ORACIT- citric acid monohydrate and trisodium citrate dihydrate liquid
Cardinal Health

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 15 ml Bottles

Active ingredient

This product is a clear, colorless solution containing Citric Acid USP 640 mg/5 mL, and Hydrous Sodium Citrate USP 490 mg/5 mL.

Purpose

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

Uses

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.

Warning

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 dosed when the patient has normal renal functions.

Directions

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.

Inactive ingredients

It also contain Methylparaben NF and Propylparaben NF as preservatives. These concentrations yield 1 mEq of sodium, equivalent to 1 mEq of bicarbonate per mL of solution.

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).

Storage

Dispense in well-closed containers. Store at Controlled Room Temperature (15-30 C).

Carolina Medical Products Co.

Post Office Box 147

Farmville, North Carolina 27828

Revised May 1986

Keep Out Of The Reach Of Children

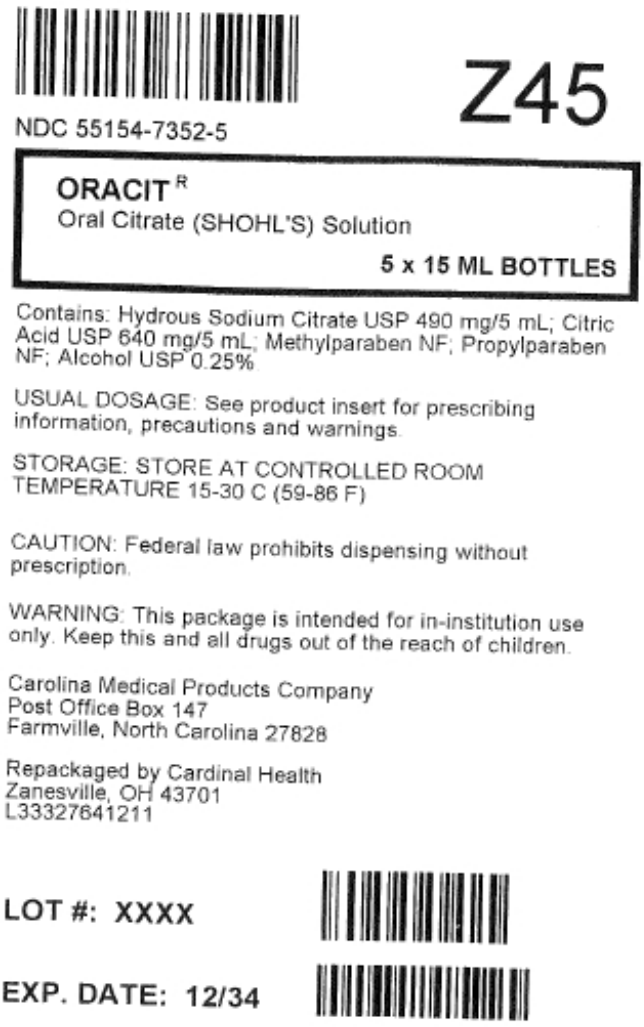
Keep this and all drugs out of the reach of children.

Principal Display Panel

Oracit®

Oral Citrate (SHOHL'S) Solution

5 x 15 mL Bottles



ORACIT

oral citrate liquid

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:55154-7352(NDC:46287-014)
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CITRIC ACID MONOHYDRATE (ANHYDROUS CITRIC ACID)	ANHYDROUS CITRIC ACID	490 mg in 5 mL
TRISODIUM CITRATE DIHYDRATE (ANHYDROUS CITRIC ACID)	ANHYDROUS CITRIC ACID	640 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
METHYLPARABEN	

PROPYLPARABEN	
ALCOHOL	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-7352-5	5 in 1 BAG		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/07/2011	

Labeler - Cardinal Health (188557102)

Establishment

Name	Address	ID/FEI	Business Operations
Cardinal Health		188557102	REPACK(55154-7352)

Revised: 4/2013 Cardinal Health