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Editoren®

Cefditoren

Description: Cefditoren (**Editoren**®) is a semi-synthetic, broad-spectrum, beta-lactamase resistant, third-generation cephalosporin antibiotic with bactericidal activity for oral administration. It is a prodrug which is hydrolyzed by esterases during absorption, and the drug is distributed in the circulating blood as active Cefditoren.

Mode of action: Cefditoren (**Editoren**®) inactivates penicillin binding proteins (PBPs) thereby interfering with peptidoglycan synthesis and inhibiting bacterial cell wall synthesis. Another consequence of beta-lactam exposure results in the loss of lipoteichoic acids from the cell wall. Lipoteichoic acids inhibit murein hydrolase activity and their absence from the cell wall triggers uncontrolled autolytic activity rendering bacterial cells susceptible to osmotic shock. This results in a reduction of cell wall stability and causes cell lysis.

Composition:
Editoren® 200 mg Tablet: Each film-coated tablet contains 245 mg Cefditoren Pivoxil INN equivalent to Cefditoren 200 mg.
Editoren® 400 mg Tablet: Each film-coated tablet contains 490 mg Cefditoren Pivoxil INN equivalent to Cefditoren 400 mg.

Indications: Editoren® is indicated for the treatment of infections in adults and adolescents (12 years of age or older) which are caused by susceptible microorganisms:

- Acute Bacterial Exacerbation of Chronic Bronchitis caused by *Haemophilus influenzae* (including ß-lactamase-producing strains)
- *Haemophilus parainfluenzae* (including ß-lactamase producing strains), *Streptococcus pneumoniae*, or *Moraxella catarrhalis* (including ß-lactamase-producing strains).
- Community-Acquired Pneumonia caused by *Haemophilus influenzae* (including ß-lactamase-producing strains), *Haemophilus parainfluenzae* (including ß-lactamase-producing strains), *Streptococcus pneumoniae* or *Moraxella catarrhalis* (including ß-lactamase producing strains).
- Pharyngitis/Tonsillitis caused by *Streptococcus pyogenes* and eradication of *Streptococcus pyogenes* from the oropharynx.
- Uncomplicated Skin and Skin-Structure Infections caused by *Staphylococcus aureus* (including ß-lactamase-producing strains) or *Streptococcus pyogenes*.

Dosage & Administration
Cefditoren tablet should be administered to adults & adolescents (>12 years) after taking meal.

Type of infection	Dosage	Duration (Days)
Community-Acquired Pneumonia	400 mg	14
Acute Bacterial Exacerbation of Chronic Bronchitis	400 mg	10
Pharyngitis	200 mg	10
Tonsillitis	200 mg	10
Uncomplicated Skin and Skin Structure Infections	200 mg	10

Patients with Renal Insufficiency: No dose adjustment is necessary for patients with mild renal impairment (CLcr: 50-80 mL/min/1.73 m^2). 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^2) and 200 mg QD be administered to patients with severe renal impairment (CLcr: <30 mL/min/1.73 m^2). 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. The pharmacokinetics of Cefditoren have not been studied in patients with severe hepatic impairment.
Geriatric patients: No dosage adjustment is required for geriatric patients with normal renal function.

Side effects: The side effects of Cefditoren is very mild and self-limiting. The most common side effects are diarrhea, nausea, headache, abdominal pain, dyspepsia, 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. It is also contraindicated in patients with carnitine deficiency or inborn errors of metabolism because of the renal excretion of carnitine. Cefditoren contains sodium caseinate, a milk protein. Patients with milk protein hypersensitivity (not lactose intolerance) should not be administered this drug.

pregnancy & lactation:
Pregnancy: The pregnancy category of **Editoren**® is B. There are no adequate and well-controlled studies in pregnant women. Cefditoren should be used during pregnancy only if clearly needed.
Lactation: Caution should be exercised when Cefditoren is administered to nursing women.

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. No clinical effects of carnitine decrease have been associated with short-term treatment. The effects on carnitine concentrations of repeat short-term courses are not known.

Drug interactions: Cefditoren had no drug-drug interactions with Oral Contraceptives containing ethinyl estradiol. Co-administration of Magnesium and Aluminum Hydroxide reduced the oral absorption of Cefditoren. Co-administration of Cefditoren with Famotidine also reduced the oral absorption of Cefditoren. As like other ß-lactam antibiotics, co-administration of probenecid with Cefditoren resulted in an increase in the plasma exposure of Cefditoren.

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

Storage: Keep out of reach of children. Store in a dry place, below 25° C temperature and protected from light.

Packaging
Editoren® 200 mg Tablet: Each carton contains 4×2 tablets in strip pack.
Editoren® 400 mg Tablet: Each carton contains 4×1 tablets in strip pack.

Opsonin Pharma
Ideas for healthcare

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