

CEFDINIR- cefdinir capsule
RedPharm Drug, Inc.

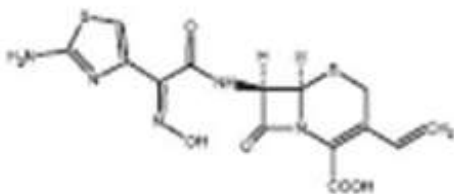
Cednifir 300mg

300 mg Rx only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefdinir capsules and other antibacterial drugs, cefdinir capsules should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION

Cefdinir capsules contains the active ingredient cefdinir, an extended-spectrum, semisynthetic cephalosporin, for oral administration. Chemically, cefdinir is [6R-[6 α ,7 β (Z)]]-7-[[[(2-amino-4 thiazolyl) (hydroxyimino) acetyl]amino]-3-ethenyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. Cefdinir is a white to slightly brownish-yellow solid. It is slightly soluble in dilute hydrochloric acid and sparingly soluble in 0.1 M pH 7.0 phosphate buffer. The molecular formula is C₁₄H₁₃N₅O₅S₂ and the molecular weight is 395.42. Cefdinir has the structural formula shown below:



Cefdinir capsules contain 300 mg of cefdinir and the following inactive ingredients: carboxymethylcellulose calcium; colloidal silicon dioxide; and magnesium stearate. The capsule shells contain D and C Red No. 28; FD and C Blue No. 1; FD and C Red No. 40; gelatin and titanium dioxide.

CLINICAL PHARMACOLOGY

Pharmacokinetics and Drug Metabolism:

Absorption:

Oral Bioavailability: Maximal plasma cefdinir concentrations occur 2 to 4 hours postdose following capsule or suspension administration. Plasma cefdinir concentrations increase with dose, but the increases are less than dose-proportional from 300 mg (7 mg/kg) to 600 mg (14 mg/kg). Following administration of suspension to healthy adults, cefdinir bioavailability is 120% relative to capsules. Estimated bioavailability of cefdinir capsules is 21% following administration of a 300 mg capsule dose, and 16% following administration of a 600 mg capsule dose. Estimated absolute bioavailability of cefdinir suspension is 25%.

Effect of Food: The C_{max} and AUC of cefdinir from the capsules are reduced by 16% and 10%, respectively, when given with a high-fat meal. The magnitude of these reductions is not likely to be clinically significant. Therefore, cefdinir may be taken without regard to food.

Cefdinir Capsules: Cefdinir plasma concentrations and pharmacokinetic parameter values following administration of single 300 and 600 mg oral doses of cefdinir to adult subjects are presented in the following table

Mean (\pm SD) Plasma Cefdinir Pharmacokinetic Parameter Values Following Administration of Capsules to Adult Subjects

Dose	C _{max} (mcg/mL)	t _{max} (hr)	AUC(mcg.hr/mL)
300 mg	1.6 (0.55)	2.9 (0.89)	7.05(2.17)
600 mg	2.87 (1.01)	3.0 (0.66)	11.1 (3.87)

Multiple Dosing: Cefdinir does not accumulate in plasma following once- or twice-daily administration to subjects with normal renal function.

Distribution:

The mean volume of distribution (V_{darea}) of cefdinir in adult subjects is 0.35 L/kg (\pm 0.29); in pediatric subjects (age 6 months-12 years), cefdinir V_{darea} is 0.67 L/kg (\pm 0.38). Cefdinir is 60% to 70% bound to plasma proteins in both adult and pediatric subjects; binding is independent of concentration.

Skin Blister: In adult subjects, median (range) maximal blister fluid cefdinir concentrations of 0.65 (0.33-1.1) and 1.1 (0.49-1.9) mcg/mL were observed 4 to 5 hours following administration of 300 and 600 mg doses, respectively. Mean (\pm SD) blister C_{max} and AUC (0- ∞) values were 48% (\pm 13) and 91% (\pm 18) of corresponding plasma values.

Tonsil Tissue: In adult patients undergoing elective tonsillectomy, respective median tonsil tissue cefdinir concentrations 4 hours after administration of single 300 and 600 mg doses were 0.25 (0.22-0.46) and 0.36 (0.22-0.80) mcg/g. Mean tonsil tissue concentrations were 24% (\pm 8) of corresponding plasma concentrations.

Sinus Tissue: In adult patients undergoing elective maxillary and ethmoid sinus surgery, respective median sinus tissue cefdinir concentrations 4 hours after administration of single 300 and 600 mg doses were <0.12 (<0.12-0.46) and 0.21 (<0.12-2.0) mcg/g. Mean sinus tissue concentrations were 16% (\pm 20) of corresponding plasma concentrations.

Lung Tissue: In adult patients undergoing diagnostic bronchoscopy, respective median bronchial mucosa cefdinir concentrations 4 hours after administration of single 300 and 600 mg doses were 0.78 (<0.06-1.33) and 1.14 (<0.06-1.92) mcg/mL, and were 31% (\pm 18) of corresponding plasma concentrations. Respective median epithelial lining fluid concentrations were 0.29 (<0.3-4.73) and 0.49 (<0.3-0.59) mcg/mL, and were 35% (\pm 83) of corresponding plasma concentrations.

Middle Ear Fluid: In 14 pediatric patients with acute bacterial otitis media, respective median middle ear fluid cefdinir concentrations 3 hours after administration of single 7 and 14 mg/kg doses were 0.21 (<0.09-0.94) and 0.72 (0.14-1.42) mcg/mL. Mean middle ear fluid concentrations were 15% (\pm 15) of corresponding plasma concentrations.

