POTASSIUM CITRATE AND CITRIC ACID- potassium citrate and citric acid monohydrate solution
Pharmaceutical Associates, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Potassium Citrate and

Citric Acid Oral Solution USP

Rx ONLY

DESCRIPTION

Potassium Citrate and Citric Acid Oral Solution USP is a stable and pleasant-tasting oral systemic alkalizer containing potassium citrate and citric acid in a sugar-free, non-alcoholic base.

Potassium Citrate and Citric Acid Oral Solution USP contains in each teaspoonful (5 mL):

POTASSIUM CITRATE Monohydrate 1100 mg

CITRIC ACID Monohydrate 334 mg

Each mL contains 2 mEq potassium ion and is equivalent to 2 mEq bicarbonate (HCO_3).

Inactive Ingredients: FD&C Red No. 40, flavoring, polyethylene glycol, propylene glycol, purified water, sodium benzoate, and sorbitol solution.

ACTIONS

Potassium citrate is absorbed and metabolized to potassium bicarbonate, thus acting as a systemic alkalizer. The effects are essentially those of chlorides before absorption and those of bicarbonates subsequently. Oxidation is virtually complete so that less than 5% of the potassium citrate is excreted in the urine unchanged.

INDICATIONS AND USAGE

Potassium Citrate and Citric Acid Oral Solution USP is an effective alkalinizing agent useful in those conditions where long-term maintenance of an alkaline urine is desirable, such as in patients with uric acid and cystine calculi of the urinary tract, especially when the administration of sodium salts is undesirable or contraindicated. In addition, it is a valuable adjuvant when administered with uricosuric agents in gout therapy, since urates tend to crystallize out of an acid urine. It is also effective in correcting the acidosis of certain renal tubular disorders where the administration of potassium citrate may be preferable. This product is highly concentrated, and when administered after meals and before bedtime, allows one to maintain an alkaline urinary pH around the clock, usually without the necessity of a 2 A.M. dose. This product alkalinizes the urine without producing a systemic alkalosis in recommended dosage. It is highly palatable, pleasant tasting and tolerable, even when administered for long periods. Potassium citrate does not neutralize the gastric juice or disturb digestion.

CONTRAINDICATIONS

Severe renal impairment with oliguria or azotemia, untreated Addison's disease, adynamia episodica hereditaria, acute dehydration, heat cramps, anuria, severe myocardial damage, and hyperkalemia from any cause.

WARNINGS

Large doses may cause hyperkalemia and alkalosis, especially in the presence of renal disease. Concurrent administration of potassium-containing medication, potassium-sparing diuretics, angiotensin-converting enzyme (ACE) inhibitors, or cardiac glycosides may lead to toxicity.

PRECAUTIONS

Should be used with caution by patients with low urinary output unless under the supervision of a physician. As with all liquids containing a high concentration of potassium, patients should be directed to dilute adequately with water to minimize the possibility of gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations; and preferably, to take each dose after meals to avoid saline laxative effect.

ADVERSE REACTIONS

Potassium Citrate and Citric Acid Oral Solution USP is generally well tolerated without any unpleasant side effects when given in recommended doses to patients with normal renal function and urinary output. However, as with any alkalinizing agent, caution must be used in certain patients with abnormal renal mechanisms to avoid development of hyperkalemia or alkalosis. Potassium intoxication causes listlessness, weakness, mental confusion, tingling of extremities, and other symptoms associated with a high concentration of potassium in the serum. Periodic determinations of serum electrolytes should be carried out in those patients with renal disease in order to avoid these complications. Hyperkalemia may exhibit the following electrocardiographic abnormalities: Disappearance of the P wave, widening and slurring of QRS complex, changes of the S-T segment, tall peaked T waves, etc.

OVERDOSAGE

The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired, hyperkalemia can result (see Contraindications and Warnings). Hyperkalemia, when detected, must be treated immediately because lethal levels can be reached in a few hours.

TREATMENT OF HYPERKALEMIA

Should hyperkalemia occur, treatment measures include the following: (1) Elimination of foods or medications containing potassium. (2) The intravenous administration of 300 to 500 mL/hr of dextrose solution (10 to 25%), containing 10 units of insulin/20 gm dextrose. (3) The use of exchange resins, hemodialysis, or peritoneal dialysis. In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the plasma potassium concentration can produce digitalis toxicity.

DOSAGE AND ADMINISTRATION

Potassium Citrate and Citric Acid Oral Solution USP should be taken diluted in water according to directions, followed by additional water, if desired. Palatability is enhanced if chilled before taking.

Usual Adult Dose

3 to 6 teaspoonfuls (15 to 30 mL), diluted with 1 glass of water, after meals and at bedtime, or as directed by a physician.

Usual Pediatric Dose

1 to 3 teaspoonfuls (5 to 15 mL), diluted with 1/2 glass of water, after meals and at bedtime, or as directed by a physician.

Usual Dosage Range

2 to 3 teaspoonfuls (10 to 15 mL), diluted with a glassful of water, taken four times a day. Potassium Citrate and Citric Acid Oral Solution USP, diluted with a glassful of water, taken four times a day will usually maintain a urinary pH of 7.0-7.6 throughout most of the 24 hours without unpleasant side effects. To check urinary pH, HYDRION Paper (pH 6.0-8.0) or NITRAZINE Paper (pH 4.5-7.5) are available and easy to use.

HOW SUPPLIED

Potassium Citrate and Citric Acid Oral Solution USP (clear pink to red colored; berry-citrus flavored) is supplied in the following oral dosage form:

NDC 0121-0676-16: 16 fl oz (473 mL) bottle

STORAGE

Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F). Protect from excessive heat and freezing.

