

# **CEFIXIME- cefixime capsule**

## **REMEDYREPACK INC.**

### **HIGHLIGHTS OF PRESCRIBING INFORMATION**

**These highlights do not include all the information needed to use CEFIXIME CAPSULES safely and effectively. See full prescribing information for CEFIXIME CAPSULES.**

**CEFIXIME capsules, for oral use.**

**Initial U.S. Approval: 1986**

### **INDICATIONS AND USAGE**

Cefixime is a cephalosporin antibacterial drug indicated in the treatment of adults and pediatric six months and older 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 and other antibacterial drugs, cefixime should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

### **DOSAGE AND ADMINISTRATION**

- Adults: 400 mg daily ( 2.1)

### **DOSAGE FORMS AND STRENGTHS**

- Capsules: 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 Ascend Laboratories, LLC at 1-877-ASC-RX01 (877-272-7901) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://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**

- Pregnancy: Cefixime should be used during pregnancy only if clearly needed. ( 8.1)
- Nursing Mothers: Consideration should be given to discontinuing nursing temporarily during treatment with cefixime. ( 8.3)
- Children: Efficacy and safety in infants aged less than six months 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: 3/2023**

---

## **FULL PRESCRIBING INFORMATION: CONTENTS\***

### **1 INDICATIONS AND USAGE**

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

### **2 DOSAGE AND ADMINISTRATION**

- 2.1 Adults
- 2.2 Pediatric Patients (6 months or older)
- 2.3 Renal Impairment

### **3 DOSAGE FORMS AND STRENGTHS**

### **4 CONTRAINDICATIONS**

### **5 WARNINGS AND PRECAUTIONS**

- 5.1 Hypersensitivity Reactions
- 5.2 Clostridium difficile-Associated Diarrhea
- 5.3 Dose Adjustment in Renal Impairment
- 5.4 Coagulation Effects
- 5.5 Development of Drug-Resistant Bacteria

### **6 ADVERSE REACTIONS**

- 6.1 Clinical Trials Experience
- 6.2 Post-marketing Experience

### **7 DRUG INTERACTIONS**

- 7.1 Carbamazepine
- 7.2 Warfarin and Anticoagulants
- 7.3 Drug/Laboratory Test Interactions

### **8 USE IN SPECIFIC POPULATIONS**

- 8.1 Pregnancy
- 8.2 Labor and Delivery
- 8.3 Nursing Mothers
- 8.4 Pediatric Use
- 8.5 Geriatric Use
- 8.6 Renal Impairment

### **10 OVERDOSAGE**

### **11 DESCRIPTION**

### **12 CLINICAL PHARMACOLOGY**

- 12.1 Mechanism of Action
- 12.3 Pharmacokinetics
- 12.4 Microbiology

### **13 NONCLINICAL TOXICOLOGY**

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

### **16 HOW SUPPLIED/STORAGE AND HANDLING**

### **17 PATIENT COUNSELING INFORMATION**

- 17.1 Information for Patients

\* 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 is indicated in the treatment of adults and pediatric patients six months of age or older with uncomplicated urinary tract infections caused by susceptible isolates of *Escherichia coli* and *Proteus mirabilis*.

#### **1.3 Pharyngitis and Tonsillitis**

Cefixime capsules 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 capsules are generally effective in the eradication of *Streptococcus pyogenes* from the nasopharynx; however, data establishing the efficacy of cefixime capsules in the subsequent prevention of rheumatic fever is not available.)

#### **1.4 Acute Exacerbations of Chronic Bronchitis**

Cefixime capsules is indicated in the treatment of adults and pediatric patients six months of age or older with acute exacerbations of chronic bronchitis caused by susceptible isolates of *Streptococcus pneumoniae* and *Haemophilus influenzae*.

#### **1.5 Uncomplicated Gonorrhea (cervical/urethral)**

Cefixime capsules is indicated in the treatment of adults and pediatric patients six months of age or older 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 capsules and other antibacterial drugs, cefixime capsules 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

capsule daily. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400 mg is recommended. The capsule 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 (6 months or older)

The recommended dose is 8 mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours. Note: A suggested dose has been determined for each pediatric weight range. Refer to Table 1. Ensure all orders that specify a dose in milliliters include a concentration, because cefixime for oral suspension is available in three different concentrations (100 mg/5 mL, 200 mg/5 mL, and 500 mg/5 mL).

