

# Ceftoren®

Cefditoren

## Description

Ceftoren® is a preparation of Cefditoren Pivoxil which is a broad spectrum third generation cephalosporin antibiotic. Cefditoren is a prodrug which is hydrolyzed by esterases during absorption, and the drug is distributed in the circulating blood as active Cefditoren. Cefditoren has antibacterial activity against gram- positive and gram-negative pathogens. The bactericidal activity of Cefditoren results from the inhibition of cell wall synthesis via affinity for penicillin-binding proteins (PBPs). Cefditoren is stable in the presence of a variety of β-lactamases, including penicillinases and some cephalosporinases.

## Indications

Ceftoren® is indicated for the treatment of mild to moderate infections in adults and adolescents (12 years of age or older) which are caused by susceptible strains of the designated microorganisms in the conditions listed below:

- Acute Bacterial Exacerbation of Chronic Bronchitis
- Community Acquired Pneumonia
- Pharyngitis
- Tonsillitis
- Uncomplicated Skin and Skin-Structure Infections

Dosage and administration\*(Adults and adolescents >=12 Years)

| Type of Infection                                  | Dosage             | Duration |
|--|--------------------|----------|
| Community Acquired Pneumonia                       | 400 mg twice daily | 14 days  |
| Acute Bacterial Exacerbation of Chronic Bronchitis | 400 mg twice daily | 10 days  |
| Pharyngitis/Tonsillitis                            | 200 mg twice daily | 10 days  |
| Uncomplicated Skin and Skin Structure Infections   | 200 mg twice daily | 10 days  |

\*Should be taken with meals

**Children:** Use of Ceftoren® is not recommended for pediatric patients less than 12 years of age. The safety and efficacy of Ceftoren® tablets in this population, including any effects of altered carnitine concentration, have not been established.

**Geriatric:** No dose adjustments are necessary in geriatric patients with normal (for their age) renal function.

**Patients with renal insufficiency:** No dose adjustment is necessary for patients with mild renal impairment (CL<sub>Cr</sub>: 50-80 mL/min/1.73 m<sup>2</sup>). It is recommended that not more than 200 mg BID be administered to patients with moderate renal impairment (CL<sub>Cr</sub>: 30-49 mL/min/1.73 m<sup>2</sup>) and 200 mg QD be administered to patients with severe renal impairment (CL<sub>Cr</sub>: <30 mL/min/1.73 m<sup>2</sup>). The appropriate dose in patients with end-stage renal disease has not been determined.

**Patients with hepatic disease:** No dose adjustments are necessary for patients with mild or moderate hepatic impairment.

### Use in pregnancy & lactation

**Pregnancy:** Cefditoren is pregnancy category B. There are no adequate and well-controlled studies in pregnant women. Cefditoren should be used during pregnancy only if clearly needed.

**Lactation:** Animal studies show that Cefditoren excreted in breast milk. Caution should be exercised when Cefditoren is administered to nursing women.

### Side effects

The most common side effects of Cefditoren are diarrhea, nausea, headache, abdominal pain, vaginal moniliasis, dyspepsia, vomiting, abnormal dreams, allergic reaction, anorexia, constipation, dizziness, dry mouth and fever.

### Contraindications

Cefditoren is contraindicated in patients with known allergy to the cephalosporin class of antibiotics or any of its components. Cefditoren contain sodium caseinate, a milk protein. Patients with milk protein hypersensitivity (not lactose intolerance) should not be administered Cefditoren.

### Precautions

Cefditoren is not recommended when prolonged antibiotic treatment is necessary, since other pivalate- containing compounds have caused clinical manifestations of carnitine deficiency when used over a period of months. Prescribing Cefditoren 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.

### Drug interactions

Antacids and Famotidine (intravenous administration) reduced the oral absorption of Cefditoren. As with other  $\beta$ -lactam antibiotics, co-administration of probenecid with Cefditoren Pivoxil resulted in an increase in the plasma exposure of Cefditoren. Multiple doses of Cefditoren had no effect on the pharmacokinetics of ethinyl estradiol, the estrogenic component in most oral contraceptives.

### Overdose

Information on Cefditoren overdosage in humans is not available. However, with other  $\beta$ -lactam antibiotics, adverse effects following overdosage have included nausea, vomiting, epigastric distress, diarrhea, and convulsions. Hemodialysis may aid in the removal of Cefditoren from the body, particularly if renal function is compromised.

### Pharmaceutical precautions

Store in a cool (below 25°C) and dry place protected from light.

### Presentation

Ceftoren® tablet: Each coated tablet contains Cefditoren 200 mg as Pivoxil INN.

### Package quantities

Ceftoren® tablet: Carton of 8 tablets in blister pack.

® Registered Trade Mark.



**ACI Limited**

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