CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

64164

DRAFT FINAL PRINTED LABELING

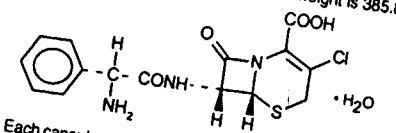
AADA 64-155
AADA 64-164
AADA 64-165
AADA 64-166

CEFACLOR CAPSULES USP
and
CEFACLOR FOR ORAL SUSPENSION USP

CEFACLOR CAPSULES USP
and
CEFACLOR FOR ORAL SUSPENSION USP

DESCRIPTION

Cefaclor, USP is a semisynthetic cephalosporin antibiotic for oral administration. It is chemically designated as 3-chloro-7-D-(2-phenylglycinamido)-3-cephem-4-carboxylic acid monohydrate. The chemical formula for cefaclor is $C_{15}H_{14}ClN_3O_4S \cdot H_2O$ and the molecular weight is 385.82.



Each capsule contains cefaclor monohydrate equivalent to 250 mg (0.68 mmol) or 500 mg (1.36 mmol) anhydrous cefaclor. The capsules also contain pregelatinized starch, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, gelatin, FD&C Blue No. 1, D&C Yellow No. 10, FD&C Red No. 40, D&C Red No. 28, titanium dioxide, sicomet black oxide and edible printing ink.

After mixing, each 5 mL of Cefaclor for Oral Suspension will contain cefaclor monohydrate equivalent to 125 mg (0.34 mmol), 187 mg (0.51 mmol), 250 mg (0.68 mmol), or 375 mg (1.0 mmol) anhydrous cefaclor. The suspensions also contain xanthan gum, sodium benzoate, sucrose, colloidal silicon dioxide, FD&C Red No. 40, flavors, sodium citrate, citric acid and simethicone emulsion.

CLINICAL PHARMACOLOGY

Cefaclor is well absorbed after oral administration to fasting subjects. Total absorption is the same whether the drug is given with or without food; however, when it is taken with food, the peak concentration achieved is 50% to 75% of that observed when the drug is administered to fasting subjects and generally appears from three fourths to 1 hour later. It has been reported that following administration of 250-mg, 500-mg, and 1-g doses to fasting subjects, average peak serum levels of approximately 7, 13, and 23 mcg/mL respectively were obtained within 30 to 60 minutes. Approximately 60% to 85% of the drug is excreted unchanged in the urine within 8 hours, the greater portion being excreted within the first 2 hours. During this 8-hour period, peak urine concentrations following the 250-mg, 500-mg and 1-g doses were approximately 600, 900 and 1,900 mcg/mL respectively. The serum half-life in normal subjects is 0.6 to 0.9 hour. In patients with reduced renal function, the serum half-life of cefaclor is slightly prolonged. In those with complete absence of renal function, the plasma half-life of the intact molecule is 2.3 to 2.8 hours. Excretion pathways in patients with markedly impaired renal function have not been determined. Hemodialysis shortens the half-life by 25% to 30%.

Microbiology - *In vitro* tests demonstrate that the bactericidal action of the cephalosporins results from inhibition of cell-wall synthesis. Cefaclor has been shown to be active against most strains of the following microorganisms, both *in vitro* and in clinical infections as described in the INDICATIONS AND USAGE section.

Aerobes, Gram-positive
- Staphylococci, including coagulase-positive, coagulase-negative, and penicillinase-producing strains
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes* (group A β-hemolytic streptococci)

Aerobes, Gram-negative
- *Escherichia coli*
- *Haemophilus influenzae*, including β-lactamase-producing ampicillin-resistant strains
- *Klebsiella* sp
- *Proteus mirabilis*

The following *in vitro* data are available, **but their clinical significance is unknown.**

Cefaclor exhibits *in vitro* minimal inhibitory concentrations (MICs) of ≤ 8 mcg/mL or less against most (≥90%) strains of the following microorganisms; however, the safety and effectiveness of cefaclor in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled clinical trials.

Aerobes, Gram-negative
- *Citrobacter diversus*
- *Moraxella (Branhamella) catarrhalis*
- *Neisseria gonorrhoeae*

Anaerobes, Gram-positive
- *Bacteroides* sp (excluding *Bacteroides fragilis*)
- Peptococci
- Peptostreptococci
- *Propionibacterium acnes*

Note: *Pseudomonas* sp, *Acinetobacter calcoaceticus* (formerly *Mima* sp and *Herellea* sp), and most strains of enterococci (*Enterococcus faecalis* [formerly *Streptococcus faecalis*], group D streptococci), *Enterobacter* sp, indole-positive *Proteus*, and *Serratia* sp are resistant to cefaclor. When tested by *in vitro* methods, staphylococci exhibit cross-resistance between cefaclor and methicillin-type antibiotics.

