CEFIXIME- cefixime tablet
Rising Pharma Holdings, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use CEFIXIME TABLETS safely and effectively. See full prescribing information for CEFIXIME TABLETS.
CEFIXIME tablets, for oral use.
Initial U.S. Approval:1986

INDICATIONS AND USAGE

Cefixime tablets are cephalosporin antibacterial drug indicated in the treatment of adults and pediatric patients weighing more than 45 kg or older than 12 years with the following infections:

- Uncomplicated Urinary Tract Infections (1.1)
- Pharyngitis and Tonsillitis (1.3)
- Acute Exacerbations of Chronic Bronchitis (1.4)
- Uncomplicated Gonorrhea (cervical/urethral) (1.5)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefixime tablets and other antibacterial drugs, cefixime tablets should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. (1.6)

DOSAGE AND ADMINISTRATION

- Adults: 400 mg daily (2.1)
- Children: weighing more than 45 kg or older than 12 years should be treated with recommended adults dose (2.2)

DOSAGE FORMS AND STRENGTHS

- Film-coated, scored Tablets 400 mg (3)

CONTRAINDICATIONS

- Contraindicated in patients with known allergy to cefixime or other cephalosporins. (4)

WARNINGS AND PRECAUTIONS

- Hypersensitivity reactions including shock and fatalities have been reported with cefixime. Discontinue use if a reaction occurs. (5.1)
- *Clostridium difficile* associated diarrhea: Evaluate if diarrhea occurs. (5.2)

ADVERSE REACTIONS

Most common adverse reactions are gastrointestinal such as diarrhea (16%), nausea (7%), loose stools (6%), abdominal pain (3%), dyspepsia (3%) and vomiting. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Rising Pharma Holdings, Inc. at 1-844-874-7464 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

DRUG INTERACTIONS

- Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly. (7.1)
- Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly with warfarin and anticoagulants. (7.2)

USE IN SPECIFIC POPULATIONS

- Pediatric Use: Efficacy and safety in infants younger than 6 months of age have not been established. (8.4)
- Geriatric Use: Clinical studies did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. (8.5)
- Renal Impairment: Cefixime may be administered in the presence of impaired renal function. Dose adjustment is required in patients whose creatinine clearance is less than 60 mL/min. (8.6)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 7/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Uncomplicated Urinary Tract Infections

Cefixime tablets are indicated in the treatment of adults and pediatric patients weighing more than 45 kg or older than 12 years with uncomplicated urinary tract infections caused by susceptible isolates of *Escherichia coli* and *Proteus mirabilis.*

1.3 Pharyngitis and Tonsillitis

Cefixime tablets are indicated in the treatment of adults and pediatric patients six months of age or older with pharyngitis and tonsillitis caused by susceptible isolates of *Streptococcus pyogenes*. (Note: Penicillin is the usual drug of choice in the treatment of *Streptococcus pyogenes* infections. Cefixime tablets are generally effective in the eradication of *Streptococcus pyogenes* from the nasopharynx; however, data establishing the efficacy of cefixime tablets in the subsequent prevention of rheumatic fever is not available.)

1.4 Acute Exacerbations of Chronic Bronchitis

Cefixime tablets are indicated in the treatment of adults and pediatric patients weighing more than 45 kg or older than 12 years with acute exacerbations of chronic bronchitis caused by susceptible isolates of *Streptococcus pneumoniae* and *Haemophilus influenzae*.

1.5 Uncomplicated Gonorrhea (cervical/urethral)

Cefixime tablets are indicated in the treatment of adults and pediatric patients weighing more than 45 kg or older than 12 years with uncomplicated gonorrhea (cervical/urethral) caused by susceptible isolates of *Neisseria gonorrhoeae* (penicillinase- and non-penicillinase-producing isolates).

1.6 Usage

To reduce the development of drug resistant bacteria and maintain the effectiveness of cefixime tablets and other antibacterial drugs, cefixime tablets should be used only to treat 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 antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

2 DOSAGE AND ADMINISTRATION

2.1 Adults

The recommended dose of cefixime is 400 mg daily. This may be given as a 400 mg tablet daily or the 400 mg tablet may be split and given as one half tablet every 12 hours. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400 mg is recommended. The tablet may be administered without regard to food.

In the treatment of infections due to *Streptococcus pyogenes*, a therapeutic dosage of cefixime should be administered for at least 10 days.

