CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

65115

DRAFT FINAL PRINTED LABELING

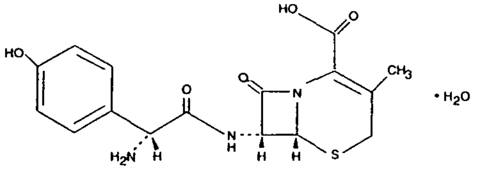
65-115 3/26/03

CEFADROXIL FOR ORAL SUSPENSION, USP

Rx only

DESCRIPTION

Cefadroxil monohydrate, USP is a semisynthetic cephalosporin antibiotic intended for oral administration. It is a white to yellowish-white crystalline powder. It is soluble in water and it is acid-stable. It is chemically designated as 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[amino(4-hydroxy-phenyl)acetyl] amino]-3-methyl-8-oxo-, monohydrate, [6R-[6α,7β(R*)]]-. It has the formula $C_{16}H_{17}N_3O_5S \cdot H_2O$ and the molecular weight of 381.40. It has the following structural formula:



Each 5 mL of reconstituted suspension for oral administration contains cefadroxil monohydrate equivalent to 125 mg, 250 mg or 500 mg of cefadroxil. In addition, Cefadroxil for Oral Suspension contains the following inactive ingredients: colloidal silicon dioxide, FD&C yellow no. 6 aluminum lake, flavor fruit gum, flavor raspberry, polysorbate 80, sodium benzoate, sucrose, xanthan gum

CLINICAL PHARMACOLOGY

Cefadroxil monohydrate is rapidly absorbed after oral administration. Following single doses of 500 mg and 1000 mg, average peak serum concentrations were approximately 16 and 28 mcg/mL, respectively. Measurable levels were present 12 hours after administration. Over 90% of the drug is excreted unchanged in the urine within 24 hours. Peak urine concentrations are approximately 1800 mcg/mL during the period following a single 500-mg oral dose. Increases in dosage generally produce a proportionate increase in cefadroxil monohydrate urinary concentration. The urine antibiotic concentration, following a 1-g dose, was maintained well above the MIC of susceptible urinary pathogens for 20 to 22 hours.

Microbiology

In vitro tests demonstrate that the cephalosporins are bactericidal because of their inhibition of cell-wall synthesis. Cefadroxil has been shown to be active against the following organisms both *in vitro* and in clinical infections (see **INDICATIONS AND USAGE**):

Beta-hemolytic streptococci
Staphylococci, including penicillinase-producing strains
Streptococcus (Diplococcus) pneumoniae
Escherichia coli
Proteus mirabilis
Klebsiella species
Moraxella (Branhamella) catarrhalis

MAR 26

Note: Most strains of *Enterococcus faecalis* (formerly *Streptococcus faecalis*) and *Enterococcus faecium* (formerly *Streptococcus faecium*) are resistant to cefadroxil monohydrate. It is not active against most strains of *Enterobacter* species, *Morganella morganii* (formerly *Proteus morganii*), and *P. vulgaris*. It has no activity against *Pseudomonas* species and *Acinetobacter calcoaceticus* (formerly *Mima* and *Herellea* species).

Susceptibility tests: Diffusion techniques

The use of antibiotic disk susceptibility test methods which measure zone diameter give an accurate estimation of antibiotic susceptibility. One such standard procedure[1] which has been recommended for use with disks to test susceptibility of organisms to cefadroxil monohydratae uses the cephalosporin class (cephalothin) disk. Interpretation involves the correlation of the diameters obtained in the disk test with the minimum inhibitory concentration (MIC) for cefadroxil monohydrate.

Reports from the laboratory giving results of the standard single-disk susceptibility test with a 30 mcg cephalothin disk should be interpreted according to the following criteria:

Zone Diameter (mm)	Interpretation
≥18	(S) Susceptible
15-17	(I) Intermediate
≤14	(R) Resistant

A report of "Susceptible" indicates that the pathogen is likely to be inhibited by generally achievable blood levels. A report of "Intermediate susceptibility" suggests that the organism would be susceptible if high dosage is used or if the infection is confined to tissue and fluids (eg, urine) in which high antibiotic levels are attained. A report of "Resistant" indicates that achievable concentrations of the antibiotic are unlikely to be inhibitory and other therapy should be selected.