Disk Susceptibility Tests

Diffusion Techniques -- Quantitative methods that require measurement of zone diameters provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. One such standardized procedure[1] that has been recommended for use with disks to test the susceptibility of microorganisms to cefaclor uses the 30-mcg cefaclor disk. Interpretation involves correlation of the diameter obtained in the disk test with the MIC for cefaclor. With this procedure, a report from the laboratory of "resistant" indicates that the infecting organism is not likely to respond to therapy. A report of "intermediate susceptibility" suggests that the organism would be susceptible if the infection is confined to tissues and fluids (eg, urine) in which high antibiotic levels can be obtained or if high dosage is used.

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

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

When Testing *H. influenzae**

Zone diameter (mm)	Interpretation
≥ 20	Susceptible (S)
17 - 19	Intermediate (I)
≤ 16	Resistant (R)

* Disk susceptibility tests performed using Haemophilus Test Medium (HTM)[1]

A report of "Susceptible" indicates that the pathogen is likely to be inhibited by usually achievable concentrations of the antimicrobial compound in blood. A report of "Intermediate" indicates that the result should be considered equivocal, and, if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone that prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that usually achievable concentrations of the antimicrobial compound in the blood are unlikely to be inhibitory and that other therapy should be selected.

Measurement of MIC or MBC and achieved antimicrobial compound concentrations may be appropriate to guide therapy in some infections. (*See* CLINICAL PHARMACOLOGY section for further information on drug concentrations achieved in infected body sites and other pharmacokinetic properties of this antimicrobial drug product.)

Standardized susceptibility test procedures require the use of laboratory control microorganisms. The 30-mcg cefaclor disk should provide the following zone diameters in these laboratory test quality control strains:

Microorganisms	Zone Diameter (mm)
E. coli ATCC 25922	23 - 27
S. aureus ATCC 25923	27 - 31

When Testing *H. influenzae**

Microorganisms	Zone Diameter (mm)
H. influenzae ATCC 49766	25 - 31

* Disk susceptibility tests performed using Haemophilus Test Medium (HTM)[1]

Dilution Techniques -- Quantitative methods that are used to determine minimum inhibitory concentrations provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. One such standardized procedure uses a standardized dilution method[2] (broth, agar, or microdilution) or equivalent with cefaclor powder. The MIC values obtained should be interpreted according to the following criteria:

MIC (mcg/mL)	Interpretation
≤ 8	Susceptible (S)
16	Intermediate (I)
≥ 32	Resistant (R)

Interpretation should be as stated above for results using diffusion techniques.

As with standard diffusion techniques, dilution methods require the use of laboratory control microorganisms. Standard cefaclor powder should provide the following MIC values:

Microorganism	MIC (mcg/mL)
E. coli ATCC 25922	1 - 4
E. faecalis ATCC 29212	> 32
S. aureus ATCC 29213	1 - 4

When Testing *H. Influenzae*[*]

Microorganism	MIC (mcg/mL)
H. Influenzae ATCC 49247	0.12 - 0.5

[*] Broth microdilution tests performed using Haemophilus Test Medium (HTM)[2]

INDICATIONS AND USAGE

Cefaclor is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Otitis media caused by *S. pneumoniae, H. influenzae,* staphylococci, and *S. pyogenes* (group A β-hemolytic streptococci)

Lower respiratory infections, including pneumonia, caused by *S. pneumoniae, H. influenzae,* and *S. pyogenes* (group A β-hemolytic streptococci)

Upper respiratory infections, including pharyngitis and tonsillitis, caused by *S. pyogenes* (group A β-hemolytic streptococci)

Note: Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Cefaclor is generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of cefaclor in the subsequent prevention of rheumatic fever are not available at present.

Urinary tract infections, including pyelonephritis and cystitis, caused by *E. coli, P. mirabilis, Klebsiella* sp, and coagulase-negative staphylococci

Skin and skin structure infections caused by *Staphylococcus aureus* and *S. pyogenes* (group A β-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to cefaclor.

CONTRAINDICATIONS

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

WARNINGS

IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF

THE PENICILLINS AND THE CEPHALOSPORINS AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including cefaclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

PRECAUTIONS

General - If an allergic reaction to cefaclor occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, eg, pressor amines, antihistamines or corticosteroids.

Prolonged use of cefaclor 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.

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.

