SODIUM CITRATE AND CITRIC ACID- sodium 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.

Sodium Citrate and Citric Acid Oral Solution USP

A Sugar-Free Systemic Alkalizer

DESCRIPTION

Sodium Citrate and Citric Acid Oral Solution USP is a stable and pleasant-tasting systemic alkalizer containing sodium citrate and citric acid in a sugar-free base. It is a nonparticulate neutralizing buffer.

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

SODIUM CITRATE Dihydrate 500 mg (0.34 Molar)

CITRIC ACID Monohydrate 334 mg (0.32 Molar)

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

Sodium citrate contains the following inactive ingredients: flavoring, polyethylene glycol, propylene glycol, purified water, sodium benzoate, and sorbitol solution.

CLINICAL PHARMACOLOGY

Sodium citrate is absorbed and metabolized to sodium 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 sodium citrate is excreted in the urine unchanged.

INDICATIONS AND USAGE

Sodium Citrate and Citric Acid Oral Solution USP is an effective alkalinizing agent. It is useful in those conditions where long-term maintenance of an alkaline urine is desirable, and is of value in the alleviation of chronic metabolic acidosis, such as results from chronic renal insufficiency or the syndrome of renal tubular acidosis, especially when the administration of potassium salts is undesirable or contraindicated. This product is also useful for buffering and neutralizing gastric hydrochloric acid quickly and effectively.

Sodium Citrate and Citric Acid Oral Solution USP is 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 the recommended dosage. This product is highly palatable, pleasant tasting, and tolerable, even when administered for long periods.

CONTRAINDICATIONS

Patients on sodium-restricted diets or with severe renal impairment.

PRECAUTIONS

Sodium Citrate and Citric Acid Oral Solution USP should be used with caution by patients with low urinary output unless under the supervision of a physician. This product should not be administered concurrently with aluminum-based antacids. Patients should be directed to dilute adequately with water and preferably, to take each dose after meals to avoid saline laxative effect. Sodium salts should be used cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary edema, and toxemia of pregnancy. Periodic examinations 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

Sodium 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 alkalosis, especially in the presence of hypocalcemia.

To report SUSPECTED ADVERSE REACTIONS, contact Pharmaceutical Associates, Inc. at 1-800-845-8210 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch..

OVERDOSAGE

Overdosage with sodium salts may cause diarrhea, nausea and vomiting, hypernoia, and convulsions.

DOSAGE AND ADMINISTRATION

Sodium Citrate and Citric Acid Oral Solution USP should be taken diluted in water, followed by additional water, if desired. SHAKE WELL BEFORE USING.

For Systemic Alkalization

Usual Adult Dose

2 to 6 teaspoonfuls (10 to 30 mL), diluted in 1 to 3 ounces 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 in 1 to 3 ounces of water, after meals and at

bedtime, or as directed by a physician. For children under two years of age, use is based on consultation with a physician.

As a neutralizing buffer

3 teaspoonfuls (15 mL), diluted with 15 mL water, taken as a single dose, or as directed by a physician.

HOW SUPPLIED

Sodium Citrate and Citric Acid Oral Solution USP (colorless, grape flavor) is supplied in the following oral dosage forms:

NDC 0121-0595-16: 16 fl oz (473 mL) bottle

NDC 0121-0595-15: 15 mL unit dose cup. Case contains 100 unit-dose cups of 15 mL (NDC 0121-0595-00), packaged in 10 trays of 10 unit-dose cups each.

NDC 0121-1190-30: 30 mL unit dose cup. Case contains 100 unit-dose cups of 30 mL (NDC 0121-1190-00) packaged in 10 trays of 10 unit-dose cups each.

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STORAGE:

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

Rx ONLY

MANUFACTURED BY:

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

R03/22

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 0121-0595-16

NSN 6505-01-097-4766

Sodium Citrate and Citric Acid Oral Solution USP

500 mg/334 mg per 5 mL

A SUGAR-FREE SYSTEMIC ALKALIZER

Each teaspoonful (5 mL) contains:

