not be given to patients with peptic ulcer disease. Potassium Citrate tablet is contraindicated in patients with renal insufficiency (glomerular filtration rate of less than 0.7 mL/kg/min), because of the danger of soft tissue calcification and increased risk for the development of hyperkalemia.

WARNINGS AND PRECAUTIONS:
Hyperkalemia: In patients with impaired mechanisms for excreting potassium, Potassium Citrate tablet administration can produce hyperkalemia and cardiac arrest. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of Potassium Citrate tablet in patients with chronic renal failure, or any other condition which impairs potassium excretion such as severe myocardial damage or heart failure, should be avoided.
Interaction with potassium-sparing diuretics: Concomitant administration of Potassium Citrate tablet and a potassium-sparing diuretics (such as triamterene, spironolactone or amiloride) should be avoided, since the simultaneous administration of these agents can produce severe hyperkalemia. If there is severe vomiting, abdominal pain or gastrointestinal bleeding, Potassium Citrate tablet should be discontinued immediately and the possibility of bowel perforation or obstruction investigated.
Precautions: Physicians should consider reminding the patient of the following: To take each dose without crushing, chewing or sucking the tablet, to take this medicine only as directed. This is especially important if the patient is also taking both diuretics and digitalis preparations; to check with physician if there is trouble swallowing tablets or if the tablet seems to stick in the throat; to check with the doctor at once if tarry stools or other evidence of gastrointestinal bleeding is noticed.

PREGNANCY AND LACTATION:
Pregnancy Category C: It is not known whether Potassium Citrate can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.
Potassium Citrate should be given to a pregnant woman only if clearly needed.
The normal Potassium ion content of human milk is about 13 mEq/L; it is not known if Potassium Citrate has an effect on the potassium content of milk. Exercise caution when Potassium Citrate is administered to a breastfeeding woman.

Children:
Safety and effectiveness in children have not been established.

ADVERSE DRUG REACTIONS:
Some patients may develop minor gastrointestinal complaints during Potassium Citrate therapy, such as abdominal discomfort, vomiting, diarrhea, loose bowel movements or nausea. These symptoms are due to the irritation of the gastrointestinal tract, and may be alleviated by taking the dose with meals or snack, or by reducing the dosage. Patients may find intact matrices in feces.

OVERDOSE AND TREATMENT:
Overdosage with potassium salts may cause hyperkalemia and alkalosis, especially in the presence of renal disease. It is necessary to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking T-waves, loss of P-wave, depression of S-T segment and prolongation of the QT interval). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest.

DRUG INTERACTIONS:
Concomitant administration of Potassium Citrate and a potassium-sparing diuretics (such as triamterene, spironolactone or amiloride) should be avoided, since the simultaneous administration of these agents can produce severe hyperkalemia.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

ADVERSE DRUG REACTION REPORTING STATEMENT:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
Alu/Alu Blister Pack x 10's (Box of 30's).

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