CSF: Data on cefdinir penetration into human cerebrospinal fluid are not available.

Metabolism and Excretion:

Cefdinir is not appreciably metabolized. Activity is primarily due to parent drug. Cefdinir is eliminated principally via renal excretion with a mean plasma elimination half-life (t_{1/2}) of 1.7 (\pm 0.6) hours. In healthy subjects with normal renal function, renal clearance is 2.0 (\pm 1.0) mL/min/kg, and apparent oral clearance is 11.6 (\pm 6.0) and 15.5 (\pm 5.4) mL/min/kg following doses of 300 and 600 mg, respectively. Mean percent of dose recovered unchanged in the urine following 300 and 600 mg doses is 18.4% (\pm 6.4) and 11.6% (\pm 4.6), respectively. Cefdinir clearance is reduced in patients with renal dysfunction (see Special Populations: Patients with Renal Insufficiency).

Because renal excretion is the predominant pathway of elimination, dosage should be adjusted in patients with markedly compromised renal function or who are undergoing hemodialysis (see DOSAGE AND ADMINISTRATION).

Special Populations:

Patients with Renal Insufficiency: Cefdinir pharmacokinetics were investigated in 21 adult subjects with varying degrees of renal function. Decreases in cefdinir elimination rate, apparent oral clearance (CL/F), and renal clearance were approximately proportional to the reduction in creatinine clearance (CL_{cr}). As a result, plasma cefdinir concentrations were higher and persisted longer in subjects with renal impairment than in those without renal impairment. In subjects with CL_{cr} between 30 and 60 mL/min, C_{max} and t_{1/2} increased by approximately 2-fold and AUC by approximately 3-fold. In subjects with CL_{cr} <30 mL/min, C_{max} increased by approximately 2-fold, t_{1/2} by approximately 5-fold, and AUC by approximately 6-fold. Dosage adjustment is recommended in patients with markedly compromised renal function (creatinine clearance <30 mL/min; see DOSAGE AND ADMINISTRATION).

Hemodialysis: Cefdinir pharmacokinetics were studied in 8 adult subjects undergoing hemodialysis. Dialysis (4 hours duration) removed 63% of cefdinir from the body and reduced apparent elimination t_{1/2} from 16 (±3.5) to 3.2 (±1.2) hours. Dosage adjustment is recommended in this patient population (see DOSAGE AND ADMINISTRATION).

Hepatic Disease: Because cefdinir is predominantly renally eliminated and not appreciably metabolized, studies in patients with hepatic impairment were not conducted. It is not expected that dosage adjustment will be required in this population.

Geriatric Patients: The effect of age on cefdinir pharmacokinetics after a single 300 mg dose was evaluated in 32 subjects 19 to 91 years of age. Systemic exposure to cefdinir was substantially increased in older subjects (N=16), C_{max} by 44% and AUC by 86%. This increase was due to a reduction in cefdinir clearance. The apparent volume of distribution was also reduced, thus no appreciable alterations in apparent elimination t_{1/2} were observed (elderly: 2.2 ± 0.6 hours vs young: 1.8 ± 0.4 hours). Since cefdinir clearance has been shown to be primarily related to changes in renal function rather than age, elderly patients do not require dosage adjustment unless they have markedly compromised renal function (creatinine clearance <30 mL/min, see Patients with Renal Insufficiency, above).

Gender and Race: The results of a meta-analysis of clinical pharmacokinetics (N=217) indicated no significant impact of either gender or race on cefdinir pharmacokinetics.

Microbiology:

Mechanism of Action:

As with other cephalosporins, bactericidal activity of cefdinir results from inhibition of cell wall synthesis. Cefdinir is stable in the presence of some, but not all, β-lactamase enzymes. As a result, many organisms resistant to penicillins and some cephalosporins are susceptible to cefdinir.

Mechanism of Resistance:

Resistance to cefdinir is primarily through hydrolysis by some β-lactamases, alteration of penicillin-binding proteins (PBPs) and decreased permeability. Cefdinir is inactive against most strains of *Enterobacter* spp., *Pseudomonas* spp., *Enterococcus* spp., penicillin-resistant streptococci, and methicillin-resistant staphylococci. β-lactamase negative, ampicillin-resistant (BLNAR) *H. influenzae* strains are typically non-susceptible to cefdinir.

Antimicrobial Activity:

Cefdinir has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections as described in INDICATIONS AND USAGE.

Gram-Positive Bacteria:

Staphylococcus aureus (methicillin-susceptible strains only)

Streptococcus pneumoniae (penicillin-susceptible strains only)

Streptococcus pyogenes

Gram-Negative Bacteria:

Haemophilus influenzae

Haemophilus parainfluenzae

Moraxella catarrhalis

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

Cefdinir exhibits in vitro minimum inhibitory concentrations (MICs) of 1 mcg/mL or less against (\geq 90%) strains of the following microorganisms; however, the safety and effectiveness of cefdinir in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled clinical trials.

Gram-Positive Bacteria:

Staphylococcus epidermidis (methicillin-susceptible strains only)

Streptococcus agalactiae

Viridans group streptococci

Gram-Negative Bacteria:

Citrobacter koseri

Escherichia coli

Klebsiella pneumoniae

Proteus mirabilis

Susceptibility Test Methods:

When available, the clinical microbiology laboratory should provide periodic reports that describe the regional/local susceptibility profile of potential nosocomial and community-acquired pathogens. These reports should aid the physician in selecting an antibacterial drug for treatment.