Standardized procedures require the use of laboratory control organisms. The 30 mcg cephalothin disk should give the following zone diameters:

Organism	Zone Diameter (mm)
Staphylococcus aureus ATCC 25923	29-37
Escherichia coli ATCC 25922	17-22

Dilution Techniques

When using the NCCLS agar dilution or broth dilution (including microdilution) method[2] or equivalent, a bacterial isolate may be considered susceptible if the MIC (minimum inhibitory concentration) value for cephalothin is 8 mcg/mL or less. Organisms are considered resistant if the MIC is 32 mcg/mL or greater. Organisms with an MIC value of less than 32 mcg/mL but greater than 8 mcg/mL are intermediate. As with standard diffusion methods, dilution procedures require the use of laboratory control organisms. Standard cephalothin powder should give MIC values in the range of 0.12 mcg/mL and 0.5 mcg/mL for *Staphylococcus aureus* ATCC 29213. For *Escherichia coli* ATCC 25922, the MIC range should be between 4 mcg/mL and 16 mcg/mL. For *Streptococcus faecalis* ATCC 29212, the MIC range should be between 8 and 32 mcg/mL.

INDICATIONS AND USAGE

Cefadroxil monohydrate is indicated for the treatment of patients with infection caused by susceptible strains of the designated organisms in the following diseases:

Urinary tract infections caused by *E. coli, P. mirabilis*, and *Klebsiella* species.

Skin and skin structure infections caused by staphylococci and/or streptococci.

Pharyngitis and/or tonsillitis caused by *Streptococcus pyogenes* (Group A beta-hemolytic streptococci).

Note: Only penicillin by the intramuscular route of administration has been shown to be effective in the prophylaxis of rheumatic fever. Cefadroxil monohydrate is generally effective in the eradication of streptococci from the oropharynx. However, data establishing the efficacy of cefadroxil monohydrate for the prophylaxis of subsequent rheumatic fever are not available.

Note: Culture and susceptibility tests should be initiated prior to and during therapy. Renal function studies should be performed when indicated.

CONTRAINDICATIONS

Cefadroxil monohydrate is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS

BEFORE THERAPY WITH CEFADROXIL MONOHYDRATE IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEFADROXIL, CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-SENSITIVITY AMONG BETA-LACTAM ANTIBIOTICS HAS BEEN CLEARLY DOCUMENTED AND MAY OCCUR IN UP TO 10% OF PATIENTS WITH A HISTORY OF PENICILLIN ALLERGY.

IF AN ALLERGIC REACTION TO CEFADROXIL MONOHYDRATE OCCURS, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, INTRAVENOUS FLUIDS, INTRAVENOUS ANTIHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including cefadroxil, and may range from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicated that a toxin produced by *Clostridium difficile* is a primary cause of "antibiotic-associated colitis."

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to discontinuation of the drug alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug effective against *Clostridium difficile*.

PRECAUTIONS

General

Cefadroxil monohydrate should be used with caution in the presence of markedly impaired renal function (creatinine clearance rate of less than 50 mL/min/1.73 M^2). (See **DOSAGE AND ADMINISTRATION**.) In patients with known or suspected renal impairment, careful clinical observation and appropriate laboratory studies should be made prior to and during therapy.

Prolonged use of cefadroxil monohydrate may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Cefadroxil monohydrate should be prescribed with caution in individuals with history of gastrointestinal disease, particularly colitis.

Drug/Laboratory Test Interactions

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

No long-term studies have been performed to determine carcinogenic potential. No genetic toxicity tests have been performed.

Pregnancy

Pregnancy Category B

Reproduction studies have been performed in mice and rats at doses up to 11 times

CEFADROXIL FOR ORAL
SUSPENSION USP
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the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cefadroxil monohydrate. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

Cefadroxil monohydrate has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.