2.2 Pediatric Patients (weighing more than 45 kg or older than 12 years)

Children weighing more than 45 kg or older than 12 years should be treated with the recommended adult dose. Clinical trials of otitis media were conducted with the chewable tablets or suspension, and the chewable tablets or suspension results in higher peak blood levels than the tablet when administered at the same dose.

Therefore, the tablet should not be substituted for the chewable tablets or suspension in the treatment of otitis media [*see Clinical Pharmacology (12.3)]*

In the treatment of infections due to *Streptococcus pyogenes*, a therapeutic dosage of cefixime should be administered for at least 10 days.

2.3 Renal Impairment

Cefixime may be administered in the presence of impaired renal function. Normal dose and schedule may be employed in patients with creatinine clearances of 60 mL/min or greater. Refer to Table 2 for dose adjustments for adults with renal impairment. Neither hemodialysis nor peritoneal dialysis removes significant amounts of drug from the body.

Table 2. Doses for Adults with Renal Impairment

Renal Dysfunction	**Tablet**
Creatinine Clearance (mL/min)	**400 mg**
	Dose/Day
60 or greater	Normal dose
21 to 59 OR renal hemodialysis	Not Appropriate
20 or less OR continuous peritoneal dialysis	0.5 tablet

3 DOSAGE FORMS AND STRENGTHS

Cefixime tablets, USP 400 mg are white to off-white, capsule shaped film coated tablets, with debossed 'F' and '400' on either side of the score line on one side and other side plain. These tablets provide 400mg of cefixime as trihydrate.

4 CONTRAINDICATIONS

Cefixime is contraindicated in patients with known allergy to cefixime or other cephalosporins.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime.

Before therapy with cefixime is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins, or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross hypersensitivity among beta-lactam antibacterial drugs has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefixime occurs, discontinue the drug.

5.2 *Clostridium difficile*-Associated Diarrhea

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cefixime, 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 isolates 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 antibacterial drug 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 antibacterial drug use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial drug treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

5.3 Dose Adjustment in Renal Impairment

The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Patients on dialysis should be monitored carefully. [*See Dosage and Administration (2)*].

5.4 Coagulation Effects

Cephalosporins, including cefixime, may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

5.5 Development of Drug-Resistant Bacteria

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

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most commonly seen adverse reactions in U.S. trials of the tablet formulation were gastrointestinal events, which were reported in 30% of adult patients on either the twice daily or the once daily regimen. Five percent (5%) of patients in the U.S. clinical trials discontinued therapy because of drug-related adverse reactions. Individual adverse reactions included diarrhea 16%, loose or frequent stools 6%, abdominal pain 3%, nausea 7%, dyspepsia 3%, and flatulence 4%.

6.2 Post-marketing Experience

The following adverse reactions have been reported following the post-approval use of cefixime. Incidence rates were less than 1 in 50 (less than 2%).

Gastrointestinal

Several cases of documented pseudomembranous colitis were identified in clinical trials. The onset of pseudomembranous colitis symptoms may occur during or after therapy.

Hypersensitivity Reactions

Anaphylactic/anaphylactoid reactions (including shock and fatalities), skin rashes, urticaria, drug fever, pruritus, angioedema, and facial edema. Erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have been reported.

Hepatic

Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, jaundice.

Renal

Transient elevations in BUN or creatinine, acute renal failure.

Central Nervous System

Headaches, dizziness, seizures.

Hemic and Lymphatic System

Transient thrombocytopenia, leukopenia, neutropenia, prolongation in prothrombin time, elevated LDH, pancytopenia, agranulocytosis, and eosinophilia.

Abnormal Laboratory Tests

Hyperbilirubinemia.

Other Adverse Reactions

Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis.

Adverse Reactions Reported for Cephalosporin-class Drugs

Allergic reactions, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage, and colitis.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. [*See Dosage and Administration (2)* and *Overdosage (10)*]. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

7 DRUG INTERACTIONS

7.1 Carbamazepine

Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.

7.2 Warfarin and Anticoagulants

Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly.

7.3 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 cefixime may result in a false-positive reaction for glucose in the 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 TesTape®**) be used. A false-positive direct Coombs test has been reported during treatment with other cephalosporins; therefore, it should be recognized that a positive Coombs test may be due to the drug.

