SODIUM CITRATE AND CITRIC ACID- sodium citrate and citric acid solution
Kesin Pharma Corporation

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 Ctric Acid Oral Solution, USP

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 non-particulate 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).
INACTIVE INGREDIENTS: grape flavoring, purified water, sodium benzoate, sorbitol and sucralose.

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 insuffi ciency or the syndrome of renal tubular acidosis, especially when the administration of potassium salts is undesirable or contraindicated. This product is also useful for buff ering and neutralizing gastric hydrochloric acid quickly and effectively.
Sodium citrate and citric acid oral solution 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 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 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 Kesin Pharma at 1-833-537-4679 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 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 81033-017-15: 15 mL unit dose cup
NDC 81033-017-50: Case containing 100 unit-dose cups of 15 mL
NDC 81033-017-30: 30 mL unit dose cup
NDC 81033-017-51: Case containing 100 unit-dose cups of 30 mL

STORAGE

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

Rx Only
Packaged by:
Kesin Pharma
Oldsmar, Florida 34677
Revised March 2025
PI Rev. 01

NDC 81033-017-50

Sodium Citrate and Citric Acid Oral Solution, USP

1.5g/1g per 15mL

Delivers 15mL

2 Cartons x 50 Unit Doce Cups

QTY 2

NDC: 81033-017-50

Product Name: **Sodium Citrate and Citric Acid Oral Solution, USP 1.5g/1g per 15mL**

Delivers: 15mL 2 Cartons x 50 Unit Dose Cups

Storage: 68°F to 77°F (20°C to 25°C)

Rx Only

EXP: 00-MAR-0000 LOT: K0000000 QTY: 2

(17) 000300 (10) K0000000 (30) 2

(01) 00381033017501 (21) 00000000000000

Packaged by and Distributed by:
Kesin Pharma Corporation - Oldsmar, FL

Internal Use Only R.01

(00)000000000000

NDC 81033-017-51

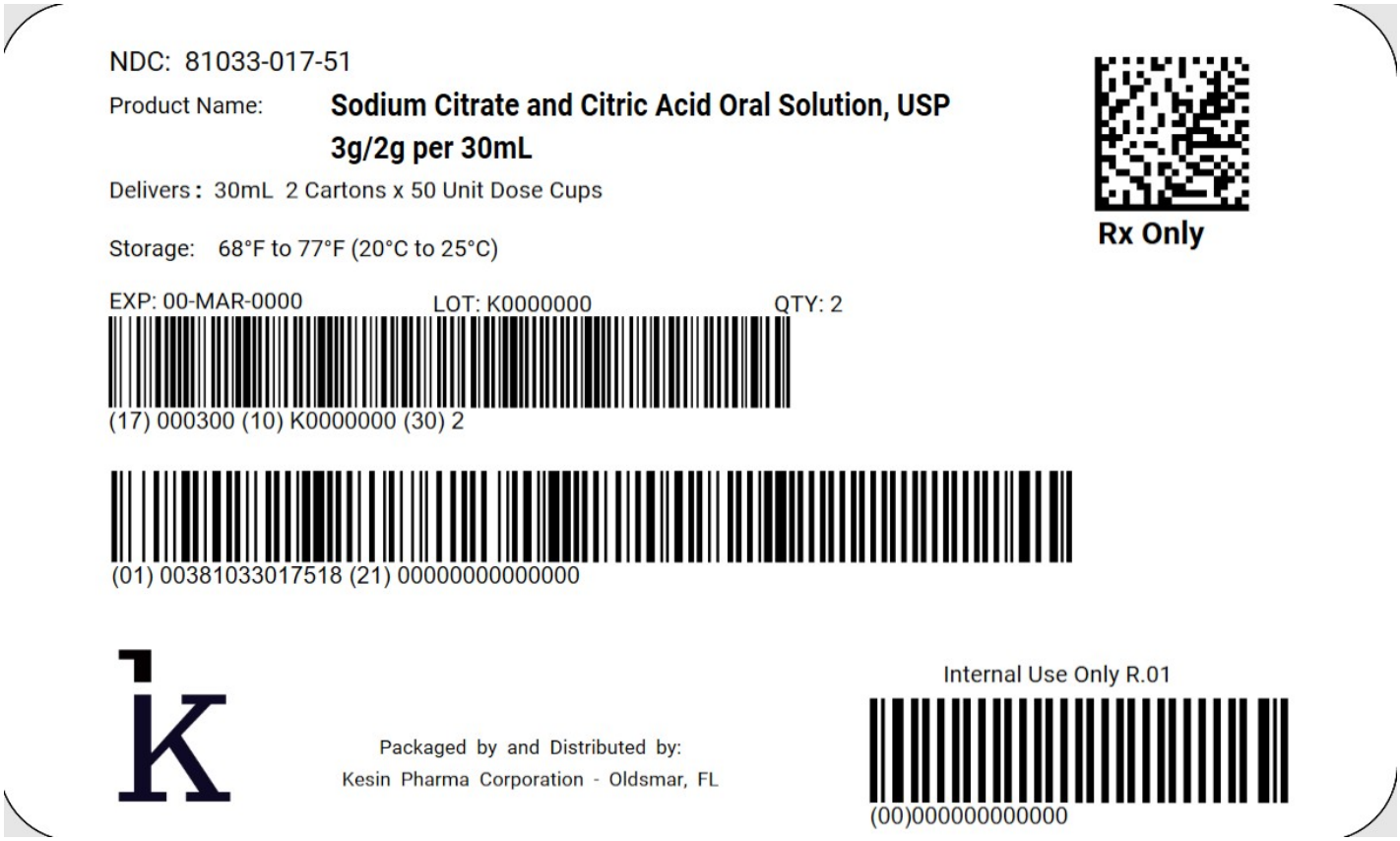
Sodium Citrate and Citric Acid Oral Solution, USP

3g/2g per 30mL

Delivers 30mL

2 Cartons x 50 Unit Dose Cups

QTY 2



SODIUM CITRATE AND CITRIC ACID

sodium citrate and citric acid solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:81033-017(NDC:84447-017)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-017-50	100 in 1 CASE	04/01/2025	
1	NDC:81033-017-15	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-017-51	100 in 1 CASE	04/01/2025	
2	NDC:81033-017-30	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		04/01/2025	

Labeler - Kesin Pharma Corporation (117447816)

Revised: 3/2025

Kesin Pharma Corporation