Dilution Techniques:

Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MICs). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized test method¹(broth and/or agar). The MIC values should be interpreted according to criteria provided in Table 1.

Diffusion Techniques:

Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. The zone size should be determined using a standardized method.²The procedure uses paper disks impregnated with 5 mcg cefdinir to test the susceptibility of bacteria. The disk diffusion interpretive criteria are provided in Table 1.

Table 1: Susceptibility Test Interpretive Criteria for Cefdinir

Microorganisms*	Minimum Inhibitory			Minimum Inhibitory		
	Concentration (mcg/mL)	I	R	(mm)	I	R
<i>Haemophilus influenzae</i>	≤ 1	-	-	≥ 20	-	--
<i>Haemophilus parainfluenzae</i>	≤ 1	-	-	≥ 20	-	--
<i>Moraxella catarrhalis</i>	≤ 1	2	≥ 4	≥ 20	17 to 19	≤ 16
<i>Streptococcus pneumoniae</i> †	≤ 0.5	1	≥ 2	-	-	-

Streptococci other than *S. pneumoniae* that are susceptible to penicillin (MIC \leq 0.12 mcg/mL), can be considered susceptible to cefdinir.

†

S. pneumoniae that are susceptible to penicillin (MIC \leq 0.06 mcg/mL) can be considered susceptible to cefdinir. Isolates of *S. pneumoniae* tested against a 1- μ g oxacillin disk with oxacillin zone sizes \geq 20 mm are susceptible to penicillin and can be considered susceptible to cefdinir. Testing of cefdinir against penicillin-intermediate or penicillin-resistant isolates is not recommended. Reliable interpretive criteria for cefdinir are not available.

Susceptibility of staphylococci to cefdinir may be deduced from testing penicillin and either cefoxitin or oxacillin. Staphylococci susceptible to oxacillin (cefoxitin) can be considered susceptible to cefdinir.³

A report of "Susceptible" indicates that antimicrobial is likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentrations at the site of infection necessary to inhibit growth of the pathogen. 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 a 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 the antimicrobial is not likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentrations usually achievable at the infection site; other therapy should be selected.

Quality Control:

Standardized susceptibility test procedures require the use of laboratory controls to monitor and ensure the accuracy and precision of supplies and reagents used in the assay, and the techniques of the individual performing the test.^{1,2,3} Standard cefdinir powder should provide the following range of MIC values as noted in Table 2. For the diffusion technique using a 5 mcg disk the criteria in Table 2 should be achieved.

Table 2: Acceptable Quality Control Ranges for Cefdinir

QC Strain	Minimum Inhibitory Concentration (mcg/mL)	Zone Diameter (mm)
<i>Escherichia coli</i> ATCC 25922	0.12 to 0.5	24 to 28
<i>Haemophilus influenzae</i> ATCC 49766	0.12 to 0.5	24 to 31
<i>Staphylococcus aureus</i> ATCC 25923	-	25 to 32
<i>Staphylococcus aureus</i> ATCC 29213	0.12 to 0.5	-
<i>Streptococcus pneumoniae</i> ATCC 49619	0.03 to 0.25	26 to 31

INDICATIONS AND USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefdinir capsules and other antibacterial drugs, cefdinir capsules should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Cefdinir capsules are indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below.

Adults and Adolescents: Community-Acquired Pneumonia:

Caused by *Haemophilus influenzae* (including β -lactamase producing strains), *Haemophilus parainfluenzae* (including β -lactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including β -lactamase producing strains) (see CLINICAL STUDIES).

Acute Exacerbations of Chronic Bronchitis:

Caused by *Haemophilus influenzae* (including β -lactamase producing strains), *Haemophilus parainfluenzae* (including β -lactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including β -lactamase producing strains).

Acute Maxillary Sinusitis:

Caused by *Haemophilus influenzae* (including β -lactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including β -lactamase producing strains).

NOTE: For information on use in pediatric patients, see Pediatric Use and DOSAGE AND ADMINISTRATION.

Pharyngitis/Tonsillitis:

Caused by *Streptococcus pyogenes* (see CLINICAL STUDIES).

NOTE: Cefdinir is effective in the eradication of *S. pyogenes* from the oropharynx. Cefdinir has not, however, been studied for the prevention of rheumatic fever following *S. pyogenes* pharyngitis/tonsillitis. Only intramuscular penicillin has been demonstrated to be effective for the prevention of rheumatic fever.

Uncomplicated Skin and Skin Structure Infections:

Caused by *Staphylococcus aureus* (including β -lactamase producing strains) and *Streptococcus pyogenes*.

Pediatric Patients :

Acute Bacterial Otitis Media:

Caused by *Haemophilus influenzae* (including β -lactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including β -lactamase producing strains).

Pharyngitis/Tonsillitis:

Caused by *Streptococcus pyogenes* (see CLINICAL STUDIES).

NOTE: Cefdinir is effective in the eradication of *S. pyogenes* from the oropharynx. Cefdinir has not, however, been studied for the prevention of rheumatic fever following *S. pyogenes* pharyngitis/tonsillitis. Only intramuscular penicillin has been demonstrated to be effective for the prevention of rheumatic fever.

Uncomplicated Skin and Skin Structure Infections:

Caused by *Staphylococcus aureus* (including β -lactamase producing strains) and *Streptococcus pyogenes*.

