Child Safety Seats via Medicaid Urged as 'Vaccine'

BY MIRIAM E. TUCKER Senior Writer

WASHINGTON — Implementation of a Medicaid-funded program that would disburse child restraint systems to low-income children and educate families about their use would be more cost effective to Medicaid than are most currently administered vaccines, Jesse A. Goldstein reported at the annual meeting of the American Academy of Pediatrics.

As with all routine vaccines, such a program would be cost-saving to society in terms of parental work loss and future productivity. And, akin to what the federally funded Vaccines for Children accomplishes for vaccination, "this program would reduce the disparities in child passenger safety prevalent in low-income communities by addressing the major barriers to adequate restraint practices-namely, access and education," said Mr. Goldstein, a fourth-year medical student at the University of Pennsylvania, Philadelphia.

The data come from the Partners for Child Passenger Safety, a research collaboration of State Farm Insurance Companies, Children's Hospital of Philadelphia, and the University of Pennsylvania (www.trau malink.chop.edu). It uses telephone interviews, on-site crash investigations, and indepth analysis in 15 states and the District of Columbia to determine how and why children are injured in crashes.

For the current analysis, a hypothetical

group of 100,000 low-income children were enrolled at birth and followed through 8 years of recommended child restraint system (CRS) use. Injury rates were derived from the PCPS database of State Farm policyholders involved in crashes from 1999 to 2003 in which a child aged 8 years or younger was present. Mortality data came from the Fatality Analysis Reporting System, and other data came from published and unpublished sources.

Program costs included administration

PROFESSIONAL BRIEF SUMMARY-CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION. Cefdinir, as with other broad-spectrum antimicrobials (antibiotics), should be prescribed with caution in individuals with a history of colitis. 03-5435-Rev. July, 2005 (Nos. 3769, 3771, 6151)

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

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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 of 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.

Community-Acquired Pneumonia caused by Haemophilus influenzae (including €lactamase producing strains), Haemophilus parainfluenzae (including €lactamase producing strains), Streptococcus pneumoniae (penicillin-susceptible strains only), and Moraxella catarrhalis (including €lactamase producing strains).

Acute Exacerbations of Chronic Bronchitis caused by Haemophilus influenzae (including Elactamase producing strains), *Haemophilus parainfluenzae* (including elactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including elactamase producing strains).

Acute Maxillary Sinusitis caused by *Haemophilus influenzae* (including *E*lactamase producing strains). Streptococcus pneumoniae (penicillin-susceptible strains only), and Moraxella catarrhalis (including *E*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 €lactamase producing strains) and Streptococcus pyogenes. Pediatric Patients

Acute Bacterial Ottitis Media caused by *Haemophilus influenzae* (including €lactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including €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 €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 INOUIRY BEFORE THERAPY WITH OMINICEF (CEPDINIK) IS INSTITUTED, CAREFOL INQUIKY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPDINIR, OTHER CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF CEFDINIR IS TO BE GIVEN TO PENICILLIN-PENICILLINS, OR OTHER DRUGS. IF CEFDINIR IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-HYPERSENSITIVITY AMONG ELACTAM 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 ANTHHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT. AS CLUICALLY INDICATED. 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 "antibioticassociated colitis."

After the diagnosis of pseudomembranous colitis has been established, appropriate therapeutic measures Should be initiated. Mild cases of pseudomembraneous colitionations and propriate integration metazonic 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 of prophylactic indication is unlikely to provide benefit to the patient and increases the risk of 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 admi nistered.

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 cefdining 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 (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 magnesi antacide containing magnesium or atuminum interfere with the absorption of cefdinir. If this ty antacid is required during OMNICEF therapy, OMNICEF should be taken at least 2 hours before or the antacid. im or aluminum interfere with the absorption of cefdinir. If this type of

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 sentered.

Probenecid: As with other \in 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 adm 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 perform 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 To mg/kg/day (window inner due finitial cose of a grap day 0.22 minute that the maximum tolerated dose of 10 mg/kg/day without adverse effects on offspring. Decreased body weight occurred in rat fetuses at \times 100 mg/kg/day, and in rat offspring at \times 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 certainty of a definition of the treatment of acute maxiliary sinusities 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.