Cefaclor should be administered with caution in the presence of markedly impaired renal function. Since the half-life of cefaclor in anuria is 2.3 to 2.8 hours, dosage adjustments for patients with moderate or severe renal impairment are usually not required. Clinical experience with cefaclor under such conditions is limited; therefore, careful clinical observation and laboratory studies should be made.

As with other β-lactam antibiotics, the renal excretion of cefaclor is inhibited by probenecid.

As a result of administration of cefaclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also

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Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Pregnancy - Pregnancy Category B - Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given 3 times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cefaclor. 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.

Nursing Mothers - Small amounts of cefaclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/mL, at 2, 3, 4, and 5 hours respectively. Trace amounts were detected at 1 hour. The effect on nursing infants is not known. Caution should be exercised when cefaclor is administered to a nursing woman.

Pediatric Use - Safety and effectiveness of this product for use in pediatric patients less than 1 month of age have not been established.

ADVERSE REACTIONS

Adverse effects considered to be related to therapy with cefaclor are listed below:

Hypersensitivity reactions have been reported in about 1.5% of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' test each occur in less than 1 in 200 patients.

Cases of **serum-sickness-like** reactions have been reported with the use of cefaclor. These are characterized by findings of erythema multiforme, rashes, and other skin manifestations accompanied by arthritis/arthralgia, with or without fever, and differ from classic serum sickness in that there is infrequently associated lymphadenopathy and proteinuria, no circulating immune complexes, and no evidence to date of sequelae of the reaction. Occasionally, solitary symptoms may occur, but do not represent a **serum-sickness-like reaction**. While further investigation is ongoing, **serum-sickness-like** reactions appear to be due to hypersensitivity and more often occur during or following a second (or subsequent) course of therapy with cefaclor. Such reactions have been reported more frequently in children than in adults with an overall occurrence ranging from 1 in 200 (0.5%) in one focused trial to 2 in 8,346 (0.024%) in overall clinical trials (with an incidence in children in clinical trials of 0.055%) to 1 in 38,000 (0.003%) in spontaneous event reports. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy; occasionally these reactions have resulted in hospitalization, usually of short duration (median hospitalization = 2 to 3 days, based on postmarketing surveillance studies). In those requiring hospitalization, the symptoms have ranged from mild to severe at the time of admission with more of the severe reactions occurring in children. Antihistamines and glucocorticoids appear to enhance resolution of the signs and symptoms. No serious sequelae have been reported.

More severe hypersensitivity reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylaxis have been reported rarely. Anaphylactoid events may be manifested by solitary symptoms including angioedema, asthenia, edema (including face and limbs), dyspnea, paresthesias, syncope, hypotension or vasodilatation. Anaphylaxis may be more common in patients with a history of penicillin allergy.

Rarely, hypersensitivity symptoms may persist for several months.

Gastrointestinal symptoms occur in about 2.5% of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

Other effects considered related to therapy included eosinophilia (1 in 50 patients), genital pruritus or vaginitis (less than 1 in 100 patients), and, rarely, thrombocytopenia or reversible interstitial nephritis.

Causal Relationship Uncertain --

CNS-Rarely, reversible hyperactivity, agitation, nervousness, insomnia, confusion, hypertonia, dizziness, hallucinations, and somnolence have been reported.

Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic - Slight elevations of AST (SGOT), ALT (SGPT), or alkaline phosphatase values (1 in 40).

Hematopoietic - As has also been reported with other β-lactam antibiotics, transient lymphocytosis, leukopenia, and rarely, hemolytic anemia and reversible neutropenia of possible clinical significance.

There have been rare reports of increased prothrombin time with or without clinical bleeding in patients receiving cefaclor and Coumadin concomitantly.

Renal - Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

OVERDOSAGE

Signs and Symptoms -- The toxic symptoms following an overdose of cefaclor may include nausea, vomiting, epigastric distress, and diarrhea. The severity of the epigastric distress and the diarrhea are dose related. If other symptoms are present, it is probable that they are secondary to an underlying disease state, an allergic reaction, or the effects of other intoxication.

Treatment -- To obtain up-to-date information about the treatment of overdose, a good resource is your certified Regional Poison Control Center. Telephone numbers of certified poison control centers are listed in the *Physicians' Desk Reference (PDR)*. In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient.

Unless 5 times the normal dose of cefaclor has been ingested, gastrointestinal decontamination will not be necessary.

Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Safeguard the patient's airway when employing gastric emptying or charcoal.

Forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion have not been established as beneficial for an overdose of cefaclor.

DOSAGE AND ADMINISTRATION

Cefaclor is administered orally.