CONTRAINDICATIONS

Cefdinir is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

WARNINGS

BEFORE THERAPY WITH CEFDINIR IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS

HYPERSENSITIVITY REACTIONS TO CEFDINIR, OTHER CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF CEFDINIR IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-HYPERSENSITIVITY AMONG β -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 CEFDINIR OCCURS, THE DRUG SHOULD BE DISCONTINUED. 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.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Cefdinir, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

PRECAUTIONS

General:

Prescribing cefdinir capsules in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria.

As with other broad-spectrum antibiotics, prolonged treatment may result in the possible emergence and overgrowth of resistant organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate alternative therapy should be administered.

Cefdinir, as with other broad-spectrum antimicrobials (antibiotics), should be prescribed with caution in individuals with a history of colitis.

In patients with transient or persistent renal insufficiency (creatinine clearance less than 30 mL/min), the total daily dose of cefdinir should be reduced because high and prolonged plasma concentrations of cefdinir can result following recommended doses (see **DOSAGE AND ADMINISTRATION**

Information for Patients :

Patients should be counseled that antibacterial drugs including cefdinir capsules should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When cefdinir capsules is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by cefdinir capsules or other antibacterial drugs in the future.

Antacids containing magnesium or aluminum interfere with the absorption of cefdinir. If this type of antacid is required during cefdinir therapy, cefdinir should be taken at least 2 hours before or after the

antacid.

Iron supplements, including multivitamins that contain iron, interfere with the absorption of cefdinir. If iron supplements are required during cefdinir therapy, cefdinir should be taken at least 2 hours before or after the supplement.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Drug Interactions:

Antacids (Aluminum- or Magnesium-Containing):

Concomitant administration of 300 mg cefdinir capsules with 30 mL Maalox[®] TC suspension reduces the rate (C_{max}) and extent (AUC) of absorption by approximately 40%. Time to reach C_{max} is also prolonged by 1 hour. There are no significant effects on cefdinir pharmacokinetics if the antacid is administered 2 hours before or 2 hours after cefdinir. If antacids are required during cefdinir capsules therapy, cefdinir capsules should be taken at least 2 hours before or after the antacid.

Probenecid:

As with other β -lactam antibiotics, probenecid inhibits the renal excretion of cefdinir, resulting in an approximate doubling in AUC, a 54% increase in peak cefdinir plasma levels, and a 50% prolongation in the apparent elimination $t_{1/2}$.

Iron Supplements and Foods Fortified With Iron:

Concomitant administration of cefdinir with a therapeutic iron supplement containing 60 mg of elemental iron (as $FeSO_4$) or vitamins supplemented with 10 mg of elemental iron reduced extent of absorption by 80% and 31%, respectively. If iron supplements are required during cefdinir therapy, cefdinir should be taken at least 2 hours before or after the supplement.

The effect of foods highly fortified with elemental iron (primarily iron-fortified breakfast cereals) on cefdinir absorption has not been studied.

There have been reports of reddish stools in patients receiving cefdinir. In many cases, patients were also receiving iron-containing products. The reddish color is due to the formation of a nonabsorbable complex between cefdinir or its breakdown products and iron in the gastrointestinal tract.

Drug/Laboratory Test Interactions

A false-positive reaction for ketones in the urine may occur with tests using nitroprusside, but not with those using nitroferricyanide. The administration of cefdinir may result in a false-positive reaction for glucose in urine using Clinitest[®], Benedict's solution, or Fehling's solution. It is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix[®] or Tes-Tape[®]) be used. Cephalosporins are known to occasionally induce a positive direct Coombs' test.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

The carcinogenic potential of cefdinir has not been evaluated. No mutagenic effects were seen in the bacterial reverse mutation assay (Ames) or point mutation assay at the hypoxanthine-guanine phosphoribosyltransferase locus (HGPRT) in V79 Chinese hamster lung cells. No clastogenic effects were observed

in vitro

in the structural chromosome aberration assay in V79 Chinese hamster lung cells or

in vivo

in the micronucleus assay in mouse bone marrow. In rats, fertility and reproductive performance were not affected by cefdinir at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m²/day).

Pregnancy:

Teratogenic Effects: Pregnancy Category B.

Cefdinir was not teratogenic in rats at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m²/day) or in rabbits at oral doses up to 10 mg/kg/day (0.7 times the human dose based on mg/kg/day, 0.23 times based on mg/m²/day). Maternal toxicity (decreased body weight gain) was observed in rabbits at the maximum tolerated dose of 10 mg/kg/day without adverse effects on offspring. Decreased body weight occurred in rat fetuses at ≥100 mg/kg/day, and in rat offspring at ≥32 mg/kg/day. No effects were observed on maternal reproductive parameters or offspring survival, development, behavior, or reproductive function.

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:

Cefdinir has not been studied for use during labor and delivery.

Nursing Mothers:

Following administration of single 600 mg doses, cefdinir was not detected in human breast milk.

Pediatric Use:

Safety and efficacy in neonates and infants less than 6 months of age have not been established. Use of cefdinir for the treatment of acute maxillary sinusitis in pediatric patients (age 6 months through 12 years) is supported by evidence from adequate and well-controlled studies in adults and adolescents, the similar pathophysiology of acute sinusitis in adult and pediatric patients, and comparative pharmacokinetic data in the pediatric population.

ADVERSE EVENTS

Clinical Trials - (Adult and Adolescent Patients):

In clinical trials, 5093 adult and adolescent patients (3841 U.S. and 1252 non-U.S.) were treated with the recommended dose of cefdinir capsules (600 mg/day). Most adverse events were mild and self-limiting. No deaths or permanent disabilities were attributed to cefdinir. One hundred forty-seven of 5093 (3%) patients discontinued medication due to adverse events thought by the investigators to be possibly, probably, or definitely associated with cefdinir therapy. The discontinuations were primarily for gastrointestinal disturbances, usually diarrhea or nausea. Nineteen of 5093 (0.4%) patients were discontinued due to rash thought related to cefdinir administration.