Nursing Mothers

Caution should be exercised when cefadroxil monohydrate is administered to a nursing mother.

Pediatric Use

(See **DOSAGE AND ADMINISTRATION.**)

Geriatric Use

Of approximately 650 patients who received cefadroxil monohydrate for the treatment of urinary tract infections in three clinical trials, 28% were 60 years and older, while 16% were 70 years and older. Of approximately 1000 patients who received cefadroxil monohydrate for the treatment of skin and skin structure infection in 14 clinical trials, 12% were 60 years and older while 4% were 70 years and over. No overall differences in safety were observed between the elderly patients in these studies and younger patients. Clinical studies of cefadroxil monohydrate for the treatment for pharyngitis or tonsillitis did not include sufficient number of patients 65 years and older to determine whether they respond differently from younger patients. Other reported clinical experience with cefadroxil monohydrate has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Cefadroxil monohydrate is substantially excreted by the kidney, and dosage adjustment is indicated for patients with renal impairment (see **DOSAGE AND ADMINISTRATION: Renal Impairment**). Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Gastrointestinal

Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment (see **WARNINGS**). Dyspepsia, nausea and vomiting have been reported rarely. Diarrhea has also occurred.

Hypersensitivity

Allergies (in the form of rash, urticaria, angioedema, and pruritis) have been observed. These reactions usually subsided upon discontinuation of the drug. Anaphylaxis has also been reported.

Other

Other reactions have included hepatic dysfunction including cholestasis and elevations in serum transaminase, genital pruritus, genital moniliasis, vaginitis, moderate transient neutropenia, fever. Agranulocytosis, thrombocytopenia, idiosyncratic hepatic failure, erythema multiforme, Stevens-Johnson syndrome, serum sickness, and arthralgia have been rarely reported.

In addition to the adverse reactions listed above which have been observed in patients treated with cefadroxil, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics:

Toxic epidermal necrolysis, abdominal pain, superinfection, renal dysfunction, toxic nephropathy, aplastic anemia, hemolytic anemia, hemorrhage, prolonged prothrombin time, positive Coombs' test, increased BUN, increased creatinine, elevated alkaline phosphatase, elevated aspartate aminotransferase (AST), elevated alanine aminotransferase (ALT), elevated bilirubin, elevated LDH, eosinophilia, pancytopenia, neutropenia.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment, when the dosage was not reduced (see **DOSAGE AND ADMINISTRATION** and **OVERDOSAGE**). If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

OVERDOSAGE

A study of children under six years of age suggested that ingestion of less than 250 mg/kg of cephalosporins is not associated with significant outcomes. No action is required other than general support and observation. For amounts greater than 250 mg/kg, induce gastric emptying.

In five anuric patients, it was demonstrated that an average of 63% of a 1 g oral dose is extracted from the body during a 6-8 hour hemodialysis session.

DOSAGE AND ADMINISTRATION

Cefadroxil monohydrate is acid-stable and may be administered orally without regard to meals. Administration with food may be helpful in diminishing potential gastrointestinal complaints occasionally associated with oral cephalosporin therapy.

Adults

Urinary Tract Infections: For uncomplicated lower urinary tract infections (i.e., cystitis) the usual dosage is 1 or 2 g per day in a single (q.d.) or divided doses (b.i.d.).

For all other urinary tract infections the usual dosage is 2 g per day in divided doses (b.i.d.).

Skin and Skin Structure Infections: For skin and skin structure infections the usual dosage is 1 g per day in single (q.d.) or divided doses (b.i.d.).

Pharyngitis and Tonsillitis: Treatment of group A beta-hemolytic streptococcal pharyngitis and tonsillitis — 1 g per day in single (q.d.) or divided doses (b.i.d.) for 10 days.

Children

For urinary tract infections, the recommended daily dosage for children is 30 mg/kg/day in divided doses every 12 hours. For pharyngitis, tonsillitis, and impetigo, the recommended daily dosage for children is 30 mg/kg/day in a single dose or in equally divided doses every 12 hours. For other skin and skin structure infections, the recommended daily dosage is 30 mg/kg/day in equally divided doses every 12 hours. In the treatment of beta-hemolytic streptococcal infections, a therapeutic dosage of cefadroxil monohydrate should be administered for at least 10 days.

