POTASSIUM CITRATE AND CITRIC ACID- potassium citrate and citric acid monohydrate solution
Westminster Pharmaceuticals, LLC

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

NDC 69367-321-16

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

cherry flavor, FD&C red #40, purified water, sodium benzoate, sodium saccharin, 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. Known hypersensitivity to any ingredient.

WARNINGS

There have been several reports, published and unpublished, concerning nonspecific small-bowel lesions consisting of stenosis, with or without ulceration, associated with the administration of enteric-coated thiazides with potassium salts. These lesions may occur with enteric-coated potassium tablets alone or when they are used with nonenteric-coated thiazides, or certain other oral diuretics. These small-bowel lesions have caused obstruction, hemorrhage, and perforation. Surgery was frequently required and deaths have occurred. Based on a large survey of physicians and hospitals, both United States and foreign, the incidence of these lesions is low, and a causal relationship in man has not been definitely established. Available information tends to implicate enteric-coated potassium salts, although lesions of this type also occur spontaneously. Therefore, coated potassium-containing formulations should be administered only when indicated, and should be discontinued immediately if abdominal pain, distention, nausea, vomiting, or gastrointestinal bleeding occur.

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. Do not exceed recommended dosage.

Discontinue use if adverse reaction occurs.

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 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. intoxication causes restlessness, 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.

Proper dilution may help prevent gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations.

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 is a (red colored; cherry flavored) oral solution and is supplied in the following oral dosage form:

NDC 69367-321-16 (16 fl oz bottles).

STORAGE

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

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Dispense in a tight, light-resistant container as defined in the USP/NF with a childresistant closure.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSAGE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Call your doctor for medical advice about side effects. You may report side effects to Westminster Pharmaceuticals, LLC at 1-844-221-7294.

Manufactured for:
Westminster Pharmaceuticals LLC.
Nashville TN, 37217
Rev. 04/21

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC: 69367-321-16
Rx Only

Potassium Citrate
and Citric Acid
Oral Solution USP

1100 mg/334 mg per 5 mL

A SUGAR-FREE
SYSTEMIC ALKALIZER

EACH TEASPOONFUL (5mL) CONTAINS:
POTASSIUM CITRATE MONOHYDRATE
1100 mg
CITRIC ACID MONOHYDRATE
334 mg

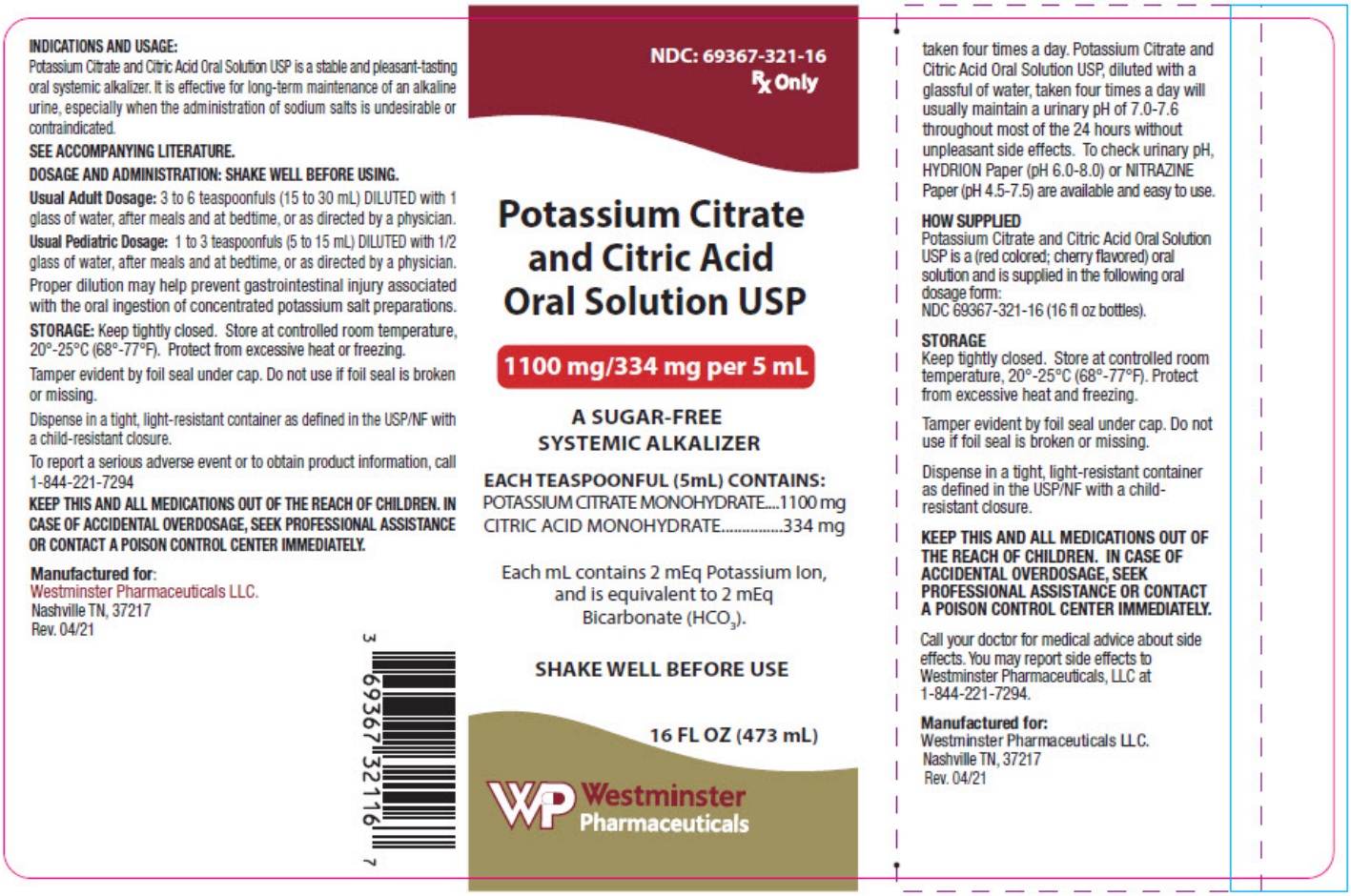
Each mL contains 2 mEq Potassium Ion,

and is equivalent to 2 mEq Bicarbonate (HCO_3).

SHAKE WELL BEFORE USE

16 FL OZ (473 mL)

Westminster Pharmaceuticals



POTASSIUM CITRATE AND CITRIC ACID

potassium citrate and citric acid monohydrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69367-321
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
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	RED	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-321-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		07/21/2021	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 7/2021 Westminster Pharmaceuticals, LLC