In the U.S., the following adverse events were thought by investigators to be possibly, probably, or definitely related to cefdinir capsules in multiple-dose clinical trials (N = 3841 cefdinir-treated patients):

The following laboratory value changes of possible clinical significance, irrespective of relationship to therapy with cefdinir, were seen during clinical trials conducted in the U.S.: Postmarketing

Experience:

The following adverse experiences and altered laboratory tests, regardless of their relationship to cefdinir, have been reported during extensive postmarketing experience, beginning with approval in Japan in 1991: shock, anaphylaxis with rare cases of fatality, facial and laryngeal edema, feeling of suffocation, serum sickness-like reactions, conjunctivitis, stomatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, erythema multiforme, erythema nodosum, acute hepatitis, cholestasis, fulminant hepatitis, hepatic failure, jaundice, increased amylase, acute enterocolitis, bloody diarrhea, hemorrhagic colitis, melena, pseudomembranous colitis, pancytopenia, granulocytopenia, leukopenia, thrombocytopenia, idiopathic thrombocytopenic purpura, hemolytic anemia, acute respiratory failure, asthmatic attack, drug-induced pneumonia, eosinophilic pneumonia, idiopathic interstitial pneumonia, fever, acute renal failure, nephropathy, bleeding tendency, coagulation disorder, disseminated intravascular coagulation, upper GI bleed, peptic ulcer, ileus, loss of consciousness, allergic vasculitis, possible cefdinir-diclofenac interaction, cardiac failure, chest pain, myocardial infarction, hypertension, involuntary movements, and rhabdomyolysis.

Cephalosporin Class Adverse Events:

The following adverse events and altered laboratory tests have been reported for cephalosporin-class antibiotics in general:

Allergic reactions, anaphylaxis, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage, false-positive test for urinary glucose, neutropenia, pancytopenia, and agranulocytosis. Pseudomembranous colitis symptoms may begin during or after antibiotic treatment (see WARNINGS).

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.

DOSAGE AND ADMINISTRATION

(see INDICATIONS AND USAGE for Indicated Pathogens)

The recommended dosage and duration of treatment for infections in adults and adolescents are described in the following chart; the total daily dose for all infections is 600 mg. Once-daily dosing for 10 days is as effective as BID dosing. Once-daily dosing has not been studied in pneumonia or skin infections; therefore, cefdinir capsules should be administered twice daily in these infections. Cefdinir capsules may be taken without regard to meals.

Adults and Adolescents (Age 13 years and Older)

Type of Infection	Dosage	Duration
Community-Acquired Pneumonia	300 mg q12h	10 days
Acute Exacerbations of Chronic Bronchitis	300 mg q12h	5 to 10 days
	or	
Acute Maxillary Sinusitis	600 mg q24h	10 days
	300mg q12h	10 days
	or	
Pharyngitis/Tonsillitis	600mg q24h	10 days
	300mg q12h	5 to 10 days
	or	
Uncomplicated Skin and Skin Structure Infections	600mg q24h	10 days

300mg q12h

10 days

Patients With Renal Insufficiency:

For adult patients with creatinine clearance less than 30 mL/min, the dose of cefdinir should be 300 mg given once daily.

Creatinine clearance is difficult to measure in outpatients. However, the following formula may be used to estimate creatinine clearance (CL_{cr}) in adult patients. For estimates to be valid, serum creatinine levels should reflect steady-state levels of renal function.

(weight) (140 – age)

Males: CL_{cr} = _____

(72) (serum creatinine)

Females: CL_{cr} = 0.85 x above value

where creatinine clearance is in mL/min, age is in years, weight is in kilograms, and serum creatinine is in mg/dL. (3)

The following formula may be used to estimate creatinine clearance in pediatric patients:

body length or height

CL_{cr} = K x _____

serum creatinine

where K = 0.55 for pediatric patients older than 1 year (4) and 0.45 for infants (up to 1 year) (5).

In the above equation, creatinine clearance is in mL/min/1.73 m², body length or height is in centimeters, and serum creatinine is in mg/dL.

For pediatric patients with a creatinine clearance of less than 30 mL/min/1.73 m², the dose of cefdinir should be 7 mg/kg (up to 300 mg) given once daily.

Patients on Hemodialysis:

Hemodialysis removes cefdinir from the body. In patients maintained on chronic hemodialysis, the recommended initial dosage regimen is a 300 mg or 7 mg/kg dose every other day. At the conclusion of each hemodialysis session, 300 mg (or 7 mg/kg) should be given. Subsequent doses (300 mg or 7 mg/kg) are then administered every other day.

HOW SUPPLIED

Cefdinir capsules USP, 300 mg, size '0' capsules having blue cap imprinted twice with "LUPIN" (in black ink) and purple body imprinted twice with "CEFDINIR" (in white ink) containing off white to creamish granular slug, are available as follows:

20 Capsules/Bottle

NDC 67296-0469-1

Store the capsules at 20°-25°C (68°-77°F); [see USP Controlled Room Temperature].