See chart for total daily dosage for children.

DAILY DOSAGE OF CEFADROXIL FOR ORAL SUSPENSION

Child's Weight				
lbs	kg	125 mg/5 mL	250 mg/5 mL	500 mg/5 mL
10	4.5	1 tsp	—	
20	9.1	2 tsp	1 tsp	
30	13.6	3 tsp	1 ½ tsp	
40	18.2	4 tsp	2 tsp	1 tsp
50	22.7	5 tsp	2 ½tsp	1 ¼ tsp
60	27.3	6 tsp	3 tsp	1 ½ tsp
70 & above	31.8+	—	—	2 tsp

Renal Impairment:

In patients with renal impairment, the dosage of cefadroxil monohydrate should be adjusted according to creatinine clearance rates to prevent drug accumulation. The following schedule is suggested. In adults, the initial dose is 1000 mg of cefadroxil monohydrate and the maintenance dose (based on the creatinine clearance rate [mL/min/1.73 M^2]) is 500 mg at the time intervals listed below.

Creatinine Clearances	Dosage Interval
0-10 mL/min	36 hours
10-25 mL/min	24 hours
25-50 mL/min	12 hours

Patients with creatinine clearance rates over 50 mL/min may be treated as if they were patients having normal renal function.

Reconstitution Directions for Oral Suspension

Bottle Size	Reconstitution Directions
75 mL	Suspend in a total of 53 mL of water. Method: Tap bottle lightly to loosen powder. Add 53 mL of water in two portions. Shake well after each addition.
100 mL	Suspend in a total of 70 mL of water. Method: Tap bottle lightly to loosen powder. Add 70 mL of water in two portions. Shake well after each addition.

After reconstitution, store in refrigerator. Shake well before using.
Keep container tightly closed. Discard unused portion after 14 days.

HOW SUPPLIED

Cefadroxil For Oral Suspension, USP is available in:

The 125 mg per 5 mL of reconstituted suspension* contains cefadroxil monohydrate equivalent to 125 mg with a light orange colored powder forming orange suspension on constitution with water. The resulting suspension has a characteristic mixed fruit flavor and is available as follows:

NDC 63304-972-04 100 mL bottles

The 250 mg per 5 mL of reconstituted suspension* contains cefadroxil monohydrate equivalent to 250 mg with a light orange colored powder forming orange suspension on constitution with water. The resulting suspension has a characteristic mixed fruit flavor and is available as follows:

NDC 63304-973-04 100 mL bottles

The 500 mg per 5 mL of reconstituted suspension* contains cefadroxil monohydrate equivalent to 500 mg with a light orange colored powder forming orange suspension on constitution with water. The resulting suspension has a characteristic mixed fruit flavor and is available as follows:

NDC 63304-974-01 75 mL bottles
NDC 63304-974-04 100 mL bottles

*SHAKE ORAL SUSPENSION WELL BEFORE USING. Keep bottle tightly closed. After reconstitution, store in refrigerator. Any unused portion of the reconstituted suspension must be discarded after 14 days.

Prior to reconstitution: Store at controlled room temperature 15° to 30° C (59° to 86° F) (see USP).

