Omnicef®

Cefdinir

Action

Omnicef (cefdinir) contain the active ingredient cefdinir, an extended-spectrum, semisynthetic cephalosporin, for oral administration.

Indications

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Omnicef and other antibacterial drugs, Omnicef 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.
Omnicef (cefdinir) is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below.
Adults and adolescents
Community-acquired pneumonia
Caused by Haemophilus influenzae (including β-lactamase producing strains), Haemophilus parainfluenzae (including β-lactamase producing strains), Streptococcus pneumoniae (penicillin-susceptible strains only), and Moraxella catarrhalis (including βlactamase producing strains).
Acute exacerbations of chronic bronchitis
Caused by Haemophilus influenzae (including β-lactamase producing strains), Haemophilus parainfluenzae (including β-lactamase producing strains), Streptococcus pneumoniae (penicillin-susceptible strains only), and Moraxella catarrhalis (including βlactamase producing strains).
Acute maxillary sinusitis
Caused by Haemophilus influenzae (including β-lactamase producing strains), Streptococcus pneumoniae (penicillin-susceptible strains only), and Moraxella catarrhalis (including β-lactamase producing strains).
NOTE: For information on use in pediatric patients, see Dosage and Administration.
Pharyngitis/tonsillitis
Caused by Streptococcus pyogenes).
Note: Cefdinir is effective in the eradication of S. pyogenes from the oropharynx. Cefdinir has not, however, been studied for the prevention of rheumatic fever following S. pyogenes pharyngitis/tonsillitis. Only intramuscular penicillin has been demonstrated to be effective for the prevention of rheumatic fever.
Uncomplicated skin and skin structure infections
Caused by Staphylococcus aureus (including β-lactamase producing strains) and Streptococcus pyogenes.
Pediatric Patients
Acute bacterial otitis media
Caused by Haemophilus influenzae (including β-lactamase producing strains), Streptococcus pneumoniae (penicillin-susceptible strains only), and Moraxella catarrhalis (including β-lactamase producing strains).
Pharyngitis/Tonsillitis
Caused by Streptococcus pyogenes.
NOTE: Cefdinir is effective in the eradication of S. pyogenes from the oropharynx. Cefdinir has not, however, been studied for the prevention of rheumatic fever following S. pyogenes pharyngitis/tonsillitis. Only intramuscular penicillin has been demonstrated to be effective for the prevention of rheumatic fever.
Uncomplicated skin and skin structure infections
Caused by Staphylococcus aureus (including β-lactamase producing strains) and Streptococcus pyogenes.
Susceptibility of staphylococci to cefdinir may be deduced from testing penicillin and either cefoxitin or oxacillin. Staphylococci susceptible to oxacillin (cefoxitin) can be considered susceptible to cefdinir.

Dosage and administration

(See Indications for indicated pathogens).
Capsules
The recommended dosage and duration of treatment for infections in adults and adolescents are described in the following chart; the total daily dose for all infections is 600 mg. Once-daily dosing for 10 days is as effective as BID dosing. Once-daily dosing has not been studied in pneumonia or skin infections; therefore, Omnicef should be administered twice daily in these infections. Omnicef may be taken without regard to meals.
Adults and adolescents (age 13 years and older)

Type of infection	Dosage	Duration
Community-acquired pneumonia	300 mg q12h	10 days
Acute exacerbations of chronic bronchitis	300 mg q12h or 600 mg q24h	5 to 10 days
Acute maxillary sinusitis	300 mg q12h or 600 mg q24h	10 days 10 days
Pharyngitis/tonsillitis	600 mg q24h 300 mg q12h or 600 mg q24h	10 days 5 to 10 days 10 days
Uncomplicated skin and skin structure infections	300 mg q12h	10 days

Patients with Renal Insufficiency
For adult patients with creatinine clearance < 30 ml/min, the dose of cefdinir should be 300 mg given once daily. Creatinine clearance is difficult to measure in outpatients. However, the following formula may be used to estimate creatinine clearance (CL_{cr}) in adult patients. For estimates to be valid, serum creatinine levels should reflect steady-state levels of renal function.

