

# CEFDIREN

CEFDITORENPIVOXIL INN

## Compositions:

Cefdiren 200 Tablet: Each tablet contains CefditorenPivoxil INN 245 mg Eqv. toCefditoren 200 mg. Cefdiren 400 Tablet: Each tablet contains CefditorenPivoxil INN 490 mg Eqv. toCefditoren 400 mg.

## Pharmacology:

Cefdiren is a third generation broad spectrum cephalosporin antibiotic for oral administration. It is a bactericidal antibiotic and is stable to hydrolysis by many beta-lactamases. It kills bacteria by interfering with the synthesis of the bacterial cell wall.

## Dosage And Administration:

Type of Infection Dosage Duration (Days) Community-Acquired Pneumonia 400 mg BID 14  
Acute Bacterial Exacerbation of Chronic Bronchitis 400 mg BID 10 Pharyngitis/Tonsillitis  
200 mg BID Uncomplicated Skin and Skin Structure Infections Should be taken with meals  
Use in Renal impaired patient: No dose adjustment is necessary for patients with mild renal impairment (CLcr: 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 (CLcr: 30-49 mL/min/1.73 m<sup>2</sup>) and 200 mg QD be administered to patients with severe renal impairment (CLcr: < 30 mL/min/1.73 m<sup>2</sup>). The appropriate dose in patients with end-stage renal disease has not been determined. Use in Hepatically impaired patient: No dose adjustments are necessary for patients with mild or moderate hepatic impairment. The pharmacokinetics of Cefditorenhave not been studied in patients with severe hepatic impairment.

## Contraindications:

Cefditoren is contraindicated in patients with known allergy to the cephalosporin class of antibiotics or any of its ingredients.

## Warning And Precaution:

Cefditoren should be prescribed with caution in individuals with a history of gastrointestinal colitis.

## Side Effects:

Most common side effects are mild and self-limiting include diarrhea, nausea, vaginal moniliasis and headache.

## Use in Pregnancy and Lactation:

Pregnancy:Cefditorenpivoxil has been assigned to pregnancy category B by the FDA. Lactation: There are no data on the excretion of Cefditorenpivoxil into human milk. Cefditoren is excreted into the milk of rats. So caution is recommended when Cefditorenpivoxil is given to nursing women.

## Drug Interaction:

Co-administration of a single dose of an antacid and H<sub>2</sub> receptor antagonists may reduce the oral absorption of Cefditorenpivoxil. As with other beta-lactam antibiotics, co-administration of probenecid with cefditorenpivoxil resulted in an increase in the plasma exposure of Cefditoren

## Overdosage:

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.

**Storage:**

Store in a cool (20°- 25° C) and dry place, keep it away from light and moisture.

**Packing:**

Cefdiren 200 Tablet: Each box contains 8 tablets in Alu-Alu blister pack. Cefdiren 400 Tablet: Each box contains 8 tablets in Alu-Alu blister pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.