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.

DOSAGE & 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].

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