Cefaclor Capsules USP

Rx Only
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefaclor Capsules USP and other antibacterial drugs, Cefaclor Capsules USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION
Cefaclor, USP is a semisynthetic cephalosporin antibiotic for oral administration. It is an orally absorbed cephalosporin designated as 3-chloro-7-D-(2-phenylglycinamido)-3-oxa-7-lactam-4-carboxylic acid monohydrate. The chemical formula for cefaclor is C_{16}H_{17}C_{7}N_{2}O_{6}·H_{2}O and the molecular weight is 385.82.

Each 250-mg capsule contains cefaclor monohydrate equivalent to 250 mg (0.66 mmol) of anhydrous cefaclor. Cefaclor is an antibiotic indicated for the treatment of clinical infections due to these microorganisms:

- Aerobes, Gram-negative
- Aerobes, Gram-positive
- Anaerobes, Gram-positive
- Anaerobes, Gram-negative

The following microorganisms, both in vitro and in clinical infections as described in the INDICATIONS AND USAGE section.

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Zone Diameter (mm)</th>
<th>MIC (g/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus</td>
<td>ATCC 29213</td>
<td>1-4</td>
</tr>
<tr>
<td>E. faecalis</td>
<td>ATCC 29212</td>
<td>&gt;32</td>
</tr>
<tr>
<td>H. influenzae</td>
<td>ATCC 49766</td>
<td>1-4</td>
</tr>
</tbody>
</table>

When testing H. influenzae * 

- Disk susceptibility test performed using Haemophilus Test Medium (HTM)/

INDICATIONS AND USAGE
Cefaclor is indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms:

- Otitis media caused by Streptococcus pneumoniae, Haemophilus influenzae, staphylococci, and Streptococcus pyogenes

- Lower respiratory tract infections, including pneumonia, caused by Streptococcus pneumoniae, Haemophilus influenzae, and Streptococcus pyogenes

- Skin and skin structure infections caused by Staphylococcus aureus and Streptococcus pyogenes

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefaclor Capsules USP and other antibacterial drugs, Cefaclor Capsule should be used only to treat or prevent 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 antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINdICATIONS
Cefaclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS
BEFORE THERAPY WITH CEFACLOR IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEFACLOR, 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 OCCURS IN UP TO 10% OF PATIENTS WITH A HISTORY OF PENICILLIN ALLERGY.

If an allergic reaction to Cefaclor occurs, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, INTRAVENOUS FLUIDS, INTRAVENOUS

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*Disk susceptibility test performed using Haemophilus Test Medium (HTM)/
ANTHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED

Antibiotics, including cefaclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. Therefore, it is important to consider the diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of Candida. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of antibiotic-associated colitis.

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Therapy with vancomycin or metronidazole is recommended. Supportive care may be appropriate until infection is controlled.

The diagnostic step in the management of pseudomembranous colitis is crucial. The use of C. difficile toxin should be considered when signs and symptoms of pseudomembranous colitis develop in a patient receiving cefaclor.

Adverse reactions occurring during treatment with cefaclor may be reported in the post-marketing phase. They should be reported to the Physicians' Desk Reference (PDR).

Allergic reactions, including anaphylaxis, Steven-Johnson syndrome, and toxic epidermal necrolysis have been reported.

Antihistamines, corticosteroids, pressor amines, and airway management should be used during pregnancy only if clearly needed.

Labor and Delivery

The effect of cefaclor on labor and delivery is unknown. Nursing Mothers

Small amounts of cefaclor have been detected in mother's milk following administration of single 500 mg doses. Average levels were 0.2, 0.2, 0.2, 0.2, and 0.2 mg/mL at 0.5, 1, 1.5, 2, and 3 hours respectively. Trace amounts were detected at 1 hour. The effect on nursing infants is not known. Caution should be exercised when cefaclor is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of this product in use in children under 1 year of age have not been established.

Postmarketing Experience

There have been rare reports of increases in prothrombin time with or without clinical bleeding in patients receiving cefaclor and Coumadin® (warfarin) concomitantly.

Rheumatology

Rheumatologic manifestations, including cefaclor should only be used to treat infections caused by beta-lactam antibiotics effective against the offending organism, including cefaclor.

Antibiotics, including cephalosporins, should be prescribed with caution in individuals with a history of serum sickness-like reactions. Serum sickness-like reactions have been reported in up to 1 in 100 patients.

Full blown anaphylaxis may be more common in children. More severe reactions occurring in pediatric patients.

Serum sickness-like reactions have been reported in 1 in 1000 patients. Pruritus, urticaria, and positive Coombs tests have been reported in 1 in 1000 patients.

More severe hypersensitivity reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylactoid reactions have been reported rarely. Anaphylactoid events may be manifested by solitary symptoms, including angioedema, asthma, edema (including face and limbs), dyspnea, shock, urticaria, hypotension, or vertigo. Anaphylaxis may be seen in patients with a history of penicillin allergy. Rarely, hypersensitivity symptoms may persist for several months.

Gastrointestinal disease, particularly colitis.

Related to the use of beta-lactam antibiotics, the renal excretion of cefaclor is inhibited by probenecid.

Antibiotics, including cephalosporins, should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Information for Patients

Patients should be counseled that antibacterial drugs should not be used to treat or prevent viral infections, except as directed or supervised by the physician.

There have been reports of increased anticoagulant effect when cefaclor and oral anticoagulants were administered concomitantly.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been performed to determine potential for carcinogenicity, mutagenicity, or impairment of fertility.

Pregnancy – Teratogenic Effects – Pregnancy Category B

Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given 3 times the maximum human dose and have revealed no harm to the fetus due to cefaclor. There are, however, 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.

Cefaclor Suspension

<table>
<thead>
<tr>
<th>Weight (mg/mL)</th>
<th>125 mg/mL</th>
<th>250 mg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 kg</td>
<td>1 tsp/1.75</td>
<td>1 tsp/1.75</td>
</tr>
<tr>
<td>18 kg</td>
<td>1 tsp/1.75</td>
<td>1 tsp/1.75</td>
</tr>
<tr>
<td>40 mg/kg/day</td>
<td></td>
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B.I.D. Treatment Option – For the treatment of otitis media and pharyngitis, the total daily dosage may be divided and administered every 12 hours.

HOW SUPPLIED

Cefaclor Capsule USP 250 mg (blue and pink body hard gelatin capsule containing blue to slightly yellowish power) and 500 mg (both capsule and capsule body) contains cefaclor (monohydrate) equivalent to 250 mg and 500 mg anhydrous cefaclor.

Bottle of 30 NDC 61442-171-30
Bottle of 100 NDC 61412-171-01
Bottle of 500 NDC 61412-171-05

Cefaclor Capsule USP 500 mg (blue cap and orange body hard gelatin capsule containing white to slightly yellowish powder imprinted with “RC200” on both capsule cap and capsule body) contains cefaclor (monohydrate) equivalent to 500 mg anhydrous cefaclor.

Bottle of 30 NDC 61442-172-30
Bottle of 100 NDC 61412-172-01
Bottle of 500 NDC 61412-172-05

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

REFERENCES


Manufactured by:
Yung Shin Pharmaceutical Ind., Co. Ltd.
Tachia, Tainan 643678, TAIWAN

Distributed by:
Carlsbad Technology, Inc.
9523 Balfour Ct.,
Carlsbad, CA 92008 USA

Reviewed: 08/10