SODIUM CITRATE AND CITRIC ACID- sodium citrate and citric acid solution
Chartwell RX, 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

A Sugar-Free Systemic Alkalizer

DESCRIPTION

Sodium Citrate and Citric Acid Oral Solution, USP is a clear stable and cherry flavored systemic alkalizer containing sodium citrate and citric acid in a sugar-free base with cherry flavor. It is a nonparticulate neutralizing buffer.

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

Sodium Citrate Dihydrate, USP 500 mg (0.34 Molar)
Citric Acid Monohydrate, USP 334 mg (0.32 Molar)

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

INACTIVE INGREDIENTS: purified water, saccharin sodium, sodium benzoate, sorbitol solution, and wild cherry flavor.

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, 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 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.

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 liquid with cherry flavor) is supplied in the following oral dosage form:

473 mL (16 fl oz) bottle	: NDC 62135-434-47
Unit Dose Cup 15 mL	: NDC 62135-868-51
20 Unit Dose Cups of 15 mL each	: NDC 62135-868-24
Unit Dose Cup 30 mL	: NDC 62135-869-43
20 Unit Dose Cups of 30 mL each	: NDC 62135-869-24

STORAGE:

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

Rx ONLY

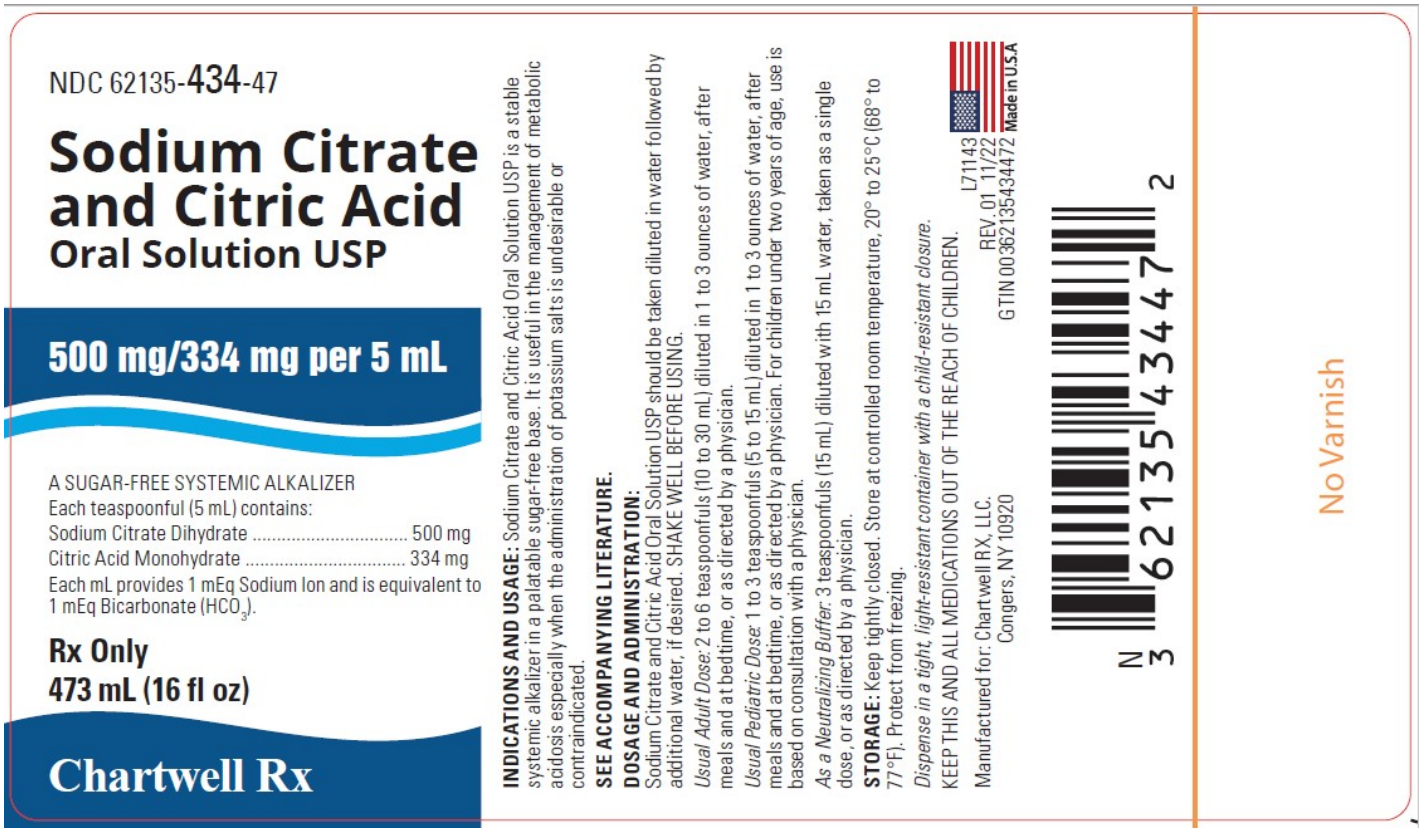
Manufactured for:
Chartwell RX, LLC
Congers, NY 10920

L71144

Rev. 03/2024

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL

Sodium Citrate and Citric Acid Oral Solution, USP 500 mg/334 mg per 5 mL - NDC 62135-434-47 - 473 mL Bottle Label



Sodium Citrate and Citric Acid Oral Solution, USP 1500 mg/1002 mg per 15 mL - NDC 62135-868-51 - 15 mL Unit Dose Label

Sodium Citrate and Citric Acid Oral Solution, USP 3000 mg/2004 mg per 30 mL - NDC 62135-869-43 - 30 mL Unit Dose Label

SODIUM CITRATE AND CITRIC ACID

sodium citrate and citric acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62135-434
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	334 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

SORBITOL SOLUTION (UNII: 8KW3E207O2)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white (clear)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-434-47	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/08/2022	

SODIUM CITRATE AND CITRIC ACID

sodium citrate and citric acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62135-868
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	1500 mg in 15 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1002 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white (clear)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62135-868-24	2 in 1 BOX	05/30/2024	
1		10 in 1 TRAY		
1	NDC:62135-868-51	15 mL in 1 CUP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/08/2022	

SODIUM CITRATE AND CITRIC ACID

sodium citrate and citric acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62135-869
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	3000 mg in 30 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	2004 mg in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white (clear)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-869-24	2 in 1 BOX	05/30/2024	
1		10 in 1 TRAY		
1	NDC:62135-869-43	30 mL in 1 CUP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/08/2022	

Labeler - Chartwell RX, LLC (079394054)

Revised: 5/2024 Chartwell RX, LLC