SODIUM CITRATE AND CITRIC ACID- sodium citrate and citric acid monohydrate solution
Belleview Biosciences 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.

Sodium Citrate and Citric Acid Oral Solution USP

DESCRIPTION

Sodium Citrate and Citric Acid Oral Solu on, USP is a stable and pleasant-tas ng systemic alkalizer containing sodium citrate and citric acid in a sugar-free base. It is a non-par culate neutralizing buff er.
Sodium Citrate and Citric Acid Oral Solu on, 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 fl avoring, purifi ed 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 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 on is generally well tolerated, without any unpleasant side eff ects, when given in recommended doses to patients with normal renal function on and urinary output. However, as with any alkalinizing agent, caution on 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 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 Solu on, USP (colorless, grape fl avor) 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°-25°C (68°-77°F). Protect from freezing.

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

PRINCIPAL DISPLAY PANEL - Bulk Drum

NDC 84447-017-01

Sodium Citrate and Citric Acid Oral Solution USP

500 mg/334 mg per 5 mL

Sugar, Alcohol, Gluten and Dye Free

Each teaspoonful (5 mL) contains:

Sodium Citrate Dihydrate.....500 mg

Citric Acid Monohydrate.....334 mg

Rx ONLY

Manufactured By:

Belleview Biosciences LLC

Brooksville, FL 34604

Sodium Citrate-Citric Acid Solution
500 mg / 334 mg per 5 mL
200,000 mL
NDC: 84447-017-01

Lot:
Mfg:

BULK SHIPMENT
PLEASE HANDLE CAREFULLY

Contains:
500 mg Sodium Citrate Dihydrate / 334 mg Citric Acid Anhydrous per 5 mL; Inactive Ingredients: Non-Crystallizing Sorbitol Solution, Sodium Benzoate, Sucralose, Grape Flavor, Purified Water

Sugar, Alcohol, Gluten and Dye Free

CAUTION:
FOR REPACKAGING ONLY
Store at controlled room temperature 15°-30°C (59°- 86°F)

Density of 1.10 g/mL

BELLEVIEW
BIOSCIENCE
Manufactured by:
Belleview Bioscience
Brooksville, FL 34604

Gross wt: _____
Tare wt: _____
Net wt: _____
Drum: _____ of _____

SODIUM CITRATE AND CITRIC ACID
sodium citrate and citric acid monohydrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:84447-017
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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84447-017-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2025	
2	NDC:84447-017-01	200000 mL in 1 DRUM; Type 0: Not a Combination Product	04/08/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/08/2025	

Labeler - Belleview Biosciences LLC (131968803)

Registrant - Belleview Biosciences LLC (131968803)

Establishment

Name	Address	ID/FEI	Business Operations
Belleview Biosciences LLC		131968803	manufacture(84447-017) , pack(84447-017) , label(84447-017)