**Clinitest® and Clinistix® are registered trademarks of Ames Division, Miles Laboratories, Inc. Tes-Tape® is a registered trademark of Eli Lilly and Company.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from published observational studies, case series, and case reports over several decades with cephalosporin use, including cefixime, in pregnant women have not established drug-associated risks of major birth defects, miscarriage, or adverse maternal or fetal outcomes *(see Data)*. Reproduction studies have been performed in mice and rats at doses equivalent to 40 and 80 times, respectively, the adult human recommended dose and have revealed no evidence of harm to the fetus due to cefixime (see *Data*).

The estimated background risk of major birth defects and miscarriage for the indicated

population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes.In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Maternal gonorrhea may be associated with preterm birth, low neonatal birth weight, chorioamnionitis, intrauterine growth restriction, small for gestational age and premature rupture of membranes. Perinatal transmission of gonorrhea to the offspring can result in infant blindness, joint infections, and bloodstream infections.

Data

Human Data

While available studies cannot definitively establish the absence of risk, published data from prospective cohort studies, case series, and case reports over several decades have not identified a consistent association with cephalosporin use, including cefixime, during pregnancy, and major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Available studies have methodological limitations, including small sample size, retrospective data collection, and inconsistent comparator groups.

Animal data

The results of embryo-fetal development studies in mice and rats show that cefixime, at doses up to 3200 mg/kg/day administered during the period of organogenesis did not adversely affect development. In these studies, in mice and rats, cefixime did not affect postnatal development or reproductive capacity of the F_1 generation or fetal development of the F_2 generation. In an embryo-fetal development study in rabbits, cefixime at doses of 3.2, 10 or 32 mg/kg given daily during the period of organogenesis (gestation days 6 through 18) resulted in abortions and/or maternal deaths at doses > 10 mg/kg (typically associated with the administration of antibiotics in this species), but no malformations were reported at lower doses. A pre- and post-natal development study of cefixime at oral doses up to 3200 mg/kg/day in rats demonstrated no effect on the duration of pregnancy, process of parturition, development and viability of offspring, or reproductive capacity of the F_1 generation and development of their fetuses (F_2).

8.2 Lactation

Risk Summary

There are no available data on the presence of cefixime in human milk, the effects on the breastfed infant, or the effects on milk production. Cefixime is present in animal milk *(see Data)*. When a drug is present in animal milk, it is likely the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for cefixime and any potential adverse effects on the breastfed infant from cefixime or from the mother's underlying condition.

Data

In a study on disposition of cefixime in pregnant and lactating rats, continuous intra-peritoneal infusion of 2.54 mg/kg/day of ^{14}C-cefixime from days 10 to 14 postpartum resulted in steady state plasma concentrations of radioactivity in the dams that were 70

times greater than in their nursing pups.

After 102 hours of drug infusion, total radioactivity in the body of the pups, including the stomach and intestinal contents, was 1.5% of the ^{14}C-cefixime estimated to be in the mother's body at steady state[1].

8.4 Pediatric Use

Safety and effectiveness of cefixime in pediatric patients younger than 6 months of age have not been established. The incidence of gastrointestinal adverse reactions, including diarrhea and loose stools, in the pediatric patients receiving the suspension, was comparable to the incidence seen in adult patients receiving tablets.

8.5 Geriatric Use

Clinical studies did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. A pharmacokinetic study in the elderly detected differences in pharmacokinetic parameters *[see Clinical Pharmacology (12.3)].* These differences were small and do not indicate a need for dosage adjustment of the drug in the elderly.

8.6 Renal Impairment

The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Patients on dialysis should be monitored carefully. [*See Dosage and Administration (2.3)*].

10 OVERDOSAGE

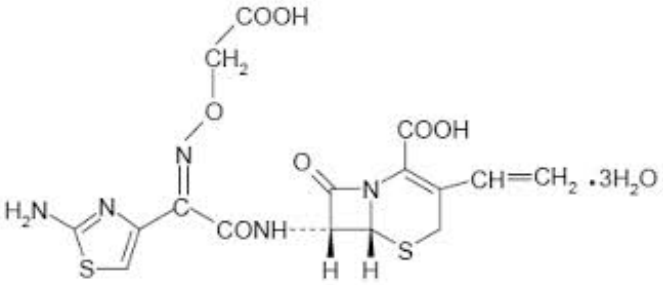
Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of cefixime did not differ from the profile seen in patients treated at the recommended doses.