Males:	CL_{cr} = (weight) (140 – age) / (72) (serum creatinine)
Females:	CL_{cr} = 0.85 × above value

Where creatinine clearance is in ml/min, age is in years, weight is in kilograms, and serum creatinine is in mg/dl.
The following formula may be used to estimate creatinine clearance in pediatric patients:
CL_{cr} = K × body length or height / serum creatinine
Where K = 0.55 for pediatric patients older than 1 year [4] and 0.45 for infants (up to 1 year).
In the above equation, creatinine clearance is in ml/min/1.73 m^2, body length or height is in centimeters, and serum creatinine is in mg/dl.
Patients on hemodialysis
Hemodialysis removes cefdinir from the body. In patients maintained on chronic hemodialysis, the recommended initial dosage regimen is a 300-mg or 7-mg/kg dose every other day. At the conclusion of each hemodialysis session, 300 mg (or 7 mg/kg) should be given. Subsequent doses (300 mg or 7 mg/kg) are then administered every other day.
Pediatric use
Safety and efficacy in neonates and infants less than 6 months of age have not been established. Use of cefdinir for the treatment of acute maxillary sinusitis in pediatric patients (age 6 months through 12 years) is supported by evidence from adequate and well-controlled studies in adults and adolescents, the similar pathophysiology of acute sinusitis in adult and pediatric patients, and comparative pharmacokinetic data in the pediatric population.
There are more suitable pharmaceutical forms for pediatric patients.
Geriatric Use
Efficacy is comparable in geriatric patients and younger adults. While cefdinir has been well-tolerated in all age groups, in clinical trials geriatric patients experienced a lower rate of adverse events, including diarrhea, than younger adults. Dose adjustment in elderly patients is not necessary unless renal function is markedly compromised.

Contraindications

Omnicef (cefdinir) is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

Warnings and precautions

Warnings
Before therapy with Omnicef (cefdinir) is instituted, careful inquiry should be made to determine whether the patient had had previous hypersensitivity reactions to cefdinir, other cephalosporins, penicillins, or other drugs. If cefdinir is to be given to penicillin sensitive patients, caution should be exercised because cross hypersensitivity among β-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 cefdinir occurs, the drug should be discontinued. Serious acute hypersensitivity reactions may require treatment with epinephrine and other.
Emergency measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, pressor amines, and airway management, as clinically indicated.
Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Omnicef 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 strains 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 antibiotic 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 antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.
Precautions
General
Prescribing Omnicef 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.
As with other broad-spectrum antibiotics, prolonged treatment may result in the possible emergence and overgrowth of resistant organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate alternative therapy should be administered.
Cefdinir, as with other broad-spectrum antimicrobials (antibiotics), should be prescribed with caution in individuals with a history of colitis.
In patients with transient or persistent renal insufficiency (creatinine clearance < 30 ml/min), the total daily dose of Omnicef should be reduced because high and prolonged plasma concentrations of cefdinir can result following recommended doses (see Dosage and administration).

Drug interactions

Antacids (aluminum- or magnesium-containing)
Concomitant administration of 300-mg cefdinir with 30 ml Maalox® TC suspension (aluminum hydroxide/magnesium hydroxide) reduces the rate (C_{max}) and extent (AUC) of absorption by approximately 40%. Time to reach C_{max} is also prolonged by 1 hour. There are no significant effects on cefdinir pharmacokinetics if the antacid is administered 2 hours before or 2 hours after cefdinir. If antacids are required during Omnicef therapy, Omnicef should be taken at least 2 hours before or after the antacid.
Probenecid
As with other β-lactam antibiotics, probenecid inhibits the renal excretion of cefdinir, resulting in an approximate doubling in AUC, a 54% increase in peak cefdinir plasma levels, and a 50% prolongation in the apparent elimination $t_{1/2}$.
Iron supplements and foods fortified with iron
Concomitant administration of cefdinir with a therapeutic iron supplement containing 60 mg of elemental iron (as $FeSO_4$) or vitamins supplemented with 10 mg of elemental iron reduced extent of absorption by 80% and 31%, respectively. If iron supplements are required during Omnicef therapy, Omnicef should be taken at least 2 hours before or after the supplement.
The effect of foods highly fortified with elemental iron (primarily iron-fortified breakfast cereals) on cefdinir absorption has not been studied.
Concomitantly administered iron-fortified infant formula (2.2 mg elemental iron/6 oz) has no significant effect on cefdinir pharmacokinetics. Therefore, Omnicef for Oral Suspension can be administered with iron-fortified infant formula.
There have been reports of reddish stools in patients receiving cefdinir. In many cases, patients were also receiving iron-containing products. The reddish color is due to the formation of a non-absorbable complex between cefdinir or its breakdown products and iron in the gastrointestinal tract.
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 cefdinir may result in a false-positive reaction for glucose in urine using Clinitest®, Benedict's solution, or Fehling's solution. It is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix® or Tes-Tape®) be used. Cephalosporins are known to occasionally induce a positive direct Coombs' test.

