

POLICY & PRACTICE

Preparing for a Pandemic

The Department of Health and Human Services is taking steps to avoid a flu pandemic this year, purchasing additional vaccine and antiviral medications that will be placed in the nation's Strategic National Stockpile. Sanofi Pasteur received a \$100 million contract to manufacture avian influenza vaccine designed to protect against the H5N1 influenza virus strain, which has caused an epidemic of avian flu in Asia. The number of individuals who could be protected by the newly contracted vaccine is still to be determined by ongoing clinical

studies, HHS said. In addition, HHS awarded a \$2.8 million contract to Glaxo-SmithKline for 84,300 treatment courses of zanamivir (Relenza). These purchases build upon a plan to buy enough vaccine for 20 million people and enough antivirals for another 20 million people. "These countermeasures provide us with tools that we have never had prior to previous influenza pandemics," HHS Secretary Mike Leavitt said in a statement.

Most Likely to Be Uninsured

The proportion and number of uninsured

children did not change in 2004, remaining at 11.2% or 8.3 million, the Census Bureau reported in its annual survey on income, poverty, and health insurance. With the 2004 uninsured rate at 19%, children in poverty were more likely to be uninsured than other children not classified as being in poverty. Children with special health care needs are also at risk, the Center for Studying Health System Change concluded in a separate report. In 2003, an estimated 13.5 million children had a special health care need, defined as an ongoing physical, emotional, behavioral, developmental, or other condition causing them to use more health services or limit their ac-

tivities. While public health insurance covered nearly two out of five of these children, about 650,000 were uninsured. Children with special health care needs also are less likely to have private insurance, and almost twice as likely to have had an unmet need for medical care in the past year.

Greater Folic Acid Fortification

Officials at the March of Dimes are calling on the U.S. government to require higher levels of folic acid fortification in grain foods. The request, which reflects a long-held policy of the March of Dimes, comes on the heels of research showing that folic acid fortification in grain foods has result-

BRIEF SUMMARY

CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

03-5404-Rev. December, 2004
(Nos. 3769, 3771, 6151)

Omnicef[®] (cefdinir) capsules
Omnicef[®] (cefdinir) for oral suspension

Rx only

INDICATIONS AND USAGE

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) capsules and OMNICEF (cefdinir) for oral suspension are 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 β -lactamase 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 β -lactamase 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 **Pediatric Use** and **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*.

CONTRAINDICATIONS

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

WARNINGS

BEFORE THERAPY WITH OMNICEF (CEFDINIR) IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS 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.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including cefdinir, and may range in severity from mild- to life-threatening. Therefore, it is important to consider this 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 clostridia. 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, appropriate therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile*.

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.

Information for Patients

Patients should be counseled that antibacterial drugs including OMNICEF should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When OMNICEF is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by OMNICEF or other antibacterial drugs in the future.

Antacids containing magnesium or aluminum interfere with the absorption of cefdinir. If this type of antacid is required during OMNICEF therapy, OMNICEF should be taken at least 2 hours before or after the antacid.

Iron supplements, including multivitamins that contain iron, interfere with the absorption of cefdinir. If iron supplements are required during OMNICEF therapy, OMNICEF should be taken at least 2 hours before or after the supplement.

Iron-fortified infant formula does not significantly interfere with the absorption of cefdinir. Therefore, OMNICEF for Oral Suspension can be administered with iron-fortified infant formula.

Diabetic patients and caregivers should be aware that the oral suspension contains 2.86 g of sucrose per teaspoon.

Drug Interactions

Antacids: (aluminum- or magnesium-containing): Concomitant administration of 300-mg cefdinir capsules with 30 mL Maalox[®] TC suspension 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 FeSO₄) 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 nonabsorbable 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenic potential of cefdinir has not been evaluated. No mutagenic effects were seen in the bacterial reverse mutation assay (Ames) or point mutation assay at the hypoxanthine-guanine phosphoribosyltransferase locus (HGPRT) in V79 Chinese hamster lung cells. No clastogenic effects were observed *in vitro* in the structural chromosome aberration assay in V79 Chinese hamster lung cells or *in vivo* in the micronucleus assay in mouse bone marrow. In rats, fertility and reproductive performance were not affected by cefdinir at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m²/day).

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/m²/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/m²/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.