**Table 1. Suggested doses for pediatric patients**

| <b>PEDIATRIC DOSAGE CHART</b>  |                          |                                     |                          |                          |
|--|--------------------------|-------------------------------------|--------------------------|--------------------------|
| Doses are suggested for each weight range and rounded for ease of administration   |                          |                                     |                          |                          |
|  |                          | <b>Cefixime for Oral Suspension</b> |                          |                          |
|  |                          | <b>100 mg/<br/>5 mL</b>             | <b>200 mg/<br/>5 mL</b>  | <b>500 mg/<br/>5 mL</b>  |
| <b>Patient Weight<br/>(kg)</b>   | <b>Dose/Day<br/>(mg)</b> | <b>Dose/Day<br/>(mL)</b>            | <b>Dose/Day<br/>(mL)</b> | <b>Dose/Day<br/>(mL)</b> |
| 5 to 7.5*  | 50                       | 2.5                                 | --                       | -                        |
| 7.6 to 10*   | 80                       | 4                                   | 2                        | -                        |
| 10.1 to 12.5   | 100                      | 5                                   | 2.5                      | 1                        |
| 12.6 to 20.5   | 150                      | 7.5                                 | 4                        | 1.5                      |
| 20.6 to 28   | 200                      | 10                                  | 5                        | 2                        |
| 28.1 to 33   | 250                      | 12.5                                | 6                        | 2.5                      |
| 33.1 to 40   | 300                      | 15                                  | 7.5                      | 3                        |
| 40.1 to 45   | 350                      | 17.5                                | 9                        | 3.5                      |
| 45.1 or greater  | 400                      | 20                                  | 10                       | 4                        |
| * The preferred concentrations of oral suspension to use are 100 mg/5 mL or 200 mg/5 mL for pediatric patients in these weight ranges. |                          |                                     |                          |                          |

Children weighing more than 45 kg or older than 12 years should be treated with the recommended adult dose.

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**

Normal dose and schedule may be employed in patients with creatinine clearances of 60 mL/min or greater. Neither hemodialysis nor peritoneal dialysis removes significant amounts of drug from the body.

## **3 DOSAGE FORMS AND STRENGTHS**

Cefixime Capsules are available for oral administration in the following dosage strength:

- Capsules provide 400 mg of cefixime as trihydrate. These are off white to yellow colour granular powder filled in size "0" hard gelatin capsules, pink opaque cap imprinted "CFX" with black ink and pink opaque body imprinted "400" with black ink.

## **4 CONTRAINDICATIONS**

Cefixime capsules are 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 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 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 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 use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial 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%. The incidence of gastrointestinal adverse reactions, including diarrhea and loose stools, in pediatric patients receiving the suspension was comparable to the incidence seen in adult patients receiving tablets.

### **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<sup>®\*\*</sup>, Benedict's solution, or Fehling's solution. It is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix<sup>®\*\*</sup> or TesTape<sup>®\*\*</sup>) 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.

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

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### ***Pregnancy Category B***

Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 40 times the human dose and have revealed no evidence of harm to the fetus due to cefixime. There are 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.

### **8.2 Labor and Delivery**

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

### **8.3 Nursing Mothers**

It is not known whether cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

### **8.4 Pediatric Use**

Safety and effectiveness of cefixime in children aged less than six months old 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

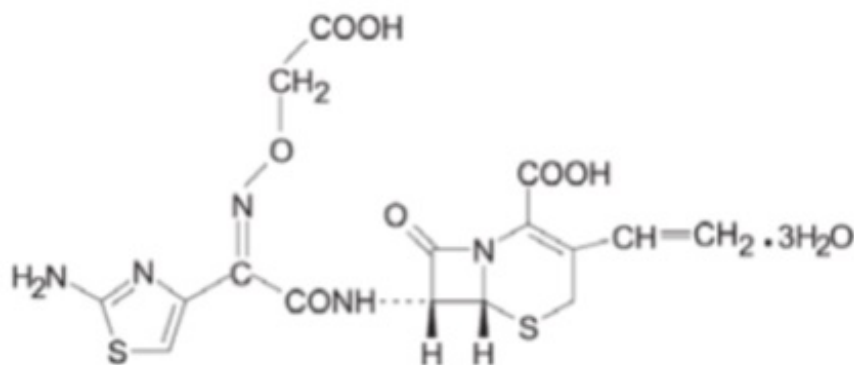
Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of cefixime did not differ 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 ( 6*R*,7*R*)-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<sup>2</sup>-( *Z*)-[ *O*-(carboxy methyl) oxime] trihydrate.