Adults - The usual adult dosage is 250 mg every 8 hours. For more severe infections (such as pneumonia) or those caused by less susceptible organisms, doses may be doubled.

Children - The usual recommended daily dosage for children is 20 mg/kg/day in divided doses every 8 hours. In more serious infections, otitis media, and infections caused by less susceptible organisms, 40 mg/kg/day are recommended, with a maximum dosage of 1 g/day.

	Cefaclor Suspension	
	20 mg/kg/day	
Child's Weight	125 mg/5 mL	250 mg/5 mL
9 kg	1/2 tsp t.i.d.	
18 kg	1 tsp t.i.d.	1/2 tsp t.i.d.
	40 mg/kg/day	
9 kg	1 tsp t.i.d.	1/2 tsp t.i.d.
18 kg		1 tsp t.i.d.

B.I.D. Treatment Option - For the treatment of otitis media and pharyngitis, the total daily dosage may be divided and administered every 12 hours.

	Cefaclor Suspension	
	20 mg/kg/day (Pharyngitis)	
Child's Weight	187 mg/5 mL	375 mg/5 mL
9 kg	1/2 tsp b.i.d.	
18 kg	1 tsp b.i.d.	1/2 tsp b.i.d.
	40 mg/kg/day (Otitis Media)	
9 kg	1 tsp b.i.d.	1/2 tsp b.i.d.
18 kg		1 tsp b.i.d.

Cefaclor may be administered in the presence of impaired renal function. Under such a condition, the dosage usually is unchanged (see PRECAUTIONS).

In the treatment of β-hemolytic streptococcal infections, a therapeutic dosage of cefaclor should be administered for at least 10 days.

HOW SUPPLIED

Capsules:

250 mg, blue and green, printed "RX 658" -
(100s) NDC 63304-658-01;
(250s) NDC 63304-658-04;
(500s) NDC 63304-658-05;
(unit-dose 100s) NDC 63304-658-80

500 mg, blue and green, printed "RX 659" -
(100s) NDC 63304-659-01;
(250s) NDC 63304-659-04;
(500s) NDC 63304-659-05;
(unit-dose 100s) NDC 63304-659-80

For Oral Suspension:

125 mg/5 mL, strawberry flavor† -
(75-mL size) NDC 63304-954-01;
(150-mL size) NDC 63304-954-02

187 mg/5 mL, strawberry flavor† -
(50-mL size) NDC 63304-955-03;
(100-mL size) NDC 63304-955-04

250 mg/5 mL, strawberry flavor† -
(75-mL size) NDC 63304-956-01;
(150-mL size) NDC 63304-956-02

375 mg/5 mL, strawberry flavor† -
(50-mL size) NDC 63304-957-03;
(100-mL size) NDC 63304-957-04

†After mixing, store in a refrigerator. Shake well before using. Keep tightly closed. The mixture may be kept for 14 days without significant loss of potency. Discard unused portion after 14 days.

"Store at controlled room temperature 15° to 30° C (59° to 86° F), protected from moisture."

CAUTION-Federal (USA) law prohibits dispensing without prescription.

