TRICITRATES- potassium citrate, sodium citrate, and citric acid monohydrate solution
PAI Holdings, 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.

Tricitrates SF Oral Solution

Rx ONLY

DESCRIPTION

Tricitrates *SF* Oral Solution is a stable and pleasant-tasting oral systemic alkalizer containing potassium citrate, sodium citrate, and citric acid in a sugar-free, non-alcoholic base.

Tricitrates *SF* Oral Solution contains in each teaspoonful (5 mL):

POTASSIUM CITRATE	
Monohydrate	550 mg
SODIUM CITRATE	
Dihydrate	500 mg
CITRIC ACID	
Monohydrate	334 mg

Each mL contains 1 mEq potassium ion and 1 mEq sodium ion and is equivalent to 2 mEq bicarbonate (HCO_3).

Inactive Ingredients: FD&C Yellow No. 6, flavoring, polyethylene glycol, propylene glycol, purified water, sodium benzoate, and sorbitol solution.

ACTIONS

Potassium citrate and sodium citrate are absorbed and metabolized to potassium bicarbonate and sodium bicarbonate, thus acting as systemic alkalizers. 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 citrates are excreted in the urine unchanged.

INDICATIONS AND ADVANTAGES

Tricitrates *SF* Oral Solution 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. 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. This product is highly concentrated, and when administered after meals and before bedtime, allows one to maintain an alkaline urine 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 and sodium citrate do not neutralize the gastric juice or disturb digestion.

CONTRAINDICATIONS

Severe renal impairment with oliguria or azotemia, untreated Addison's disease, or severe myocardial damage. In certain situations, when patients are on a sodium-restricted diet, the use of potassium citrate may be preferable; or, when patients are on a potassium-restricted diet, the use of sodium citrate may be preferable.

PRECAUTIONS AND WARNINGS

Should be used with caution by patients with low urinary output or reduced glomerular filtration rates unless under the supervision of a physician. Aluminum-based antacids should be avoided in these patients. Patients should be directed to dilute adequately with water and, preferably, to take each dose after meals, to minimize the possibility of gastrointestinal injury associated with oral ingestion of potassium salt preparations and to avoid saline laxative effect. Sodium salts should be used cautiously in patients with cardiac failure, hypertension, peripheral and pulmonary edema, and toxemia of pregnancy.

Concurrent administration of potassium-containing medication, potassium-sparing diuretics, angiotensin-converting enzyme (ACE) inhibitors, or cardiac glycosides may lead to toxicity. Periodic examination and determinations of serum electrolytes, particularly serum bicarbonate level, should be carried out in those patients with renal disease in order to avoid these complications.

ADVERSE REACTIONS

Tricitrates *SF* Oral Solution 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, especially in the presence of hypocalcemia. Potassium intoxication causes listlessness, weakness, mental confusion, and tingling of extremities.

DOSAGE AND ADMINISTRATION

Tricitrates *SF* Oral Solution should be taken diluted in water, 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 in water, four times a day, after meals and at

bedtime, or as directed by a physician.

Usual Pediatric Dose

1 to 3 teaspoonfuls (5 to 15 mL), diluted in water, four times a day, after meals and at bedtime, or as directed by a physician.

Usual Dosage Range

2 to 3 teaspoonfuls (10 to 15 mL), diluted with water, taken four times a day, will usually maintain a urinary pH of 6.5-7.4. 3 to 4 teaspoonfuls (15 to 20 mL), diluted with 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 urine pH, HYDRION Paper (pH 6.0-8.0) or NITRAZINE Paper (pH 4.5-7.5) are available and easy to use.

OVERDOSAGE

Overdosage with sodium salts may cause diarrhea, nausea and vomiting, hypernoia, and convulsions. Overdosage with potassium salts may cause hyperkalemia and alkalosis, especially in the presence of renal disease.

HOW SUPPLIED

Tricitrates *SF* Oral Solution (orange colored, raspberry flavored) is supplied in the following oral dosage form:

NDC 0121-0677-16: 16 fl oz (473 mL) bottles

STORAGE

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

SHAKE WELL BEFORE USING.