CLINICAL STUDIES

and Drug Metabolism:

Absorption:

Oral Bioavailability: Maximal plasma cefdinir concentrations occur 2 to 4 hours postdose following capsule or suspension administration. Plasma cefdinir concentrations increase with dose, but the increases are less than dose-proportional from 300 mg (7 mg/kg) to 600 mg (14 mg/kg). Following

administration of suspension to healthy adults, cefdinir bioavailability is 120% relative to capsules. Estimated bioavailability of cefdinir capsules is 21% following administration of a 300 mg capsule dose, and 16% following administration of a 600 mg capsule dose. Estimated absolute bioavailability of cefdinir suspension is 25%.

Effect of Food: The C_{max} and AUC of cefdinir from the capsules are reduced by 16% and 10%, respectively, when given with a high-fat meal. The magnitude of these reductions is not likely to be clinically significant. Therefore, cefdinir may be taken without regard to food.

Cefdinir Capsules: Cefdinir plasma concentrations and pharmacokinetic parameter values following administration of single 300 and 600 mg oral doses of cefdinir to adult subjects are presented in the following table:

Mean (±SD) Plasma Cefdinir Pharmacokinetic Parameter Values Following Administration of Capsules to Adult Subjects

Dose	C _{max} (mcg/mL)	t _{max} (hr)	AUC(mcg.hr/mL)
300 mg	1.60(0.55)	2.9(0.89)	7.05(2.17)
600 mg	2.87(1.01)	3.0(0.66)	11.1(3.87)

Multiple Dosing: Cefdinir does not accumulate in plasma following once- or twice-daily administration to subjects with normal renal function.

Distribution:

The mean volume of distribution (V_{darea}) of cefdinir in adult subjects is 0.35 L/kg (±0.29); in pediatric subjects (age 6 months-12 years), cefdinir V_{darea} is 0.67 L/kg (±0.38). Cefdinir is 60% to 70% bound to plasma proteins in both adult and pediatric subjects; binding is independent of concentration.

Skin Blister: In adult subjects, median (range) maximal blister fluid cefdinir concentrations of 0.65 (0.33-1.1) and 1.1 (0.49-1.9) mcg/mL were observed 4 to 5 hours following administration of 300 and 600 mg doses, respectively. Mean (±SD) blister C_{max} and AUC (0-∞) values were 48% (±13) and 91% (±18) of corresponding plasma values.

Tonsil Tissue: In adult patients undergoing elective tonsillectomy, respective median tonsil tissue cefdinir concentrations 4 hours after administration of single 300 and 600 mg doses were 0.25 (0.22-0.46) and 0.36 (0.22-0.80) mcg/g. Mean tonsil tissue concentrations were 24% (±8) of corresponding plasma concentrations.

Sinus Tissue: In adult patients undergoing elective maxillary and ethmoid sinus surgery, respective median sinus tissue cefdinir concentrations 4 hours after administration of single 300 and 600 mg doses were <0.12 (<0.12-0.46) and 0.21 (<0.12-2.0) mcg/g. Mean sinus tissue concentrations were 16% (±20) of corresponding plasma concentrations.

Lung Tissue: In adult patients undergoing diagnostic bronchoscopy, respective median bronchial mucosa cefdinir concentrations 4 hours after administration of single 300 and 600 mg doses were 0.78 (<0.06-1.33) and 1.14 (<0.06-1.92) mcg/mL, and were 31% (±18) of corresponding plasma concentrations. Respective median epithelial lining fluid concentrations were 0.29 (<0.3-4.73) and 0.49 (<0.3-0.59) mcg/mL, and were 35% (±83) of corresponding plasma concentrations.

Middle Ear Fluid: In 14 pediatric patients with acute bacterial otitis media, respective median middle ear fluid cefdinir concentrations 3 hours after administration of single 7 and 14 mg/kg doses were 0.21 (<0.09-0.94) and 0.72 (0.14-1.42) mcg/mL. Mean middle ear fluid concentrations were 15% (±15) of corresponding plasma concentrations.

CSF: Data on cefdinir penetration into human cerebrospinal fluid are not available.

Metabolism and Excretion:

Cefdinir is not appreciably metabolized. Activity is primarily due to parent drug. Cefdinir is eliminated principally via renal excretion with a mean plasma elimination half-life ($t_{1/2}$) of 1.7 (± 0.6) hours. In healthy subjects with normal renal function, renal clearance is 2.0 (± 1.0) mL/min/kg, and apparent oral clearance is 11.6 (± 6.0) and 15.5 (± 5.4) mL/min/kg following doses of 300 and 600 mg, respectively. Mean percent of dose recovered unchanged in the urine following 300 and 600 mg doses is 18.4% (± 6.4) and 11.6% (± 4.6), respectively. Cefdinir clearance is reduced in patients with renal dysfunction (see Special Populations: Patients with Renal Insufficiency).

Because renal excretion is the predominant pathway of elimination, dosage should be adjusted in patients with markedly compromised renal function or who are undergoing hemodialysis (see DOSAGE AND ADMINISTRATION).

Special Populations:

Patients with Renal Insufficiency: Cefdinir pharmacokinetics were investigated in 21 adult subjects with varying degrees of renal function. Decreases in cefdinir elimination rate, apparent oral clearance (CL/F), and renal clearance were approximately proportional to the reduction in creatinine clearance (CL_{cr}). As a result, plasma cefdinir concentrations were higher and persisted longer in subjects with renal impairment than in those without renal impairment. In subjects with CL_{cr} between 30 and 60 mL/min, C_{max} and $t_{1/2}$ increased by approximately 2-fold and AUC by approximately 3-fold. In subjects with CL_{cr} <30 mL/min, C_{max} increased by approximately 2-fold, $t_{1/2}$ by approximately 5-fold, and AUC by approximately 6-fold. Dosage adjustment is recommended in patients with markedly compromised renal function (creatinine clearance <30 mL/min; see DOSAGE AND ADMINISTRATION).