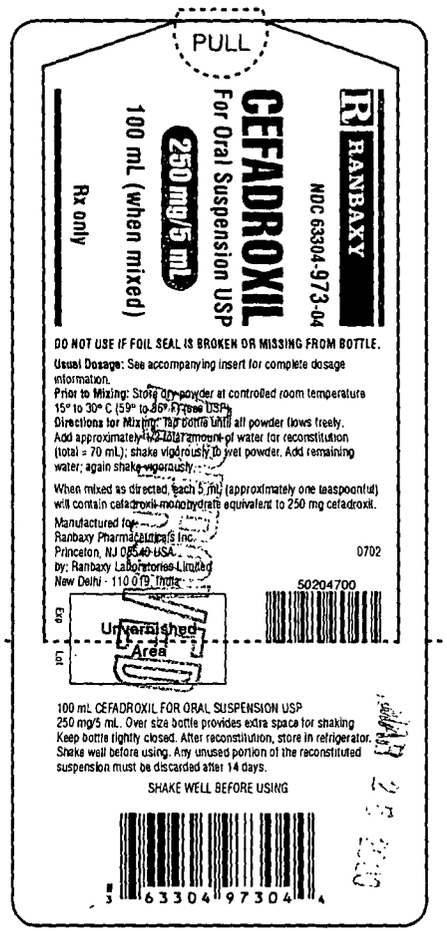
References

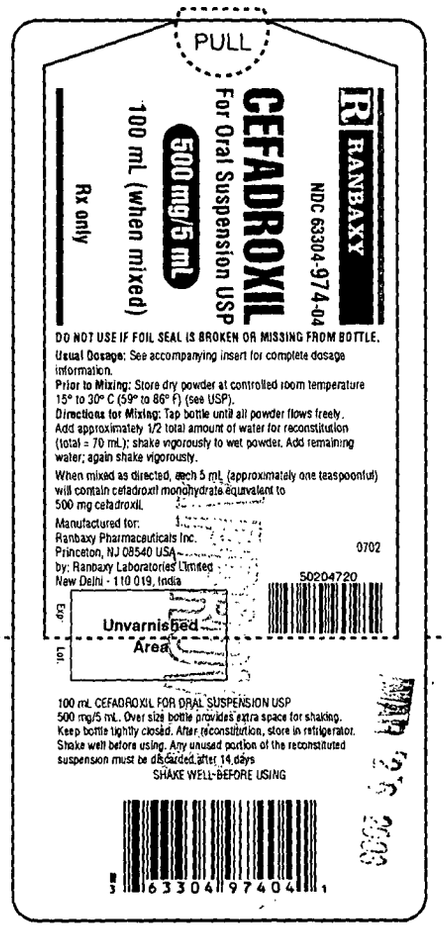
1. National Committee for Clinical Laboratory Standards, Approved Standard, *Performance Standards for Antimicrobial Disk Susceptibility Test*, 4th Edition, Vol. 10 (7): M2-A4, Villanova, PA, April, 1990.
2. National Committee for Clinical Laboratory Standards, Approved Standard: *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically*, 2nd Edition, Vol. 10 (8): M7-A2, Villanova, PA, April, 1990.

Manufactured for:
Ranbaxy Pharmaceutical Inc.
Princeton, NJ 08540 USA
By: Ranbaxy Laboratories Limited
New Delhi – 110 019, India
August 2002

FDA-3

PULL
RANBAXY
NDC 63304-972-04
CEFADROXIL
For Oral Suspension USP
125 mg/5 mL
100 mL (when mixed)
Rx only
DO NOT USE IF FOIL SEAL IS BROKEN OR MISSING FROM BOTTLE.
Usual Dosage: See accompanying insert for complete dosage information.
Prior to Mixing: Store dry powder at controlled room temperature 15° to 30°C (59° to 86°F) (see USP).
Directions for Mixing: Tap bottle until all powder flows freely. Add approximately 1/2 (or a specific amount of water for reconstitution (total = 70 mL). Shake vigorously to wet powder. Add remaining water, again shake vigorously.
When mixed as directed, each 5 mL (approximately one teaspoonful) will contain cefadroxil monohydrate equivalent to 125 mg cefadroxil.
Manufactured for:
Ranbaxy Pharmaceuticals Inc.
Plaganton, NJ 08540 USA
by:Ranbaxy Laboratories Limited
New Delhi - 110 019 India
0702
50204690
Unvarnished Area
Exp
Lot
100 mL CEFADROXIL FOR ORAL SUSPENSION USP
125 mg/5 mL. Over size bottle provides extra space for shaking
Keep bottle tightly closed. After reconstitution, store in refrigerator.
Shake well before using. Any unused portion of the reconstituted suspension must be discarded after 14 days.
SHAKE WELL BEFORE USING
3 63304 97204 7