Manufactured By

Pharmaceutical Associates, Inc.
Greenville, SC 29605

R08/22

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 0121-0677-16

Tricitrates SF
Oral Solution

550 mg/500 mg/334 mg per 5 mL

A SUGAR-FREE SYSTEMIC ALKALIZER

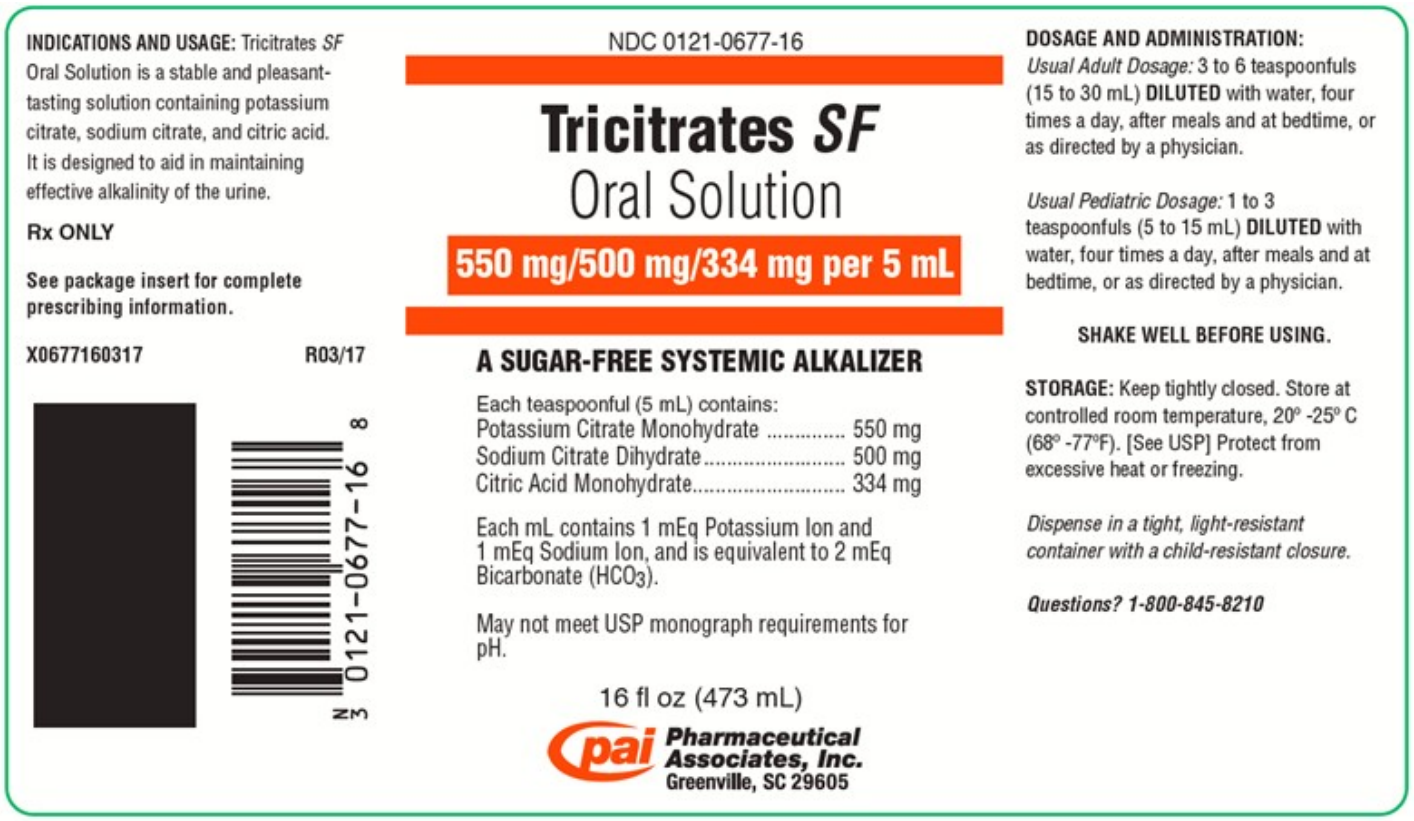
Each teaspoonful (5 mL) contains:
Potassium Citrate Monohydrate 550 mg
Sodium Citrate Dihydrate 500 mg
Citric Acid Monohydrate 334 mg

Each mL contains 1 mEq Potassium Ion and 1 mEq Sodium Ion, and is equivalent to 2 mEq Bicarbonate (HCO_3).

May not meet USP monograph requirements for pH.

16 fl oz (473 mL)

Pharmaceutical
Associates, Inc.
Greenville, SC 29605



TRICITRATES

potassium citrate, sodium citrate, and citric acid monohydrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0121-0677
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	550 mg in 5 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	SODIUM CITRATE	500 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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0677-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/25/2005	

Labeler - PAI Holdings, LLC (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	manufacture(0121-0677)