Urilit

Potassium citrate

Description
Potassium citrate is used to treat a kidney stone condition called renal tubular acidosis.

Mode of action
After given orally, the metabolism of absorbed citrate produces an alkaline load, which increases urinary pH and urinary citrate. In addition 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 which produces the urine that is less conducive to the crystallization of stone-forming salts (calcium oxalate, calcium phosphate and uric acid). Increased citrate in the urine decreases calcium ion activity and thus the saturation of calcium oxalate. Citrate also inhibits the spontaneous nucleation of calcium oxalate and calcium phosphate (brushite). The increase in urinary pH also decreases calcium ion activity and increases the ionization of uric acid to more soluble urate ion.

Pharmacokinetics
After orally taken, the rise in urinary citrate following a single dose begins by the first hour and lasts for 12 hours. With multiple doses the rise in the citrate excretion reaches its peak by the third day. When the treatment is withdrawn, urinary citrate begins to decline toward the pre-treatment level on the first day. The rise in citrate excretion is directly dependent on the dosage. 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. Potassium citrate is metabolized in liver to potassium bicarbonate and excreted through urine.

Composition
Urilit Tablet: Each Tablet Contains Potassium Citrate BP 1.08 gm

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

Dosage & administration
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.

o Severe hypocitraturia (urinary citrate < 150 mg/day): therapy should be - initiated at 60 -mEq/day; two or three times per day with -meals or within 30 minutes after meals or bedtime snack
o Mild to moderate hypocitraturia (urinary citrate >150 mg/day): therapy -should be initi-ated at 30 mEq/day; two or three times -per day with meals or within 30 minutes -after meals or bedtime snack

Doses greater than 100 mEq/day have not been studied and should be avoided.
Serum electrolytes & complete blood count should be monitored every four months.

Use in children
Safety and effectiveness in children have not been established.

Contraindications
Severe renal insufficiency; sodium-restricted diet (sodium citrate); untreated Addison's disease; severe myocardial damage; acute dehydration; patients with hyperkalemia; patients with delayed gastric emptying, esophageal compression, intestinal obstruction or stricture, or those taking anticholinergic medication; patients with active urinary tract infection

Side effects
Some patients may develop minor gastrointestinal complaints during the therapy, such as abdominal discomfort, vomiting, diarrhoea, 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 a snack, or by reducing the dosage. Patients may find intact wax matrices in their faeces. Bradycardia may occur (1% to 10% of patients)

Use in pregnancy & lactation
Animal reproduction studies have not been conducted. It is also not known whether it can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. It 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 it has an effect on this content. Caution should be exercised when it is administered to a nursing woman.

Precautions
In patients with impaired mechanisms for excreting potassium, potassium citrate administration can produce hyperkalaemia and cardiac arrest. Irritation of the gastrointestinal tract may be alleviated by taking the dose with meals.

Drug interactions
Concomitant administration of Potssium citrate and a potassium-sparing diuretic should be best avoided, since the simultaneous administration of these agents can produce severe hyperkalaemia.
Drugs that slow gastrointestinal transit time can be expected to increase the gastrointestinal irritation produced by potassium salts.

Over dosage
Overdose symptoms include Diarrhea, nausea, vomiting, hypernoia (excessive mental activity), convulsions, hyperkalemia, alkalosis.
Treatment measures for hyperkalaemia include the following:
(1) Elimination of potassium-rich foods, medications containing potassium, and of potassium-sparing diuretics;
(2) Intravenous administration of 300 - 500 mL/h of 10% glucose solution containing 10 - 20 units of insulin/1000 mL
(3) Correction of acidosis, if present, with intravenous sodium bicarbonate; and
(4) Use of exchange resins, haemodialysis or peritoneal dialysis.

Storage
Store in a dry place and protected from light. Keep out of reach of children. Keep the container tightly closed.

Packaging
Urilit Tablet: Each plastic container contains 15/30/50 tablets.

Opsonin
Opsonin Pharma
Ideas for healthcare

Manufactured by
Opsonin Pharma Limited
Barisal, Bangladesh.