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

ed in a one-third drop in serious birth defects of the brain and spine. The Food and Drug Administration requires 140 mcg of folic acid per 100 g of grain. Since 1996, the March of Dimes has recommended the FDA set the level in enriched grain foods at 350 mcg per 100 g of grain.

Reporting Neonatal Herpes

A group of experts in obstetrics and gynecology and pediatrics is calling on the Centers for Disease Control and Prevention to request reporting of cases of neonatal herpes from all states and U.S. territories. The call to action, which was published in the September issue of the

journal Sexually Transmitted Diseases, notes that a lack of reliable epidemiological data may be partly responsible for the continued development of neonatal herpes cases. While diseases such as congenital syphilis are reportable in 47 states, only 7 states—Connecticut, Florida, Massachusetts, Nebraska, Ohio, South Dakota, and Washington—require reporting of neonatal herpes. The CDC can request reports on various conditions, but the states have the regulatory authority to require reporting. The epidemiological data from reported cases of neonatal herpes would help to resolve debates over testing, treatment, and prevention strategies, the re-

searchers wrote. The analysis was supported by GlaxoSmithKline Inc.

Obesity in California

California's children seem to have a weight problem, especially in the largest cities, a study from the California Center for Public Health Advocacy reported. Using data from the California Physical Fitness Test, which is administered in public schools to grades 5, 7, and 9, the study showed overweight rates rose 6% over 3 years, to 28.1 per 100 children in 2004 from 26.5 per 100 children in 2001. The increase occurred among boys and girls and among children of all racial/ethnic backgrounds. Seven of

the 10 largest cities in California had rates of childhood overweight in 2004 that were higher than the statewide average, with rates from 36% in Los Angeles to 24% in San Francisco. In 65% of California counties, at least one in four children was overweight. The center called for policies to support parents in providing opportunities for their children to make healthy choices about eating and activity, and for state and local leaders to address the problem in schools and communities.

—Jennifer Silverman

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.

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.

ADVERSE EVENTS

Clinical Trials - OMNICEF Capsules (Adult and Adolescent Patients):

In clinical trials, 5093 adult and adolescent patients (3841 US and 1252 non-US) were treated with the recommended dose of cefdinir capsules (600 mg/day). Most adverse events were mild and self-limiting. No deaths or permanent disabilities were attributed to cefdinir. One hundred forty-seven of 5093 (3%) patients discontinued medication due to adverse events thought by the investigators to be possibly, probably, or definitely associated with cefdinir therapy. The discontinuations were primarily for gastrointestinal disturbances, usually diarrhea or nausea. Nineteen of 5093 (0.4%) patients were discontinued due to rash thought related to cefdinir administration.

In the US, the following adverse events were thought by investigators to be possibly, probably, or definitely related to cefdinir capsules in multiple-dose clinical trials (N = 3841 cefdinir-treated patients):

Incidence ≥ 1%	Diarrhea	15%
	Vaginal moniliasis	4% of women
	Nausea	3%
	Headache	2%
	Abdominal pain	1%
	Vaginitis	1% of women
Incidence <1% but >0.1%	Rash	0.9%
	Dyspepsia	0.7%
	Flatulence	0.7%
	Vomiting	0.7%
	Abnormal stools	0.3%
	Anorexia	0.3%
	Constipation	0.3%
	Dizziness	0.3%
	Dry mouth	0.3%
	Asthenia	0.2%
	Insomnia	0.2%
	Leukorrhea	0.2% of women
	Moniliasis	0.2%
	Pruritus	0.2%
	Somnolence	0.2%

^a 1733 males, 2108 females

The following laboratory value changes of possible clinical significance, irrespective of relationship to therapy with cefdinir, were seen during clinical trials conducted in the US:

