Potassium Citrate

Tascit®

1080 mg (10 mEq) Extended-Release Tablet
1620 mg (15 mEq) Extended-Release Tablet
Antiurolithic

FORMULATION

Each extended-release tablet contains:
Potassium citrate (as monohydrate).....1080 mg (10 mEq) or 1620 mg (15 mEq)

PRODUCT DESCRIPTIONS

Potassium Citrate (Tascit) 1080 mg (10 mEq) Extended-Release Tablet: Cream-mottled, elliptical tablet, plain on both sides

Potassium Citrate (Tascit) 1620 mg (15 mEq) Extended-Release Tablet: Cream-mottled, modified oval tablet, plain on both sides

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, and, to a smaller extent, by increasing the filterable load of citrate. Increased urinary citrate and pH decrease calcium ion activity by increasing calcium complexation to dissociated anions and 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.

PHARMACOKINETICS

Potassium citrate is oxidized in the body to form potassium bicarbonate. Oxidation is virtually complete. Less than 5% of the citrate is excreted unchanged in the urine.

INDICATIONS

For the management of:
- Renal tubular acidosis (RTA) with calcium stones
- Hypocitraturic calcium oxalate nephrolithiasis of any etiology
- Uric acid lithiasis with or without calcium stones

For the prevention of stone relapse after extracorporeal shock wave lithotripsy (ESWL) or lithotomy

DOSAGE AND ADMINISTRATION

General Dosing Recommendations:
- Potassium citrate extended-release tablet is in a wax matrix slow-release preparation. The tablet should be swallowed whole, not crushed, chewed or sucked to prevent premature release of active ingredient.
- Take the tablet 30 minutes after meals.
- Limit salt intake by avoiding food with high salt content while on potassium citrate therapy.
- Increase fluid intake. Urine volume should be at least two liters per day.

Adult Dose:

Severe Hypocitraturia (urinary citrate <150 mg/day):
Orally, 60 mEq/day taken in two or three divided doses (30 mEq two times/day or 20 mEq three times/day)

Mild to Moderate Hypocitraturia (urinary citrate >150 mg/day):
Orally, 30 mEq/day taken in two or three divided doses (15 mEq two times/day or 10 mEq three times/day).

Or, as prescribed by a physician.

CONTRAINDICATIONS

- Hypersensitivity to any component of the product
- Patients with hyperkalemia or who have conditions predisposing them to hyperkalemia such as:
  - Chronic renal failure
  - Uncontrolled diabetes mellitus
  - Familial hyperkalemic periodic paralysis *(adynamia episodica hereditaria)*
  - Acute dehydration
  - Strenuous physical exercise in unconditioned individuals
  - Adrenal insufficiency
  - Extensive tissue breakdown
  - Severe myocardial damage
  - Administration of potassium-sparing diuretic (e.g., triamterene, spironolactone or amiloride)
- Patients with slow gastric emptying, esophageal compression, intestinal obstruction or stricture
- Patients on anticholinergic therapy
- Patients with active peptic ulcer disease
- Patients with active urinary tract infection (with either urea-splitting bacteria or other organisms, in association with either calcium or struvite stones)
- Patients with renal insufficiency (glomerular filtration rate of less than 0.7 mL/kg/min)
- Patients with respiratory or metabolic acidosis

WARNINGS AND PRECAUTIONS

Hyperkalemia: Potassium citrate administration can produce hyperkalemia and cardiac arrest in patients with impaired mechanisms for potassium excretion. Potentially fatal hyperkalemia may develop rapidly and may be asymptomatic. Use of potassium citrate should therefore be avoided in patients with chronic renal failure, or any other condition which impairs potassium excretion such as severe myocardial damage or heart failure.

Gastrointestinal Lesions: In the event of severe vomiting, abdominal pain or gastrointestinal bleeding, potassium citrate treatment should be discontinued immediately and the possibility of bowel perforation or obstruction investigated. Patient should also be instructed to inform physician at once if tarry stools or other evidence of gastrointestinal bleeding is noticed.

General: Regular serum potassium monitoring is recommended. Acid-base balance, other serum electrolyte levels, and electrocardiogram (ECG) should periodically be determined. Careful attention should likewise be given to the patient's clinical status, particularly in the presence of cardiac disease, renal disease or acidosis.

Discontinue potassium citrate treatment in the occurrence of hyperkalemia, a significant rise in serum creatinine, or a significant fall in blood hematocrit or hemoglobin.

INTERACTIONS WITH OTHER MEDICAMENTS

Potassium-sparing Diuretics: Concomitant administration of potassium citrate and potassium-sparing diuretics (e.g., triamterene, spironolactone, or amiloride) should be avoided, since simultaneous administration of these agents can produce severe hyperkalemia.
Drugs that slow gastrointestinal transit time: These agents (e.g., anticholinergics) can be expected to increase the gastrointestinal irritation caused by potassium salts.

STATEMENT ON USAGE FOR HIGH RISK GROUPS

Pregnancy: 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.

Lactation: 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 milk potassium content. Exercise caution when potassium citrate is administered to a breastfeeding woman.

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

UNDESIRABLE EFFECTS

Potassium citrate therapy may cause minor gastrointestinal complaints such as abdominal discomfort, vomiting, diarrhea, loose bowel movements, and nausea. These symptoms are due to irritation of the gastrointestinal tract, and may be avoided by taking the dose with meals or snack, or dose reduction. Intact matrices may appear in the 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-wave, 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.

Measures for treating hyperkalemia include the following:
- Patients should be closely monitored for arrhythmias and electrolyte changes.
- Elimination of potassium-containing medications and of agents with potassium sparing properties such as potassium-sparing diuretics, angiotensin receptor blockers (ARBs), angiotensin converting enzyme (ACE) inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDs), certain nutritional supplements and many others.
- Elimination of foods containing high levels of potassium such as almonds, bananas, beans, grapefruit juice, halibut, milk, salmon, spinach, tuna and many others.
- Intravenous calcium gluconate if the patient is at no risk or low risk of developing digitalis toxicity.
- Intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1000 mL.
- Correction of acidosis, if present, with intravenous sodium bicarbonate.
- Hemodialysis or peritoneal dialysis.
- Exchange resins may be used. However, this measure alone is not sufficient for the acute treatment of hyperkalemia.

Lowering potassium levels too rapidly in patients taking digitalis can produce digitalis toxicity.

STORAGE CONDITION

Store at temperatures not exceeding 30°C. Keep the product out of sight and reach of children

CAUTION

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

AVAILABILITY

Potassium Citrate (Tascit) 1080mg(10mEq) Extended-Release Tablet in flex foil, box of 30's and 100's
Potassium Citrate (Tascit) 1620mg (15mEq) Extended-Release Tablet in flex foil of 4's, box of 100's

Manufactured by AMHERST LABORATORIES, INC.
UNILAB Pharma Campus, Barangay Mamplasan
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Trusted Quality Healthcare

Date of Revision : June 2015
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