Molecular weight = 507.50 as the trihydrate. Chemical Formula is C<sub>16</sub>H<sub>15</sub>N<sub>5</sub>O<sub>7</sub>S<sub>2</sub>·3H<sub>2</sub>O

The structural formula for cefixime is:



- I nactive ingredients contained in cefixime capsules 400 mg are: colloidal silicon dioxide, croscarmellose sodium, low substituted hydroxypropyl cellulose, magnesium stearate and mannitol. The capsule shell contains the following inactive ingredients: black iron oxide, butyl alcohol, dehydrated alcohol, gelatin, iron oxide red, isopropyl alcohol, potassium hydroxide, propylene glycol, shellac, sodium lauryl sulphate, strong ammonia solution and titanium dioxide.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

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

### 12.3 Pharmacokinetics

Cefixime tablets and suspension, 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 oral suspension produces average peak concentrations approximately 25% to 50% higher than the tablets, when tested in normal *adult* volunteers. Two hundred and 400 mg doses of oral suspension produce average peak concentrations of 3 mcg/mL (range 1 to 4.5 mcg/mL) and 4.6 mcg/mL (range 1.9 to 7.7 mcg/mL), respectively, when tested in normal *adult* volunteers. 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. Crossover 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, a single 400 mg tablet or 400 mg of cefixime suspension. Peak serum concentrations occur between 2 and 5 hours following a single administration of 200 mg of suspension. Peak serum concentrations occur between 3 and 8 hours following oral administration of a single 400 mg capsule.

### ***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 or suspension, 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 $\pm$ SD) for Cefixime in Both Young & Elderly Subjects |                 |                 |
|--|-----------------|-----------------|
| Pharmacokinetic parameter  | Young           | Elderly         |
| C <sub>max</sub> (mg/L)  | 4.74 $\pm$ 1.43 | 5.68 $\pm$ 1.83 |
| T <sub>max</sub> (h)*  | 3.9 $\pm$ 0.3   | 4.3 $\pm$ 0.6   |
| AUC (mg.h/L)*  | 34.9 $\pm$ 12.2 | 49.5 $\pm$ 19.1 |
| T <sub>1/2</sub> (h)*  | 3.5 $\pm$ 0.6   | 4.2 $\pm$ 0.4   |
| C <sub>ave</sub> (mg/L)*   | 1.42 $\pm$ 0.50 | 1.99 $\pm$ 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 to these bacteria has not been established in adequate and well-controlled clinical trials.

Gram-positive Bacteria

*Streptococcus agalactiae*

Gram-negative Bacteria

*Citrobacter amalonaticus*

*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 rats, fertility and reproductive performance were not affected by cefixime at doses up to 25 times the adult therapeutic dose.

## **16 HOW SUPPLIED/STORAGE AND HANDLING**

Cefixime Capsules 400 mg

Off white to yellow color granular powder filled in size “0” hard gelatin capsules, pink opaque cap imprinted “CFX” with black ink and pink opaque body imprinted “400” with black ink.

NDC: 70518-2749-00

NDC: 70518-2749-01

NDC: 70518-2749-02

NDC: 70518-2749-03

NDC: 70518-2749-04

NDC: 70518-2749-05

PACKAGING: 10 in 1 BOTTLE PLASTIC

PACKAGING: 1 in 1 BOTTLE PLASTIC

PACKAGING: 2 in 1 BOTTLE PLASTIC

PACKAGING: 2 in 1 BOX

PACKAGING: 1 in 1 POUCH

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

Repackaged and Distributed By:

Remedy Repack, Inc.

625 Kolter Dr. Suite #4 Indiana, PA 1-724-465-8762

## **17 PATIENT COUNSELING INFORMATION**

## 17.1 Information for Patients

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 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.

Repackaged and Distributed By:

Remedy Repack, Inc.

