ORACIT- citric acid and sodium citrate solution
CMP Pharma, 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.

ORACIT®
Oral Citrate (Shohl's) Solution
CMP Pharma, Inc.

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. It also contains Methylparaben NF and Propylparaben NF as preservatives. 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

ORACIT® 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). ORACIT® is also effective in treatment for acidosis of certain renal tubular disorders.

CONTRAINDICATIONS

ORACIT® 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 CMP Pharma, Inc., toll free at 1-844-321-1443 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

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

HOW SUPPLIED

ORACIT® is supplied in 500 mL bottles (NDC 46287-014-01), 30 mL unit dose bottles, 10 bottles per carton (NDC 46287-014-30), and 15 mL unit dose bottles, 10 bottles per carton (NDC 46287-014-15).

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].

CMP Pharma, Inc.
Post Office Box 147
Farmville, North Carolina 27828

Revised December 2022
3082 R1222

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

NDC 46287-014-01
500 mL

Oracit®
ORAL CITRATE (SHOHL'S) SOLUTION

CONTAINS: Hydrous Sodium Citrate USP 490 mg/5 mL; Citric Acid USP 640 mg/5 mL; Methylparaben NF; Propylparaben NF; Alcohol USP 0.25%.

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: 00346287014010

Rx Only

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Farmville, NC 27828

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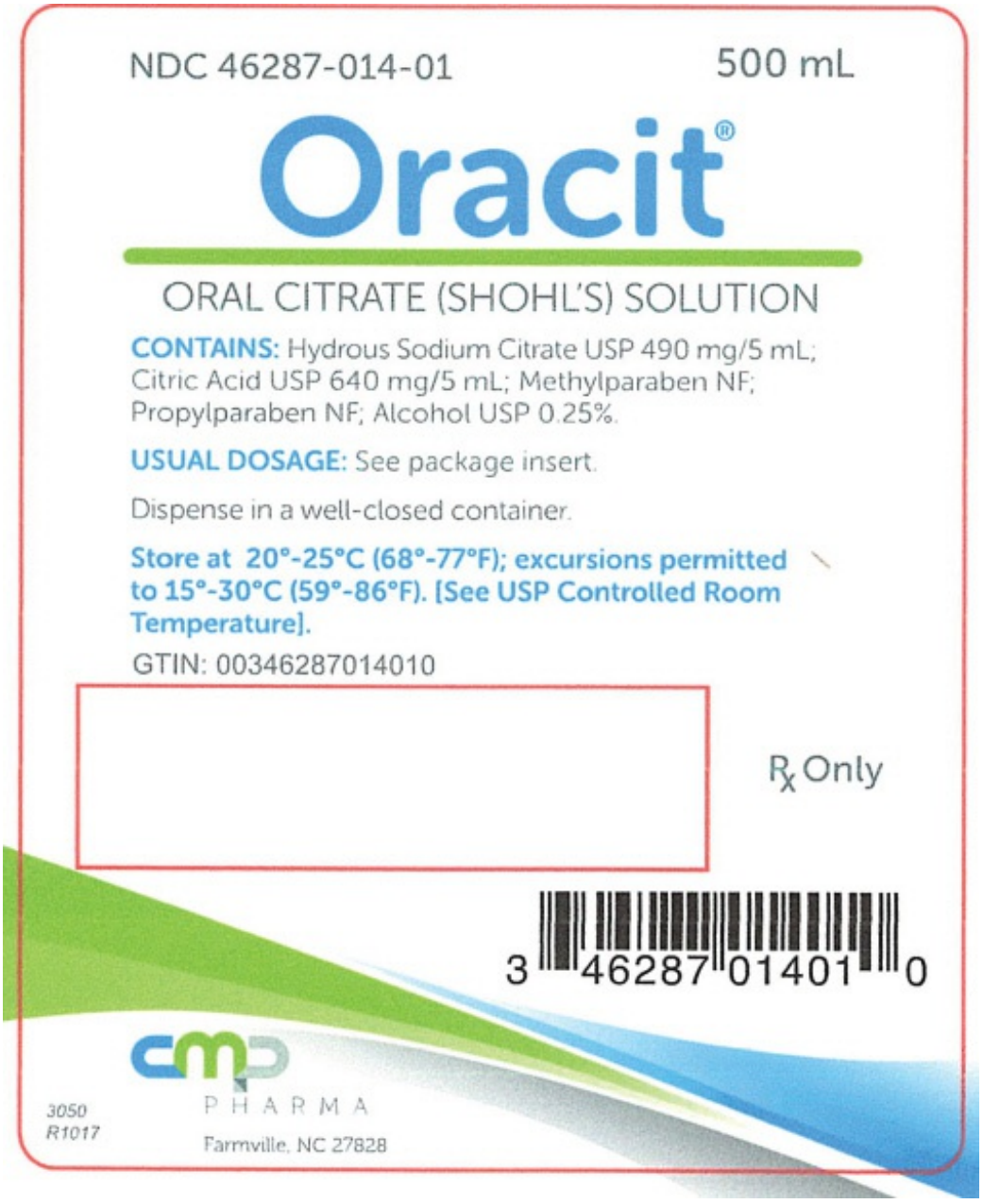

ORACIT
citric acid and sodium citrate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:46287-014
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46287-014-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/1984	
2	NDC:46287-014-30	10 in 1 CARTON	05/15/1984	
2		30 mL in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:46287-014-15	10 in 1 CARTON	05/15/1984	
3		15 mL in 1 BOTTLE, 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		05/15/1984	

Labeler - CMP Pharma, Inc. (005224175)

Establishment

Name	Address	ID/FEI	Business Operations
CMP Pharma, Inc.		005224175	MANUFACTURE(46287-014)