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.

and education, initial disbursement of convertible seats beginning at birth, reinvestment for booster seats at age 4 years, and a 5% annual replacement rate. It was assumed that the program would increase appropriate CRS use for low-income children by 23% for 0- to 3-year-olds and by 35% for children aged 4-7 years. Under these assumptions, implementation of the program would prevent 63 injuries and 2 deaths per 100,000 children. Over the course of 8 years, it would prevent 400 injuries and 17 deaths, resulting in 564 lifeyears saved, Mr. Goldstein reported.

Without the proposed program, annual crash-related outcome costs were estimat-

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):

ADVERSE EVENTS ASSOCIATED WITH CEFDINIR CAPSULES

US TRIALS IN ADULI AND ADULESCENT PATIENTS (N=3841) ^a			
Incidence × 1%	Diarrhea Vaginal moniliasis	15% 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%	

a 1733 males, 2108 females

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

LABORATORY VALUE CHANGES OBSERVED WITH CEFDINIR CAPSULES US TRIALS IN ADULT AND ADOLESCENT PATIENTS (N-3841)

_		(11-50-17)	
	Incidence $\times 1\%$	δ Urine leukocytes	2%
		δ Urine protein	2%
		δ Gamma-glutamyltransferase ^a	1%
		α Lymphocytes, δ Lymphocytes	1%, 0.2%
_		δ Microhematuria	1%
	Incidence <1% but >0.1%	δ Glucose ^a	0.9%
		δ Urine glucose	0.9%
		δ White blood cells, α White blood cells	0.9%, 0.79
		δ Alanine aminotransferase (ALT)	0.7%
		δ Eosinophils	0.7%
		δ Urine specific gravity, α Urine specific gravity ^a	0.6%, 0.29
		α Bicarbonate ^a	0.6%
		δ Phosphorus, α Phosphorus ^a	0.6%, 0.39
		δ Aspartate aminotransferase (AST)	0.4%
		δ Alkaline phosphatase	0.3%
		δ Blood urea nitrogen (BUN)	0.3%
		α Hemoglobin	0.3%
		δ Polymorphonuclear neutrophils (PMNs), α PMNs	0.3%, 0.29
		δ Bilirubin	0.2%
		δ Lactate dehydrogenase ^a	0.2%
		δ Platelets	0.2%
		δ Potassium ^a	0.2%
		δ Urine pH ^a	0.2%
		1	

a N<3841 for these parameters

Clinical Trials - OMNICEF for Oral Suspension (Pediatric Patients)

In clinical trials - Omitocer for oral Suspension (returner equation). 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):

ADVERSE EVENTS ASSOCIATED WITH CEFDINIR SUSPENSION US TRIALS IN PEDIATRIC PATIENTS

	(N=1783) ^a	
Incidence × 1%	Diarrhea	8%
	Rash	3%
	Vomiting	1%
Incidence <1% but >0.1%	Cutaneous moniliasis	0.9%
	Abdominal pain	0.8%
	Leukopeniab	0.3%
	Vaginal moniliasis	0.3% of girls
	Vaginitis	0.3% of girls
	Abnormal stools	0.2%
	Dyspepsia	0.2%
	Hyperkinesia	0.2%
	Increased ASTb	0.2%
	Maculopapular rash	0.2%
	Nausea	0.2%

ed at \$4.2 million in medical costs, \$350,000 in parental work loss, and \$8.3 million in future victim productivity per 100,000 children. Implementation of CRS disbursement and education would reduce annual medical costs by about \$1 million, parental work loss costs by \$100,000, and future productivity costs by \$2.7 million.

Over the 8-year projection, the program would save nearly \$7 million in medical costs. At the same time, program administration costs were estimated at \$6 million for the first year and \$10 million cumulatively.

From the societal perspective (including all medical and nonmedical costs), the program would be cost-saving. From Medicaid's perspective-including only medical costs-the program would need to spend \$17,000 to save one life-year. "This value is well below the threshold of \$50,000-\$80,000 that most are willing to pay for an added year of life," Mr. Goldstein noted.

Indeed, a CRS disbursement/education program falls into the lower-cost end of the list of vaccines currently funded under VFC, well below the cost per life-year saved for varicella vaccine (\$19,700 or \$65,000, depending on the vaccine price estimate), hepatitis B vaccine (\$26,000), and pneumococcal vaccine (\$147,000). Only Haemophilus influenzae type b (cost saving to insurer) and measles-mumpsrubella (\$6,000) were more cost effective.