11 DESCRIPTION

Cefixime is a semisynthetic, cephalosporin antibacterial for oral administration. Chemically, it is (*6R,7R*)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-vinyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7^{2}-(*Z*)-[O-(carboxy methyl) oxime] trihydrate.

Molecular weight = 507.50 as the trihydrate. Chemical Formula is $C_{16}H_{15}N_5O_7S_2.3H_2O$

The structural formula for cefixime is:



Cefixime is available for oral administration as 400 mg film coated tablets. Inactive ingredients contained in the cefixime tablets, USP 400 mg are: dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, titanium dioxide, and triacetin.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Cefixime is a semisynthetic cephalosporin antibacterial drug [*See Microbiology (12.4)*].

12.3 Pharmacokinetics

Cefixime tablets, given orally, are about 40% to 50% absorbed whether administered with or without food; however, time to maximal absorption is increased approximately 0.8 hours when administered with food. A single 200 mg tablet of cefixime produces an average peak serum concentration of approximately 2 mcg/mL (range 1 to 4 mcg/mL); a single 400 mg tablet produces an average peak concentration of approximately 3.7 mcg/mL (range 1.3 to 7.7 mcg/mL).

The area under the time versus concentration curve (AUC) is greater by approximately 10% to 25% with the oral suspension than with the tablet after doses of 100 to 400 mg, when tested in normal *adult* volunteers. This increased absorption should be taken into consideration if the oral suspension is to be substituted for the tablet. Because of the lack of bioequivalence, tablets should not be substituted for oral suspension in the treatment of otitis media [*see Dosage and Administration (2)*]. Cross-over studies of tablet versus suspension have not been performed in children.

The 400 mg capsule is bioequivalent to the 400 mg tablet under fasting conditions. However, food reduces the absorption following administration of the capsule by approximately 15% based on AUC and 25% based on C_{max}.

Peak serum concentrations occur between 2 and 6 hours following oral administration of a single 200 mg tablet or a single 400 mg tablet.

Distribution

Serum protein binding is concentration independent with a bound fraction of approximately 65%. In a multiple dose study conducted with a research formulation which is less bioavailable than the tablet , there was little accumulation of drug in serum or urine after dosing for 14 days. Adequate data on CSF levels of cefixime are not available.

Metabolism and Excretion

There is no evidence of metabolism of cefixime in vivo. Approximately 50% of the absorbed dose is excreted unchanged in the urine in 24 hours. In animal studies, it was noted that cefixime is also excreted in the bile in excess of 10% of the administered dose. The serum half-life of cefixime in healthy subjects is independent of dosage form and averages 3 to 4 hours but may range up to 9 hours in some normal volunteers.

Special Populations

Geriatrics: Average AUCs at steady state in elderly patients are approximately 40% higher than average AUCs in other healthy adults.

Differences in the pharmacokinetic parameters between 12 young and 12 elderly subjects who received 400 mg of cefixime once daily for 5 days are summarized as follows:

Pharmacokinetic Parameters (mean ± SD) for Cefixime in Both Young and Elderly		
Pharmacokinetic parameter	**Young**	**Elderly**
C_{max} (mg/L)	4.74 ± 1.43	5.68 ± 1.83
T_{max} (h)*	3.9 ± 0.3	4.3 ± 0.6
AUC (mg.h/L)*	34.9 ± 12.2	49.5 ± 19.1
$T_{1/2}$ (h)*	3.5 ± 0.6	4.2 ± 0.4
C_{ave} (mg/L)*	1.42 ± 0.50	1.99 ± 0.75
* Difference between age groups was significant. ($p<0.05$)		

However, these increases were not clinically significant [*See Dosage and Administration (2)*].

Renal Impairment: In subjects with moderate impairment of renal function (20 to 40 mL/min creatinine clearance), the average serum half-life of cefixime is prolonged to 6.4 hours. In severe renal impairment (5 to 20 mL/min creatinine clearance), the half-life increased to an average of 11.5 hours. The drug is not cleared significantly from the blood by hemodialysis or peritoneal dialysis. However, a study indicated that with doses of 400 mg, patients undergoing hemodialysis have similar blood profiles as subjects with creatinine clearances of 21 to 60 mL/min.

12.4 Microbiology

Mechanism of Action

As with other cephalosporins, the bactericidal action of cefixime results from inhibition of cell wall synthesis. Cefixime is stable in the presence of certain beta-lactamase enzymes. As a result, certain organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamases may be susceptible to cefixime.