MANUFACTURED BY

Pharmaceutical Associates, Inc. Greenville, SC 29605
www.paipharma.com

R03/17

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 0121-0676-16

Potassium Citrate
and Citric Acid
Oral Solution USP
1100 mg/334 mg per 5 mL

A SUGAR-FREE SYSTEMIC ALKALIZER

Each teaspoonful (5 mL) contains:
Potassium Citrate Monohydrate…..1100 mg
Citric Acid Monohydrate…..334 mg

Each mL contains 2 mEq Potassium Ion, and is equivalent to 2 mEq Bicarbonate (HCO_3).

Rx ONLY

16 fl oz (473 mL)

Pharmaceutical Associates, Inc.
Greenville, SC 29605

INDICATIONS AND USAGE: Potassium Citrate and Citric Acid Oral Solution USP is a stable and pleasant-tasting oral

systemic alkalizer. It is effective for long-term maintenance of an alkaline urine, especially when the administration of sodium salts is undesirable or contra-indicated.

SEE ACCOMPANYING LITERATURE

DOSAGE AND ADMINISTRATION:

Usual Adult Dosage: 3 to 6 teaspoonfuls (15 to 30 mL) **DILUTED** with 1 glass of water, after meals and at bedtime, or as directed by a physician.

SHAKE WELL BEFORE USING.

STORAGE: Keep tightly closed. Store at controlled room temperature. 20° -25° C (68° -77° F). Protect from excessive heat or freezing.

Dispense in a tight, light-resistance container with a child-resistant closure.

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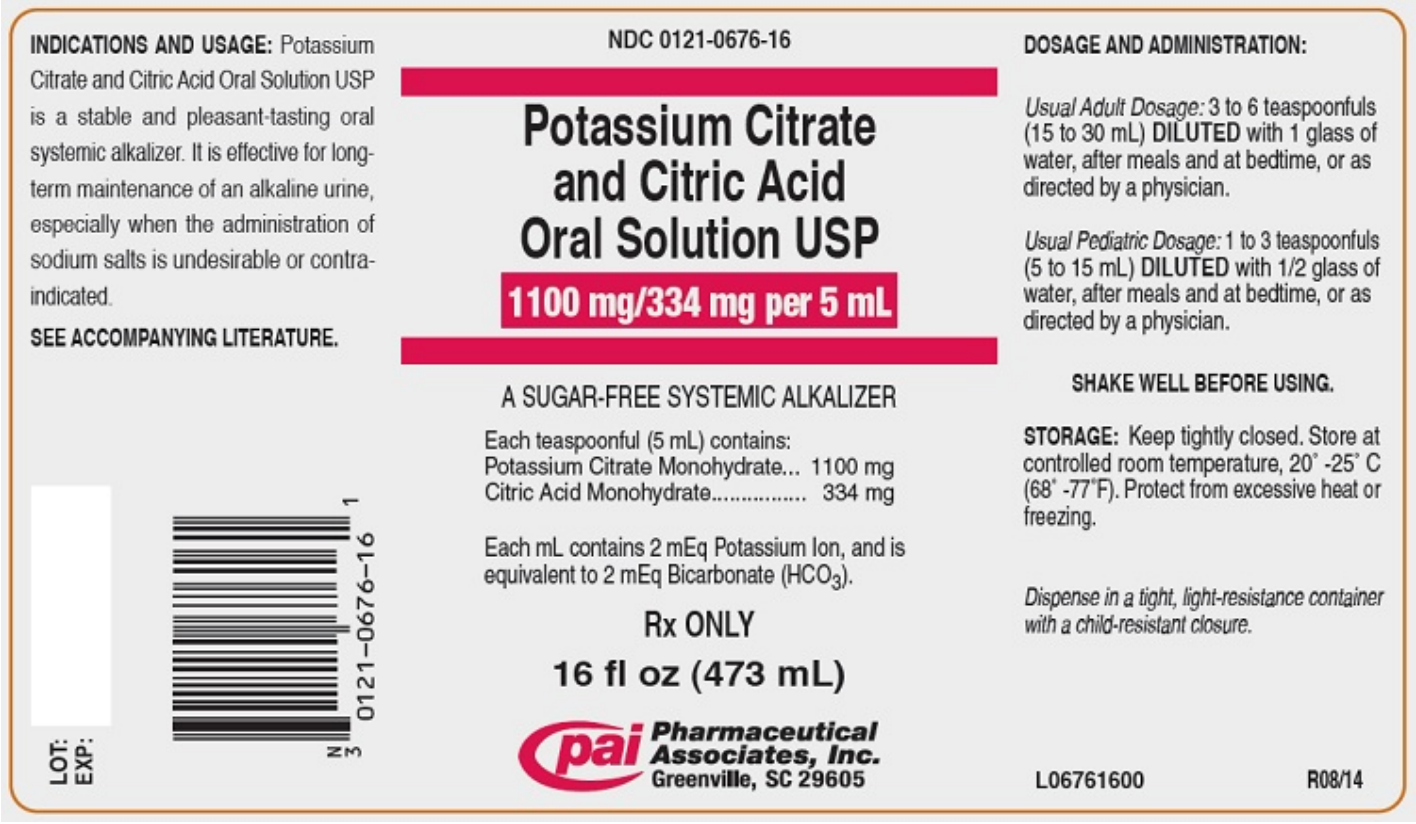
R08/14



POTASSIUM CITRATE AND CITRIC ACID

potassium citrate and citric acid monohydrate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0121-0676
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CITRATE (UNII: EE90ONI6FF) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	POTASSIUM CITRATE	1100 mg in 5 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	334 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0676-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/07/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/07/1997	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0676)

Revised: 8/2017 Pharmaceutical Associates, Inc.