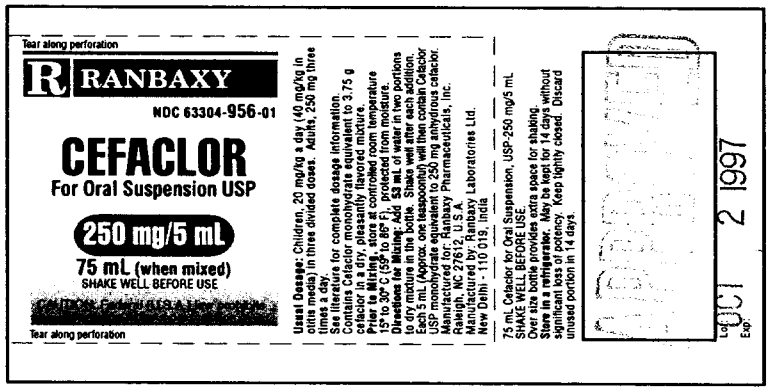
REFERENCES

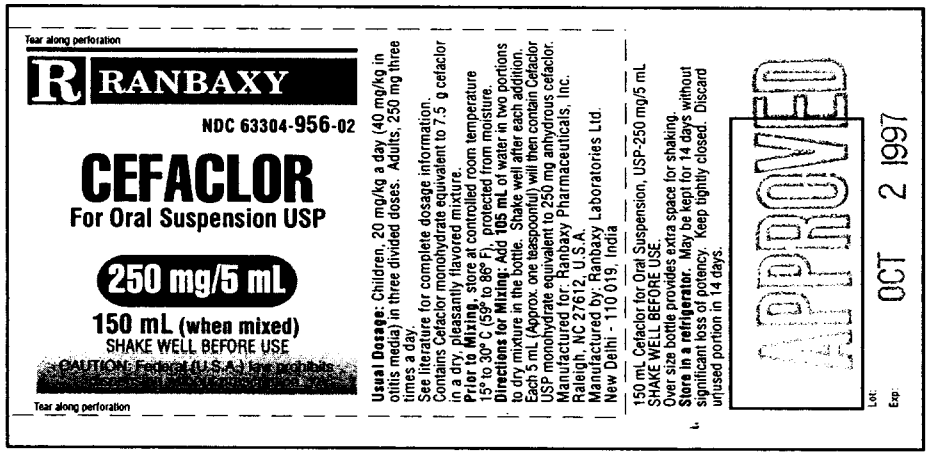
1. National Committee for Clinical Laboratory Standards, Performance standards for antimicrobial disk susceptibility tests - 5th ed., Approved Standard NCCLS Document M2-A5, Vol 13, No 24, NCCLS, Villanova, PA, 1993.
2. National Committee for Clinical Laboratory Standards, Methods for dilution antimicrobial susceptibility tests for bacteria that grow aerobically - 3rd ed., Approved Standard NCCLS Document M7-A3, Vol 13, No 25, NCCLS, Villanova, PA, 1993.

Revised : May 1997

Manufactured for :
Ranbaxy Pharmaceuticals Inc.
Raleigh, NC 27612, U.S.A.

Manufactured by :
Ranbaxy Laboratories Limited
New Delhi-110 019, India


Tear along perforation
RANBAXY
NDC 63304-956-01
CEFACLOR
For Oral Suspension USP
250 mg/5 mL
75 mL (when mixed)
SHAKE WELL BEFORE USE
Tear along perforation
Usual Dosage: Children, 20 mg/kg a day (40 mg/kg in otitis media) in three divided doses. Adults, 250 mg three times a day.
See literature for complete dosage information.
Contains Cefaclor monohydrate equivalent to 3.75 g cefaclor in a dry, pleasantly flavored mixture.
Prior to Mixing, store at controlled room temperature 15° to 30°C (59° to 86°F), protected from moisture.
Directions for Mixing: Add 53 mL of water in two portions to dry mixture in the bottle. Shake well after each addition.
Each 5 mL (Approx. one teaspoonful) will then contain Cefaclor USP monohydrate equivalent to 250 mg anhydrous cefaclor.
Manufactured for: Ranbaxy Pharmaceuticals, Inc.
Raleigh, NC 27612, U.S.A.
Manufactured by: Ranbaxy Laboratories Ltd.
New Delhi - 110 019, India
75 mL Cefaclor for Oral Suspension, USP-250 mg/5 mL
SHAKE WELL BEFORE USE
Over size bottle provides extra space for shaking.
Store in a refrigerator. May be kept for 14 days without significant loss of potency. Keep tightly closed. Discard unused portion in 14 days.
APPROVED
Lot:
Exp: OCT 2 1997


Tear along perforation
RANBAXY
NDC 63304-956-02
CEFACLOR
For Oral Suspension USP
250 mg/5 mL
150 mL (when mixed)
SHAKE WELL BEFORE USE
Tear along perforation
Usual Dosage: Children, 20 mg/kg a day (40 mg/kg in otitis media) in three divided doses. Adults, 250 mg three times a day.
See literature for complete dosage information.
Contains Cefaclor monohydrate equivalent to 7.5 g cefaclor in a dry, pleasantly flavored mixture.
Prior to Mixing, store at controlled room temperature 15° to 30°C (59° to 86°F), protected from moisture.
Directions for Mixing: Add 105 mL of water in two portions to dry mixture in the bottle. Shake well after each addition.
Each 5 mL (Approx. one teaspoonful) will then contain Cefaclor USP monohydrate equivalent to 250 mg anhydrous cefaclor.
Manufactured for: Ranbaxy Pharmaceuticals, Inc.
Raleigh, NC 27612, U.S.A.
Manufactured by: Ranbaxy Laboratories Ltd.
New Delhi - 110 019, India
150 mL Cefaclor for Oral Suspension, USP-250 mg/5 mL
SHAKE WELL BEFORE USE
Over size bottle provides extra space for shaking.
Store in a refrigerator. May be kept for 14 days without significant loss of potency. Keep tightly closed. Discard unused portion in 14 days.
APPROVED
Lot:
Exp: OCT 2 1997