Hemodialysis: Cefdinir pharmacokinetics were studied in 8 adult subjects undergoing hemodialysis. Dialysis (4 hours duration) removed 63% of cefdinir from the body and reduced apparent elimination $t_{1/2}$ from 16 (± 3.5) to 3.2 (± 1.2) hours. Dosage adjustment is recommended in this patient population (see DOSAGE AND ADMINISTRATION).

Hepatic Disease: Because cefdinir is predominantly renally eliminated and not appreciably metabolized, studies in patients with hepatic impairment were not conducted. It is not expected that dosage adjustment will be required in this population.

Geriatric Patients: The effect of age on cefdinir pharmacokinetics after a single 300 mg dose was evaluated in 32 subjects 19 to 91 years of age. Systemic exposure to cefdinir was substantially increased in older subjects (N=16), C_{max} by 44% and AUC by 86%. This increase was due to a reduction in cefdinir clearance. The apparent volume of distribution was also reduced, thus no appreciable alterations in apparent elimination $t_{1/2}$ were observed (elderly: 2.2 ± 0.6 hours vs young: 1.8 ± 0.4 hours). Since cefdinir clearance has been shown to be primarily related to changes in renal function rather than age, elderly patients do not require dosage adjustment unless they have markedly compromised renal function (creatinine clearance <30 mL/min, see Patients with Renal Insufficiency, above).

Gender and Race: The results of a meta-analysis of clinical pharmacokinetics (N=217) indicated no significant impact of either gender or race on cefdinir pharmacokinetics.

Microbiology:

Mechanism of Action:

As with other cephalosporins, bactericidal activity of cefdinir results from inhibition of cell wall synthesis. Cefdinir is stable in the presence of some, but not all, β -lactamase enzymes. As a result, many organisms resistant to penicillins and some cephalosporins are susceptible to cefdinir.

Mechanism of Resistance:

Resistance to cefdinir is primarily through hydrolysis by some β -lactamases, alteration of penicillin-binding proteins (PBPs) and decreased permeability. Cefdinir is inactive against most strains of

Enterobacter spp., Pseudomonas spp., Enterococcus spp., penicillin-resistant streptococci, and methicillin-resistant staphylococci. β -lactamase negative, ampicillin-resistant (BLNAR) H. influenzae strains are typically non-susceptible to cefdinir.

Antimicrobial Activity:

Cefdinir has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections as described in INDICATIONS AND USAGE.

Gram-Positive Bacteria:

Staphylococcus aureus (methicillin-susceptible strains only)

Streptococcus pneumoniae (penicillin-susceptible strains only)

Streptococcus pyogenes

Gram-Negative Bacteria:

Haemophilus influenzae

Haemophilus parainfluenzae

Moraxella catarrhalis

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

Cefdinir exhibits in vitro minimum inhibitory concentrations (MICs) of 1 mcg/mL or less against (\geq 90%) strains of the following microorganisms; however, the safety and effectiveness of cefdinir in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled clinical trials.

Gram-Positive Bacteria:

Staphylococcus epidermidis (methicillin-susceptible strains only)

Streptococcus agalactiae

Viridans group streptococci

Gram-Negative Bacteria:

Citrobacter koseri

Escherichia coli

Klebsiella pneumoniae

Proteus mirabilis

Susceptibility Test Methods:

When available, the clinical microbiology laboratory should provide periodic reports that describe the regional/local susceptibility profile of potential nosocomial and community-acquired pathogens. These reports should aid the physician in selecting an antibacterial drug for treatment.

Dilution Techniques:

Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MICs). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized test method¹(broth and/or agar). The MIC values should be interpreted according to criteria provided in Table 1.

Diffusion Techniques:

Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. The zone size should be determined using a standardized method.²The procedure uses paper disks impregnated with 5 mcg cefdinir to test the

susceptibility of bacteria. The disk diffusion interpretive criteria are provided in Table 1.

Table 1: Susceptibility Test Interpretive Criteria for Cefdinir

Microorganisms*	Minimum Inhibitory Concentration (mcg/mL)		Minimum Inhibitory (mm)		
	S	I R	S	I	R
Haemophilus influenzae	≤ 1	- -	≥ 20	-	--
Haemophilus parainfluenzae	≤ 1	- -	≥ 20	-	--
Moraxella catarrhalis	≤ 1	2 ≥ 4	≥ 20	17 to 19	≤ 16
Streptococcus pneumoniae †	≤ 0.5	1 ≥ 2	=	-	-

*Streptococci other than *S. pneumoniae* that are susceptible to penicillin (MIC ≤ 0.12 mcg/mL), can be considered susceptible to cefdinir.

†*S. pneumoniae* that are susceptible to penicillin (MIC ≤ 0.06 mcg/mL) can be considered susceptible to cefdinir. Isolates of *S. pneumoniae* tested against a 1-µg oxacillin disk with oxacillin zone sizes ≥ 20 mm are susceptible to penicillin and can be considered susceptible to cefdinir. Testing of cefdinir against penicillin-intermediate or penicillin-resistant isolates is not recommended. Reliable interpretive criteria for cefdinir are not available.

Susceptibility of staphylococci to cefdinir may be deduced from testing penicillin and either cefoxitin or oxacillin. Staphylococci susceptible to oxacillin (cefoxitin) can be considered susceptible to cefdinir.³

A report of "Susceptible" indicates that antimicrobial is likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentrations at the site of infection necessary to inhibit growth of the pathogen. 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 a 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 the antimicrobial is not likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentrations usually achievable at the infection site; other therapy should be selected.