Resistance

Resistance to cefixime in isolates of *Haemophilus influenzae* and *Neisseria gonorrhoeae* is most often associated with alterations in penicillin-binding proteins (PBPs). Cefixime may have limited activity against Enterobacteriaceae producing extended spectrum beta-

lactamases (ESBLs). *Pseudomonas* species, *Enterococcus* species, strains of Group D streptococci, *Listeria monocytogenes*, most strains of staphylococci (including methicillin-resistant strains), most strains of *Enterobacter* species, most strains of *Bacteroides fragilis*, and most strains of *Clostridium* species are resistant to cefixime.

Antimicrobial Activity

Cefixime has been shown to be active against most isolates of the following microorganisms, both *in vitro* and in clinical infections [*see Indications and Usage (1)*]:

Gram-positive Bacteria

Streptococcus pneumoniae

Streptococcus pyogenes

Gram-negative Bacteria

Escherichia coli

Haemophilus influenzae

Moraxella catarrhalis

Neisseria gonorrhoeae

Proteus mirabilis

The following *in vitro* data are available, but their clinical significance is unknown. At least 90 percent of the following bacteria exhibit an *in vitro* minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for cefixime against isolates of similar genus or organism group. However, the efficacy of cefixime in treating clinical infections caused by these bacteria has not been established in adequate and well-controlled clinical trials.

Gram-positive Bacteria

Streptococcus agalactiae

Gram-negative Bacteria

Citrobacter malonaticus

Citrobacter diversus

Haemophilus parainfluenzae

Klebsiella oxytoca

Klebsiella pneumoniae

Pasteurella multocida

Proteus vulgaris

Providencia species

Salmonella species

Serratia marcescens

Shigella species

Susceptibility Testing

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: https://www.fda.gov/STIC.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Lifetime studies in animals to evaluate carcinogenic potential have not been conducted. Cefixime did not cause point mutations in bacteria or mammalian cells, DNA damage, or chromosome damage *in vitro* and did not exhibit clastogenic potential *in vivo* in the mouse micronucleus test. In the fertility and reproductive performance study in rats, no difference between control and drug-treated animals was detected in mating behavior, pregnancy rate, or litter parameters (determined at sacrifice on day 13 of pregnancy) at oral doses up to 1000 mg/kg/day (25 times the adult therapeutic dose) administered to males (for 68 days prior to pairing and during the cohabitation period) and females (for 14 days before pairing to weaning).

15 REFERENCES

1. Halperin-Walega, E. Batra VK, Tonelli AP, Barr A, Yacobi A. 'Disposition of Cefixime in the Pregnant and Lactating Rat. Transfer to the Fetus and Nursing Pup'. *Drug Metabolism and Disposition*. 1988:16(1):pp130–134.

16 HOW SUPPLIED/STORAGE AND HANDLING

Cefixime tablets, USP 400 mg are white to off-white, capsule shaped film coated tablets, with debossed 'F' and '400' on either side of the score line on one side and other side plain containing 400 mg of cefixime as the trihydrate and are supplied as follows:

NDC 64980-430-01 Bottle of 10 tablets with child-resistant closure

Store at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

17.1 Information for Patients

Drug Resistance

Patients should be counseled that antibacterial drugs, including cefixime, should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When cefixime 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 cefixime or other antibacterial drugs in the future.

Diarrhea

Advise patients that diarrhea is a common problem caused by antibacterial drugs which usually ends when the antibacterial drug is discontinued. Sometimes after starting treatment with antibacterial drugs, 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 antibacterial drug. If this occurs, patients should contact their physician as soon as possible.

Manufactured in India by:

FDC Limited

Distributed by:

Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Issued: 04/2025

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Cefixime Tablets, USP 400 mg

Rx only

NDC 64980-430-01: Bottle of 10 tablets with child-resistant closure

CEFIXIME

cefixime tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64980-430
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CEFIXIME (UNII: 97I1C92E55) (CEFIXIME ANHYDROUS - UNII:XZ7BG04GJX)	CEFIXIME ANHYDROUS	400 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	2 pieces
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	F;400
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64980-430-01	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206358	12/12/2025	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - FDC Limited (650078413)

Establishment

Name	Address	ID/FEI	Business Operations
FDC Limited		650651164	ANALYSIS(64980-430) , MANUFACTURE(64980-430)