Prescribing Information

UROCIT®-K POTASSIUM CITRATE
Wax Matrix tablets 5 & 10 meq

BRIEF SUMMARY; CONSULT THE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE: 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.

CONTRAINDICATIONS: UROCIT®-K 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 agent (such as triamterene, spironolactone or amiloride).

UROCIT-K 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, UROCIT-K should not be given to patients with peptic ulcer disease.

UROCIT-K 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: HYPERKALEMIA: In patients with impaired mechanisms for excreting potassium, UROCIT-K administration can produce hyperkalemia and cardiac arrest. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of UROCIT-K 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 UROCIT-K and a potassium-sparing diuretic (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 gastro-intestinal bleeding, UROCIT-K should be discontinued immediately and the possibility of bowel perforation or obstruction investigated.

PRECAUTIONS:

INFORMATION FOR PATIENTS:
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.

LABORATORY TESTS: Regular serum potassium determinations are recommended. Careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease or acidosis.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Long-term carcinogenicity studies in animals have not been performed.

PREGNANCY CATEGORY C : Animal reproduction studies have not been conducted with UROCIT-K. It is also not known whether UROCIT-K can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. UROCIT-K should be given to a pregnant woman only if clearly needed.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Some patients may develop minor gastrointestinal complaints during UROCIT-K therapy, such as abdominal discomfort, vomiting, diarrhea, loose bowel movements or nausea.

OVERDOSAGE: In overdosage of UROCIT-K treat for hyperkalemia.

DOSAGE AND ADMINISTRATION: Treatment with UROCIT-K should be added to a regimen that limits salt intake (avoidance of foods with high salt content and of added salt at the table) and encourages high fluid intake (urine volume should be at least two liters per day). The objective of treatment with UROCIT-K is to provide UROCIT-K in sufficient dosage to restore normal urinary citrate (greater than 320 mg/day and as close to the normal mean of 640 mg/day as possible), and to increase urinary pH to a level of 6.0 to 7.0.

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), UROCIT-K 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.

Doses of UROCIT-K greater than 100 meq/day have not been studied and should be avoided.

HOW SUPPLIED: UROCIT-K is available for oral administration in tablet form in the following sizes:
(NDC 0178-0600-01) 5 meq potassium citrate and (NDC 0178-0610-01) 10 meq potassium citrate, packaged in bottles of 100 each.

RX ONLY Rev 08980

References: 1. Preminger GM, Sakhaee K, Skurla C, et al. Prevention of recurrent calcium stone formation with potassium citrate therapy in patients with distal renal tubular acidosis. J Urol. 1985;134:20-23. **2.** Pak CYC, Peterson R, Sakhaee K, et al. Correction of hypocitraturia and prevention of stone formation by combined thiazide and potassium citrate therapy in thiazide-unresponsive hypercalciuric nephrolithiasis. Am J Med. 1985;79:284-288. **3.** Pak CYC, Fuller C. Idiopathic hypocitraturic calcium-oxalate nephrolithiasis successfully treated with potassium citrate. Ann Intern Med. 1986;104:33-37.