Sodium Citrate Dihydrate.....500 mg

Citric Acid Monohydrate.....334 mg

Each mL provides 1 mEq Sodium Ion and is

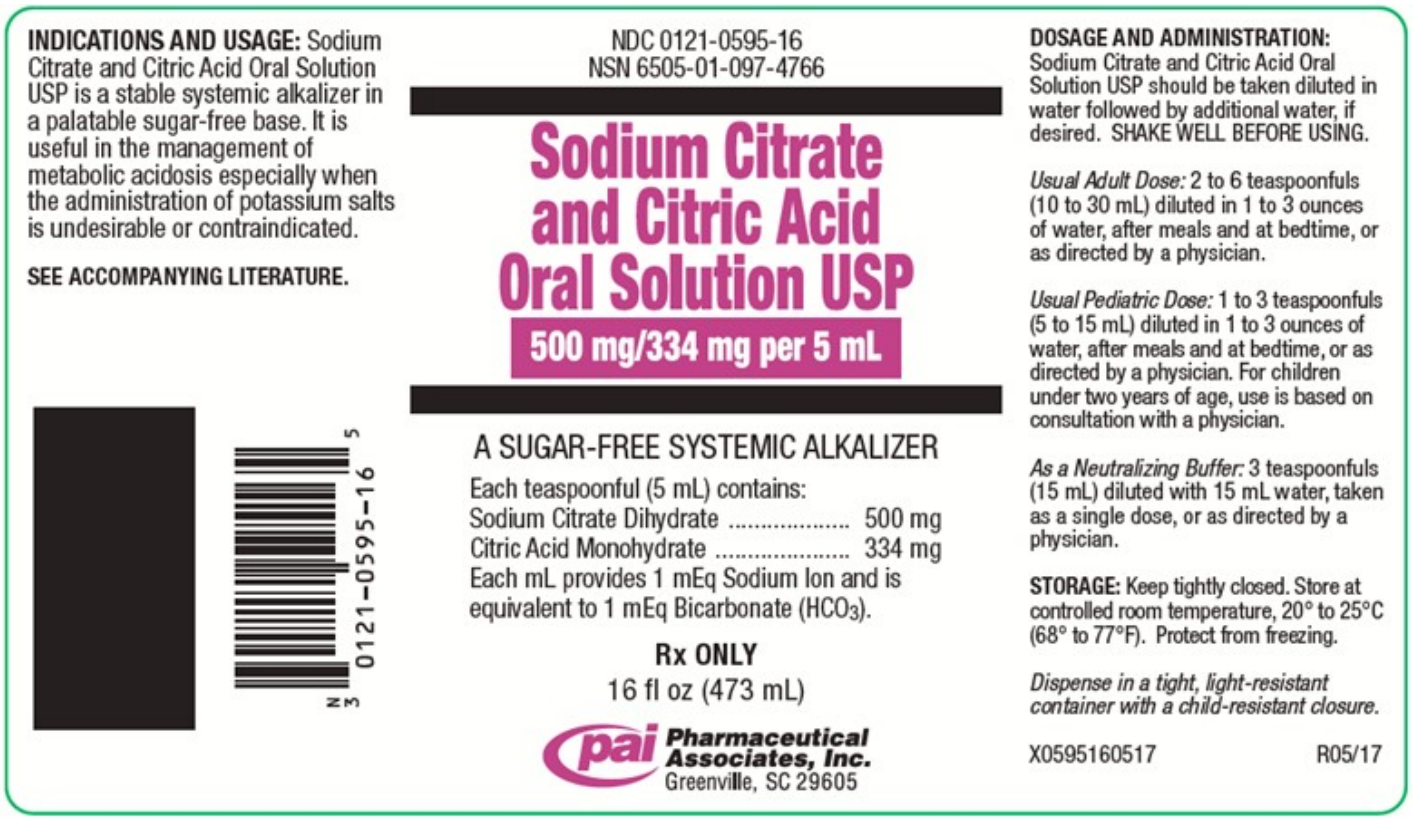
equivalent to 1 mEq Bicarbonate (HCO3).

Rx ONLY

16 fl oz (473 mL)

Pharmaceutical Associates, Inc.

Greenville, SC 29605



PRINCIPAL DISPLAY PANEL - 15 mL Unit Dose Cup Label

Delivers **15 mL**

NDC 0121-0595-15

S ODIUMC ITRATEand
C ITRICA CIDO RAL
S OLUTIONUSP (Sugar Free)

1.5 g/ 1 g per 15 mL

SHAKE WELL-DILUTE AS DIRECTED

Package Not Child-Resistant

Rx ONLY

PHARMACEUTICAL ASSOCIATES, INC.

GREENVILLE, SC 29605

SEE INSERT

PRINCIPAL DISPLAY PANEL - 30 mL Unit Dose Cup Label

Delivers **30 mL**

NDC 0121-1190-30

S ODIUMC ITRATEand
C ITRICA CIDO RAL
S OLUTIONUSP (Sugar Free)

3 g/ 2 g per 30 mL

SHAKE WELL-DILUTE AS DIRECTED

Package Not Child-Resistant

Rx ONLY

PHARMACEUTICAL ASSOCIATES, INC.

GREENVILLE, SC 29605

SEE INSERT

SODIUM CITRATE AND CITRIC ACID

sodium citrate and citric acid monohydrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0121-0595

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	SODIUM CITRATE	500 mg in 5 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	334 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0595-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/1969	
2	NDC:0121-0595-00	10 in 1 CASE	01/01/1969	
2		10 in 1 TRAY		
2	NDC:0121-0595-15	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:0121-0595-30	10 in 1 CASE	01/01/1969	
3		10 in 1 TRAY		
3		30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1969	

SODIUM CITRATE AND CITRIC ACID

sodium citrate and citric acid monohydrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0121-1190
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CITRATE (UNII: 1Q73Q2JULR) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	SODIUM CITRATE	500 mg in 5 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	334 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

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Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0121-1190-00	10 in 1 CASE	01/01/1969	
1		10 in 1 TRAY		
1	NDC:0121-1190-30	30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1969	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0595, 0121-1190)

Revised: 11/2024 Pharmaceutical Associates, Inc.