Quality Control:

Standardized susceptibility test procedures require the use of laboratory controls to monitor and ensure the accuracy and precision of supplies and reagents used in the assay, and the techniques of the individual performing the test.^{1,2,3} Standard cefdinir powder should provide the following range of MIC values as noted in Table 2. For the diffusion technique using a 5 mcg disk the criteria in Table 2 should be achieved.

Table 2: Acceptable Quality Control Ranges for Cefdinir

QC Strain	Minimum Inhibitory Concentration (mcg/mL)	Zone Diameter (mm)
<i>Escherichia coli</i> ATCC 25922	0.12 to 0.5	24 to 28
<i>Haemophilus influenzae</i> ATCC 49766	0.12 to 0.5	24 to 21
<i>Staphylococcus aureus</i> ATCC 25923	-	25 to 32
<i>Staphylococcus aureus</i> ATCC 29213	0.12 to 0.5	-
<i>Streptococcus pneumoniae</i> ATCC 49619	0.03 to 0.25	26 to 31

REFERENCES

1. National Committee for Clinical Laboratory Standards. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, 4th ed. Approved Standard, NCCLS Document M7-A4, Vol 17(2). NCCLS, Villanova, PA, Jan 1997.
2. National Committee for Clinical Laboratory Standards. Performance Standards for Antimicrobial Disk Susceptibility Tests, 6th ed. Approved Standard, NCCLS Document M2-A6, Vol 17(1). NCCLS, Villanova, PA, Jan 1997.
3. Cockcroft DW, Gault MH. Prediction of creatinine clearance from serum creatinine. Nephron, 1976;16:31-41.
4. Schwartz GJ, Haycock GB, Edelmann CM, Spitzer A. A simple estimate of glomerular filtration rate in children derived from body length and plasma creatinine. Pediatrics 1976;58:259-63.
5. Schwartz GJ, Feld LG, Langford DJ. A simple estimate of glomerular filtration rate in full-term infants during the first year of life. J Pediatrics 1984;104:849-54.

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Mandideep 462 046

INDIA

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Clinistix[®] and Clinitest[®] are registered trademarks of Miles Diagnostics.

Tes-tape[®] is a registered trademark of Lilly.

Revised 15th December 2009

ID#:218628

NDC: 67296-0469-1

CEFDINIR

300MG

20 Capsules

Rx Only

Lot: _____

Exp: _____

Usual adult dosage: See package insert

Store at controlled room temperature: 20-25 C (68-77 F)

Mfg. by: Lupin Limited
Mandideep 462 046 India
68180-711-60

Dist. by: Redpharm Drug Eden Prairie, MN 55344

LCN: 59525



5
04691
67296
3

NDC: 67296-0469-2

CEFDINIR

300MG

14 Capsules

Rx Only

Lot: _____

Exp: _____

Usual adult dosage: See package insert

Store at controlled room temperature: 20-25 C (68-77 F)

Mfg. by: Lupin Limited
Mandideep 462 046 India
68180-711-60

Dist. by: Redpharm Drug Eden Prairie, MN 55344

LCN: 622715



2
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67296
3

NDC: 67296-0469-3

CEFDINIR

300MG

10 Capsules

Rx Only

Lot: 802305X2

Exp: 11/21

Usual adult dosage: See package insert

Store at controlled room temperature: 20-25 C (68-77 F)

Mfg: Lupin Limited
Mandideep 462 046 India
68180-711-60

Dist. by: Redpharm Drug Eden Prairie, MN 55344

SIN255020



(01)00367296046939
(21)100000000000013
(17)211130
(10)802305X2



9
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3

NDC: 67296-0469-1
CEFDINIR
300MG
20 Capsules


Rx Only

Lot: A0001A 1 Exp: 12/11

Usual adult dosage: See package insert
Store at controlled room temperature: 20-25 C (68-77 F)

Mfg. by: Lupin Limited
Mandideep 462 046 India
68180-711-60

Dist. by: Redpharm Drug Eden Prairie, MN 55344 LCN: 59525



5
04691
3 67296

NDC: 67296-0469-1
CEFDINIR
300MG
20 Capsules


Rx Only

Lot: A0001A 1 Exp: 12/11

Usual adult dosage: See package insert
Store at controlled room temperature: 20-25 C (68-77 F)

Mfg. by: Lupin Limited
Mandideep 462 046 India
68180-711-60

Dist. by: Redpharm Drug Eden Prairie, MN 55344 LCN: 59525



5
04691
3 67296

CEFDINIR

cefdinir capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:67296-0469(NDC:68180-711)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CEFDINIR (UNII: C10FAO63WC) (CEFDINIR - UNII:C10FAO63WC)	CEFDINIR	300 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

GELATIN (UNII: 2G86QN327L)

MAGNESIUM STEARATE (UNII: 70097M6I30)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	blue (blue cap) , purple (purple body)	Score	no score
Shape	CAPSULE (CAPSULES)	Size	22mm
Flavor		Imprint Code	LUPIN;CEFDINIR
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-0469-1	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/24/2011	
2	NDC:67296-0469-2	14 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	
3	NDC:67296-0469-3	10 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065264	05/01/2007	

Labeler - RedPharm Drug, Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
RedPharm Drug, Inc.		828374897	repack(67296-0469) , relabel(67296-0469)

Revised: 1/2021

RedPharm Drug, Inc.