PULL
RANBAXY
NDC 63304-973-04
CEFADROXIL
For Oral Suspension USP
250 mg/5 mL
100 mL (when mixed)
Rx only
DO NOT USE IF FOIL SEAL IS BROKEN OR MISSING FROM BOTTLE.
Usual Dosage: See accompanying insert for complete dosage information.
Prior to Mixing: Store dry powder at controlled room temperature 15° to 30° C (59° to 86° F) [see USP].
Directions for Mixing: Tap bottle until all powder flows freely. Add approximately half the amount of water for reconstitution (total = 70 mL); shake vigorously to wet powder. Add remaining water; again shake vigorously.
When mixed as directed, each 5 mL (approximately one teaspoonful) will contain cefadroxil monohydrate equivalent to 250 mg cefadroxil.
Manufactured for:
Ranbaxy Pharmaceuticals Inc.
Princeton, NJ 08540 USA
by: Ranbaxy Laboratories Limited
New Delhi - 110 019, India
0702
50204700
Exp
Lot
Unvarnished Area
100 mL CEFADROXIL FOR ORAL SUSPENSION USP
250 mg/5 mL. Over size bottle provides extra space for shaking
Keep bottle tightly closed. After reconstitution, store in refrigerator.
Shake well before using. Any unused portion of the reconstituted suspension must be discarded after 14 days.
SHAKE WELL BEFORE USING
3 63304 97304 4