Fertility, pregnancy and lactation

Pregnancy
Teratogenic Effects
Pregnancy Category B.
Cefdinir was not teratogenic in rats at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m^2/day) or in rabbits at oral doses up to 10 mg/kg/day (0.7 times the human dose based on mg/kg/day, 0.23 times based on mg/m^2/day). Maternal toxicity (decreased body weight gain) was observed in rabbits at the maximum tolerated dose of 10 mg/kg/day without adverse effects on offspring. Decreased body weight occurred in rat fetuses at ≥ 100 mg/kg/day, and in rat offspring at ≥ 32 mg/kg/day. No effects were observed on maternal reproductive parameters or offspring survival, development, behavior, or reproductive function.
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.
Labor and delivery
Cefdinir has not been studied for use during labor and delivery.
Nursing mothers
Following administration of single 600-mg doses, cefdinir was not detected in human breast milk.

Undesirable effects

Postmarketing experience
The following adverse experiences and altered laboratory tests, regardless of their relationship to cefdinir, have been reported during extensive postmarketing experience, beginning with approval in Japan in 1991: shock, anaphylaxis with rare cases of fatality, facial and laryngeal edema, feeling of suffocation, serum sickness-like reactions, conjunctivitis, stomatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, erythema multiforme, erythema nodosum, acute hepatitis, cholestasis, fulminant hepatitis, hepatic failure, jaundice, increased amylase, acute enterocolitis, bloody diarrhea, hemorrhagic colitis, melena, pseudomembranous colitis, pancytopenia, granulocytopenia, leukopenia, thrombocytopenia, idiopathic thrombocytopenic purpura, hemolytic anemia, acute respiratory failure, asthmatic attack, drug-induced pneumonia, eosinophilic pneumonia, idiopathic interstitial pneumonia, fever, acute renal failure, nephropathy, bleeding tendency, coagulation disorder, disseminated intravascular coagulation, upper GI bleed, peptic ulcer, ileus, loss of consciousness, allergic vasculitis, possible cefdinir-diclofenac interaction, cardiac failure, chest pain, myocardial infarction, hypertension, involuntary movements, and rhabdomyolysis.
Cephalosporin class adverse events
The following adverse events and altered laboratory tests have been reported for cephalosporin-class antibiotics in general:
Allergic reactions, anaphylaxis, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage, false-positive test for urinary glucose, neutropenia, pancytopenia, and agranulocytosis.
Pseudomembranous colitis symptoms may begin during or after antibiotic treatment (see Warnings).
Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced (see Doasge and Administration and Overdosage). If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:
- Jordan

Jordan Food and Drug Administration- Rational Drug Use and Pharmacovigilance Department
e-mail: jpc@jfda.jo
Website: https://primaryreporting.who-umc.org/JO
Tel: + (962-6) 5632000
QR Code:

Overdose

Information on cefdinir overdosage in humans is not available. In acute rodent toxicity studies, a single oral 5600-mg/kg dose produced no adverse effects. Toxic signs and symptoms following overdosage with other β-lactam antibiotics have included nausea, vomiting, epigastric distress, diarrhea, and convulsions. Hemodialysis removes cefdinir from the body. This may be useful in the event of a serious toxic reaction from overdosage, particularly if renal function is compromised.

Special precautions for storage

Do not store above 30°C.
Store in the original package.

Presentations

Capsules

Omnicef 300 mg	Each capsule contains 300 mg cefdinir. Omnicef 300 mg Capsules are size (1) flesh cap/body capsules, imprinted with "JPI011" on body and cap, containing pale yellowish white powder or granules in 50 ml high-density polyethylene (HDPE) jars with child resistant caps (CRCs). Pack size: 10 Capsules.

Excipients
Carmellose calcium, magnesium stearate ad polyoxyl 40 stearate.

Marketing Authorization Holder and Batch releaser

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Council of Arab Health Ministers, Union of Arab Pharmacists

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

hikma.

Size:
170x250 mm

Pantone.
2766