Incidence ≥ 1%	↑Urine leukocytes	2%
	↑Urine protein <td>2%</td>	2%
	↑Gamma-glutamyltransferase ^a <td>1%</td>	1%
	↓Lymphocytes, ↓Lymphocytes <td>1%, 0.2%</td>	1%, 0.2%
	↑Microhematuria <td>1%</td>	1%
Incidence <1% but >0.1%	↑Glucose ^a	0.9%
	↑Urine glucose	0.9%
	↑White blood cells, ↓White blood cells	0.9%, 0.7%
	↑Alanine aminotransferase (ALT)	0.7%
	↑Eosinophils	0.7%
	↑Urine specific gravity, ↓Urine specific gravity ^a	0.6%, 0.2%
	↓Bicarbonate ^a	0.6%
	↑Phosphorus, ↓Phosphorus ^a	0.6%, 0.3%
	↑Aspartate aminotransferase (AST)	0.4%
	↑Alkaline phosphatase	0.3%
	↑Blood urea nitrogen (BUN)	0.3%
	↓Hemoglobin	0.3%
	↑Polymorphonuclear neutrophils (PMNs), ↓PMNs	0.3%, 0.2%
	↑Bilirubin	0.2%
	↑Lactate dehydrogenase ^a	0.2%
	↑Platelets	0.2%
	↑Potassium ^a	0.2%
	↑Urine pH ^a	0.2%

^a N=3841 for these parameters

Clinical Trials - OMNICEF for Oral Suspension (Pediatric Patients):

In clinical trials, 2289 pediatric patients (1783 US and 506 non-US) were treated with the recommended dose of cefdinir suspension (14 mg/kg/day). Most adverse events were mild and self-limiting. No deaths or permanent disabilities were attributed to cefdinir. Forty of 2289 (2%) patients discontinued medication due to adverse events considered by the investigators to be possibly, probably, or definitely associated with cefdinir therapy. Discontinuations were primarily for gastrointestinal disturbances, usually diarrhea. Five of 2289 (0.2%) patients were discontinued due to rash thought related to cefdinir administration.

In the US, the following adverse events were thought by investigators to be possibly, probably, or definitely related to cefdinir suspension in multiple-dose clinical trials (N=1783 cefdinir-treated patients):

Incidence ≥ 1%	Diarrhea	8%
	Rash	3%
	Vomiting	1%
Incidence <1% but >0.1%	Cutaneous moniliasis	0.9%
	Abdominal pain	0.8%
	Leukopenia ^b	0.3%

Vaginal moniliasis	0.3% of girls
Vaginitis	0.3% of girls
Abnormal stools	0.2%
Dyspepsia	0.2%
Hyperkinesia	0.2%
Increased AST ^b	0.2%
Maculopapular rash	0.2%
Nausea	0.2%

^a 977 males, 806 females
^b Laboratory changes were occasionally reported as adverse events.

NOTE: In both cefdinir- and control-treated patients, rates of diarrhea and rash were higher in the youngest pediatric patients. The incidence of diarrhea in cefdinir-treated patients ≤ 2 years of age was 17% (95/557) compared with 4% (51/1226) in those >2 years old. The incidence of rash (primarily diaper rash in the younger patients) was 8% (43/557) in patients ≤ 2 years of age compared with 1% (8/1226) in those >2 years old.

The following laboratory value changes of possible clinical significance, irrespective of relationship to therapy with cefdinir, were seen during clinical trials conducted in the US:

Incidence ≥ 1%	↑Lymphocytes, ↓Lymphocytes	2%, 0.8%
	↑Alkaline phosphatase	1%
	↓Bicarbonate ^a	1%
	↑Eosinophils	1%
	↑Lactate dehydrogenase	1%
	↑Platelets	1%
	↑PMNs, ↓PMNs	1%, 1%
	↑Urine protein	1%
Incidence <1% but >0.1%	↑Phosphorus, ↓Phosphorus	0.9%, 0.4%
	↑Urine pH	0.8%
	↓White blood cells, ↑White blood cells	0.7%, 0.3%
	↓Calcium ^a	0.5%
	↓Hemoglobin	0.5%
	↑Urine leukocytes	0.5%
	↑Monocytes	0.4%
	↑AST	0.3%
	↑Potassium ^a	0.3%
	↑Urine specific gravity, ↓Urine specific gravity	0.3%, 0.1%
	↓Hematocrit ^a	0.2%

^a N=1387 for these parameters

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: Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, erythema multiforme, erythema nodosum, serum sickness, conjunctivitis, stomatitis, acute hepatitis, cholestasis, fulminant hepatitis, hepatic failure, jaundice, increased amylase, shock, anaphylaxis, facial and laryngeal edema, feeling of suffocation, 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 OVERDOSAGE). If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

OVERDOSAGE

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.

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