Several states have programs that supply child safety seats among low-income populations using a variety of funding mechanisms, but most do not involve Medicaid.

A legislative proposal in Illinois would increase seatbelt violation fines from the current \$25 to \$200 to provide child safety seats on a sliding-scale fee to low-income families. It also would allow Medicaid to reimburse the time of certified child passenger safety technicians at eligible locations to educate families who receive sliding-fee child safety seats, said Jahari Piersol of the Illinois Department of Transportation.

Limiting Topics **During Visit** Aids Retention

hen providing parents with anticipatory guidance, less is apparently more.

Parental recall of topics discussed during a well-child visit dwindles as the number of topics increases, Dr. Shari L. Barkin and her associates reported: Parents absorb the information best when physicians limit their discussions to less than nine subjects.

"Limiting the number of topics discussed, rather than attempting to squeeze more informational content into the visit, might lead to increased retention, a necessary starting point for behavior change," wrote Dr. Barkin of Wake Forest University, Winston-Salem, N.C., and her colleagues (Ambul. Pediatr. 2005;5:372-6).

The investigators examined provider-parent agreement and parental recall of subjects discussed during 861 well-child visits. Most of the parents surveyed were mothers (90%), and most of the mothers (59%) reported at least a high school education.

The most discussed topics were car restraints, nutrition, dental care, and reading aloud. Other topics included exercise, firearms, smoking, and media use. Most providers (454) discussed 5-8 topics; 158 covered 1-4 topics, and 249 did 9-13 topics.

Immediately after the visit, parents and providers filled out surveys about the discussions. There was good agreement (at least 70%) about what was and was not discussed, but overall, parents reported discussing slightly fewer topics than did providers (mean topics 6.33 vs. 6.9, respectively). The best agreement between parents and providers occurred when five to eight topics had been discussed. When there were fewer than five topics, parents reported having discussed more topics than providers reported; in discussions of more than nine topics, parents recalled fewer topics than providers recalled.

Parental recall dwindled with time, the investigators wrote. One month after the visit, parents who heard the fewest subjects recalled discussing more than their providers had reported post visit (mean 5.58 vs. 3.12, respectively).

Parents who heard the most topics recalled fewer topics than their providers had reported post visit (mean 8.63 vs. 10.16, respectively).

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 volume 1001 contains and control acade parents, rates of marries and rates were light in the youngest pediatric patients. The incidence of diarrhea in cefdinin-treated patients A2 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 A2 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:

LABORATORY VALUE CHANGES OF POSSIBLE CLINICAL SIGNIFICANCE OBSERVED WITH **CEFDINIR SUSPENSION US TRIALS IN PEDIATRIC PATIENTS** (N=1783)

Incidence $\times 1\%$	δ Lymphocytes, α Lymphocytes	2%, 0.8%	
	δ Alkaline phosphatase	1%	
	α Bicarbonate ^a	1%	
	δ Eosinophils	1%	
	δ Lactate dehydrogenase	1%	
	δ Platelets	1%	
	δ PMNs, α PMNs	1%, 1%	
	δ Urine protein	1%	
Incidence <1% but >0.1%	δ Phosphorus, α Phosphorus	0.9%, 0.4%	
	δ Urine pH	0.8%	
	α White blood cells, δ White blood cells	0.7%, 0.3%	
	α Calcium ^a	0.5%	
	α Hemoglobin	0.5%	
	δ Urine leukocytes	0.5%	
	δ Monocytes	0.4%	
	δAST	0.3%	
	δ Potassium ^a	0.3%	
	δ Urine specific gravity, α Urine specific gravity	0.3%, 0.1%	
	or Hamataarita	0.20%	

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-like reactions, conjunctivitis, stomatitis, acute hepatitis, cholestasis, eryinema nodosum, serum steckness-inke reactions, conjunctivitis, stomatitis, acute nepatitis, 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 bled, petic ulcer, ileus, loss of consciousness, anlergic vasculitis, possible cefdini-ticlofenac interaction, cardiac failure, chest pain, myocardial infarction, hypertension, involuntary movements, and habdomyolysi

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 €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 corr nised

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