PULL
RANBAXY
NDC 63304-974-04
CEFADROXIL
For Oral Suspension USP
500 mg/5 mL
100 mL (when mixed)
Rx only
DO NOT USE IF FOIL SEAL IS BROKEN OR MISSING FROM BOTTLE.
Usual Dosage: See accompanying insert for complete dosage information.
Prior to Mixing: Store dry powder at controlled room temperature 15° to 30° C (59° to 86° F) (see USP).
Directions for Mixing: Tap bottle until all powder flows freely. Add approximately 1/2 total amount of water for reconstitution (total = 70 mL); shake vigorously to wet powder. Add remaining water; again shake vigorously.
When mixed as directed, each 5 mL (approximately one teaspoonful) will contain cefadroxil monohydrate equivalent to 500 mg cefadroxil.
Manufactured for:
Ranbaxy Pharmaceuticals Inc.
Princeton, NJ 08540 USA
by: Ranbaxy Laboratories Limited
New Delhi - 110 019, India
0702
50204720
Exp
Lot
Unvarnished Area
100 mL CEFADROXIL FOR ORAL SUSPENSION USP
500 mg/5 mL. Over size bottle provides extra space for shaking.
Keep bottle tightly closed. After reconstitution, store in refrigerator.
Shake well before using. Any unused portion of the reconstituted suspension must be discarded after 14 days
SHAKE WELL BEFORE USING
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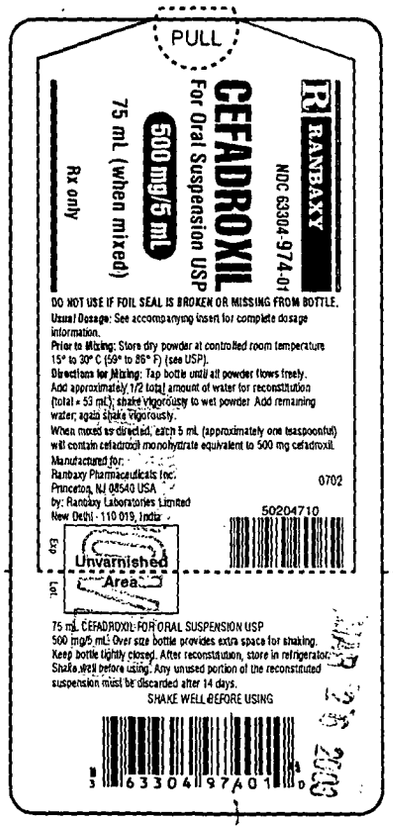
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RANBAXY
NDC 63304-974-01
CEFADROXIL
For Oral Suspension USP
500 mg/5 mL
75 mL (when mixed)
Rx only
DO NOT USE IF FOIL SEAL IS BROKEN OR MISSING FROM BOTTLE.
Usual Dosage: See accompanying insert for complete dosage information.
Prior to Mixing: Store dry powder at controlled room temperature 15° to 30° C (59° to 86° F) (see USP).
Directions for Mixing: Tap bottle until all powder flows freely. Add approximately 1/2 total amount of water for reconstitution (total = 53 mL); shake vigorously to wet powder. Add remaining water; again shake vigorously.
When mixed as directed, each 5 mL (approximately one teaspoonful) will contain cefadroxil monohydrate equivalent to 500 mg cefadroxil.
Manufactured for:
Ranbaxy Pharmaceuticals Inc.
Princeton, NJ 08540 USA
by: Ranbaxy Laboratories Limited
New Delhi - 110 019, India
0702
50204710
Exp
Lot
Unvarnished Area
75 mL CEFADROXIL FOR ORAL SUSPENSION USP
500 mg/5 mL. Over size bottle provides extra space for shaking.
Keep bottle tightly closed. After reconstitution, store in refrigerator.
Shake well before using. Any unused portion of the reconstituted suspension must be discarded after 14 days.
SHAKE WELL BEFORE USING
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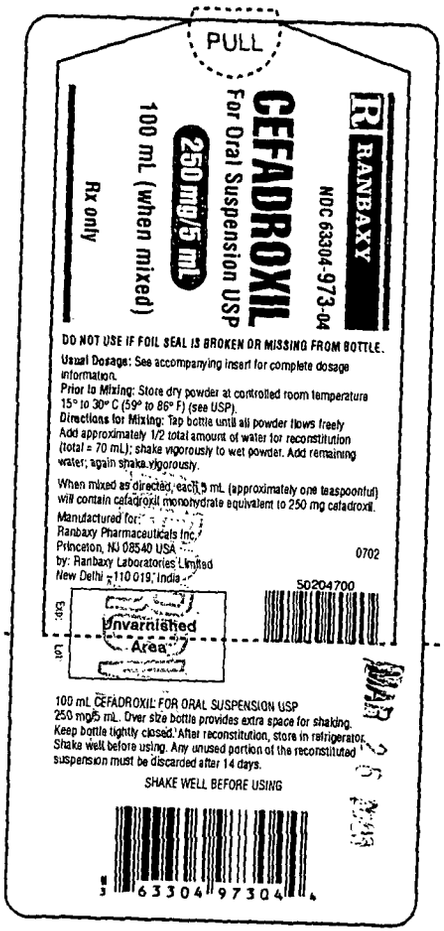
PULL
RANBAXY
NDC 63304-973-04
CEFADROXIL
For Oral Suspension USP
250 mg/5 mL
100 mL (when mixed)
Rx only
DO NOT USE IF FOIL SEAL IS BROKEN OR MISSING FROM BOTTLE.
Usual Dosage: See accompanying insert for complete dosage information.
Prior to Mixing: Store dry powder at controlled room temperature 15° to 30° C (59° to 86° F) (see USP).
Directions for Mixing: Tap bottle until all powder flows freely. Add approximately 1/2 total amount of water for reconstitution (total = 70 mL); shake vigorously to wet powder. Add remaining water; again shake vigorously.
When mixed as directed, each 5 mL (approximately one teaspoonful) will contain cefadroxil monohydrate equivalent to 250 mg cefadroxil.
Manufactured for:
Ranbaxy Pharmaceuticals Inc.
Princeton, NJ 08540 USA
by: Ranbaxy Laboratories Limited
New Delhi - 110 019, India
0702
50204700
Exp.
Lot
Unvarnished Area
100 mL CEFADROXIL FOR ORAL SUSPENSION USP
250 mg/5 mL. Over size bottle provides extra space for shaking.
Keep bottle tightly closed. After reconstitution, store in refrigerator.
Shake well before using. Any unused portion of the reconstituted suspension must be discarded after 14 days.
SHAKE WELL BEFORE USING
3 63304 97304 4