ORAL CITRATE SOLUTION- citric acid and sodium citrate solution
Brandywine Pharmaceuticals, 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 Solution
Brandywine Pharmaceuticals, LLC

Rx Only

DESCRIPTION

The product is a clear, colorless solution containing Citric Acid USP 640 mg/5 mL, and Hydrous Sodium Citrate USP 490 mg/5 mL. These concentrations yield 1 mEq of sodium, equivalent to 1 mEq of bicarbonate per mL of solution.

ACTION

Oral citrate solution is used as a systemic and urinary alkalinizer. Less than 5% of the citrate is excreted in the urine unchanged, since citrate oxidation is to a great extent complete.

INDICATIONS

Oral Citrate Solution is indicated for the treatment of metabolic acidosis. This solution is also useful in conditions where long-term maintenance of alkaline urine is needed (e.g. uric acid and cystine calculi of the urinary tract). Oral Citrate Solution is also effective in treatment for acidosis of certain renal tubular disorders.

CONTRAINDICATIONS

Oral Citrate Solution is contraindicated in patients with severe renal impairment, oliguria or azotemia, untreated Addison's disease, adynamia episodica hereditaria, acute dehydration, heat cramp, anuria, severe myocardial damage, and hyperkalemia.

PRECAUTIONS

The citrate solution should be used with caution in patients with impaired renal function to avoid hypernatremia or alkalosis in the presence of hypocalcemia. Periodic determinations of serum electrolyte levels (especially bicarbonate levels) should be done in patients with renal disease to avoid cardiac failure, hypertension, peripheral and pulmonary edema, and toxemia of pregnancy. The solution should be diluted with water and preferably taken after meals to avoid saline laxative effects.

ADVERSE REACTIONS

Citrate solution is generally well tolerated when given in recommended doses when the patient has normal renal functions. To report suspected adverse reactions, contact Brandywine Pharmaceuticals, LLC at 610-314-7943 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DOSAGE AND ADMINISTRATION

The dose of Oral Citrate Solution is 10 to 30 mL, diluted with water, after meals and at bedtime. The dose should be titrated to achieve the desired effects.

HOW SUPPLIED

Oral Citrate Solution is supplied in a 473 mL bottle (NDC 71321-604-16).

PHARMACIST

Dispense in well-closed containers.

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature].

Brandywine Pharmaceuticals, LLC
West Chester, PA USA
Revised February 2024

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 71321-604-16
473 mL

ORAL CITRATE (SHOHL'S) SOLUTION

CONTAINS: Hydrous Sodium Citrate USP 490 mg/5 mL;
Citric Acid USP 640 mg/5 mL;

grape flavor, purified water, sodium

benzoate, sodium saccharin, sorbitol

USUAL DOSAGE: See package insert.

Dispense in a well-closed container.

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature].

GTIN: 00371321604162

Rx Only

Brandywine Pharmaceuticals, LLC

West Chester, PA USA

ORAL CITRATE SOLUTION

citric acid and sodium citrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71321-604
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	490 mg in 5 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	640 mg in 5 mL

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71321-604-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/21/2024	

Labeler - Brandywine Pharmaceuticals, LLC (080581956)

Establishment

Name	Address	ID/FEI	Business Operations
Brandywine Pharmaceuticals, LLC		080581956	label(71321-604)