625 Kolter Dr. Suite #4 Indiana, PA 1-724-465-8762

DRUG: CEFIXIME

GENERIC: CEFIXIME

DOSAGE: CAPSULE

ADMINISTRATION: ORAL

NDC: 70518-2749-0

NDC: 70518-2749-1

NDC: 70518-2749-2

NDC: 70518-2749-3

NDC: 70518-2749-4

COLOR: pink

SHAPE: CAPSULE

SCORE: No score

SIZE: 21 mm

IMPRINT: CFX;400

PACKAGING: 10 in 1 BOTTLE, PLASTIC

PACKAGING: 1 in 1 BOTTLE PLASTIC

PACKAGING: 2 in 1 BOTTLE PLASTIC

PACKAGING: 1 in 1 POUCH

PACKAGING: 2 in 1 BOX

- CEFIXIME 400mg in 1

- SILICON DIOXIDE
- AMMONIA
- SODIUM LAURYL SULFATE
- SHELLAC
- PROPYLENE GLYCOL
- POTASSIUM HYDROXIDE
- FERRIC OXIDE RED
- TITANIUM DIOXIDE
- GELATIN
- BUTYL ALCOHOL
- ISOPROPYL ALCOHOL
- MANNITOL
- MAGNESIUM STEARATE
- HYDROXYPROPYL CELLULOSE
- CROSCARMELLOSE SODIUM
- ALCOHOL
- FERROSO FERRIC OXIDE

[illegible]

## Cefixime Capsule

NDC #: 70518-2749-04

Expires:

LOT #:

Org NDC: 67877-0584-50

MFG: Ascend Labs, LLC, Montvale, NJ 07645

400 mg

QTY: 1 Capsule

Capsule PINK CFX,400

Keep this and all medication out of the reach of children

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Usual Dosage: See Insert



RX ONLY

Repackaged By:  
RemedyRepack Inc.,  
Indiana, PA 15701, 724.465.8762

LOT #:  
NDC #:  
MFG #:  
EXP #:  
MFG #:  
EXP #:  
MFG #:  
EXP #:  
MFG #:  
EXP #:

## Cefixime Capsule

NDC #: 70518-2749-05

Expires:

LOT #:

Org NDC: 67877-0584-50

MFG: Ascend Labs, LLC, Montvale, NJ 07645

400 mg

QTY: 2 Per Box

Capsule PINK CFX,400

Keep this and all medication out of the reach of children

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Usual Dosage: See Insert



RX ONLY

Repackaged By:  
RemedyRepack Inc.,  
Indiana, PA 15701, 724.465.8762

LOT #:  
NDC #:  
MFG #:  
EXP #:  
MFG #:  
EXP #:  
MFG #:  
EXP #:  
MFG #:  
EXP #:

## CEFIXIME

cefixime capsule

### Product Information

|                         |                         |                    |                               |
|-------------------------|-------------------------|--------------------|-------------------------------|
| Product Type            | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70518-2749(NDC:67877-584) |
| Route of Administration | ORAL                    |                    |                               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength  | Strength |
|--|--------------------|----------|
| CEFIXIME (UNII: 971IC92E55) (CEFIXIME ANHYDROUS - UNII:XZ7BG04GJX) | CEFIXIME ANHYDROUS | 400 mg   |

### Inactive Ingredients



| Ingredient Name  | Strength |
|--|----------|
| <b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)                    |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                          |          |
| <b>HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED</b> (UNII: 2165RE0K14) |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                       |          |
| <b>MANNITOL</b> (UNII: 3OWL53L36A)                                 |          |
| <b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)                        |          |
| <b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)                            |          |
| <b>ALCOHOL</b> (UNII: 3K9958V90M)                                  |          |
| <b>GELATIN</b> (UNII: 2G86QN327L)                                  |          |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                         |          |
| <b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)                      |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                         |          |
| <b>SHELLAC</b> (UNII: MB5IUD6JUA)                                  |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                    |          |
| <b>AMMONIA</b> (UNII: 5138Q19F1X)                                  |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                         |          |
| <b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)                     |          |

### Product Characteristics

|                 |         |                     |          |
|-----------------|---------|---------------------|----------|
| <b>Color</b>    | pink    | <b>Score</b>        | no score |
| <b>Shape</b>    | CAPSULE | <b>Size</b>         | 21mm     |
| <b>Flavor</b>   |         | <b>Imprint Code</b> | CFX;400  |
| <b>Contains</b> |         |                     |          |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70518-2749-0 | 10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/21/2020           | 05/28/2020         |
| 2 | NDC:70518-2749-1 | 1 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 06/02/2020           | 10/06/2020         |
| 3 | NDC:70518-2749-2 | 2 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 01/26/2021           |                    |
| 4 | NDC:70518-2749-3 | 2 in 1 BLISTER PACK; Type 0: Not a Combination Product     | 03/09/2021           | 12/28/2021         |
| 5 | NDC:70518-2749-5 | 2 in 1 BOX   | 07/07/2023           |                    |
| 5 | NDC:70518-2749-4 | 1 in 1 POUCH; Type 0: Not a Combination Product            |                      |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA210574                               | 05/21/2020           |                    |

Revised: 7/2025

REMEDYREPACK INC.