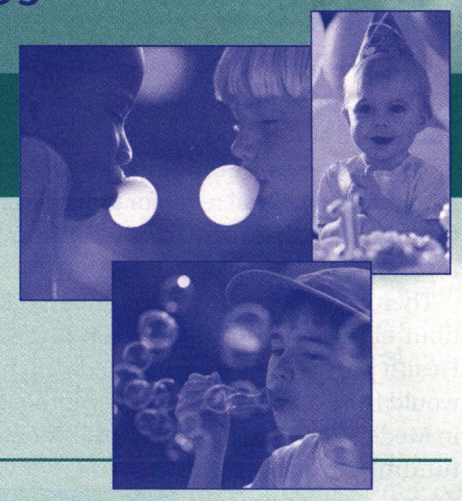
Childhood Asthma and Allergies:
Improving Evidence-based Treatment and the Role of Inhaled Corticosteroids



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Activity Purpose
This activity is intended to update practicing pediatricians, primary care physicians, and other health care practitioners on the growing burden of childhood asthma and allergic rhinitis and provide current evidence on the appropriate diagnosis and treatment of these potentially coexisting conditions.

Statement of Need
Asthma is the leading serious chronic childhood illness, affecting ~6.3 million children younger than 18 years. In 2001, 4.2 million children had an asthma episode. These asthma attacks substantially impact children, families, and the health care system. Children miss 14 million days of school annually because of asthma. For children younger than 15 years, asthma is the third leading cause of hospitalization. Although only 22% of the US population is younger than 15 years, >43% of hospital discharges for asthma occurred in this age group.

Children with asthma also may have concomitant allergic rhinitis. There is increasing knowledge of the interrelationship among allergic airways diseases, and evidence suggests that asthma and allergic rhinitis are linked epidemiologically and pathophysiologically, supporting the concept of "one airway, one disease." Importantly, symptoms of allergic rhinitis have been reported to occur in as many as 86% of patients with asthma, while asthma affects up to 43% of patients with allergic rhinitis. The Centers for Disease Control reports that allergic rhinitis and asthma each account for ~9 million annual visits to office-based physicians. Finally, seasonal allergic rhinitis affects 10–25% of the population and is more common among children and adolescents than adults.

Despite the dissemination of asthma (NAEPP) and allergic rhinitis (ARIA) guidelines that recommend inhaled and nasal corticosteroids as preferred therapy, appropriate use of these medications by pediatricians and primary care physicians continues to be an important clinical goal.

Learning Objectives
After this activity, participants should be able to improve health outcomes for children with asthma and allergic rhinitis by:

1. Identifying the interrelationship between asthma and allergic disorders
2. Recognizing the importance of early diagnosis
3. Applying new evidence supporting the efficacy and safety of nasal and inhaled corticosteroids

Target Audience
This educational activity is designed for pediatricians, physician assistants, nurses, nurse practitioners, family physicians, and other health care practitioners with an interest in pediatric allergic airways diseases.

Accreditation Statement
National Jewish Medical and Research Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

This activity has been jointly planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of National Jewish Medical and Research Center and Clarus Health, LLC.

Designation Statement
National Jewish Medical and Research Center designates this educational activity for a maximum of 1 hour in category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

National Jewish is provider approved by the California Board of Registered Nursing, Provider Number CEP 12724, for 1.0 contact hours.

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For Additional Information Visit
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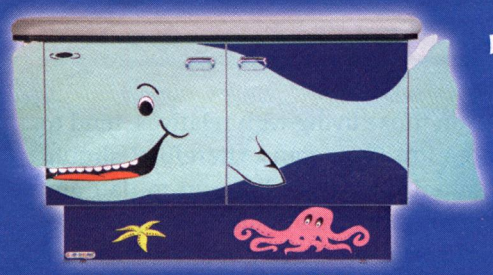
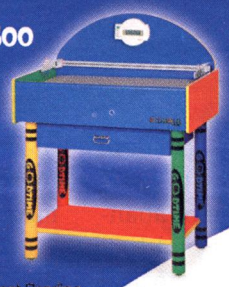


Whale

Patent Pending



Infant 500

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Stool

MC 40

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Rocket Scale

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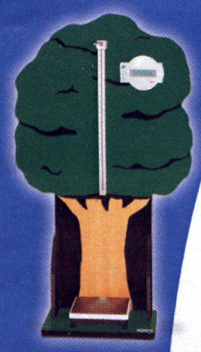

Tree Scale

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Youth Bed

The giraffe, monkey, and hippo are guaranteed to put a smile on your little patients' faces while providing all the essential needs for their care and comfort. Side rails are adjustable for easy access to patient. Headboard can be removed if necessary and is available in many sizes.
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Patent # DES 383,543
Patents Pending

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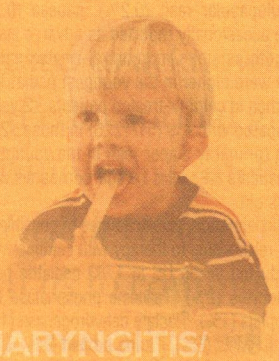

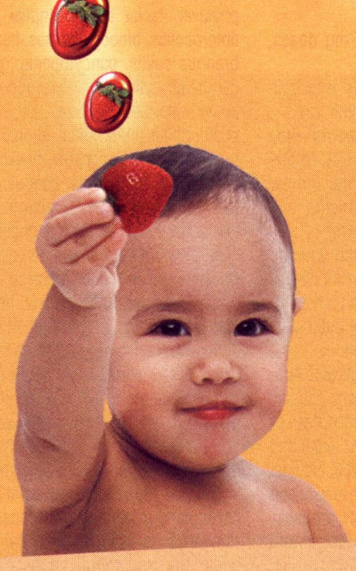

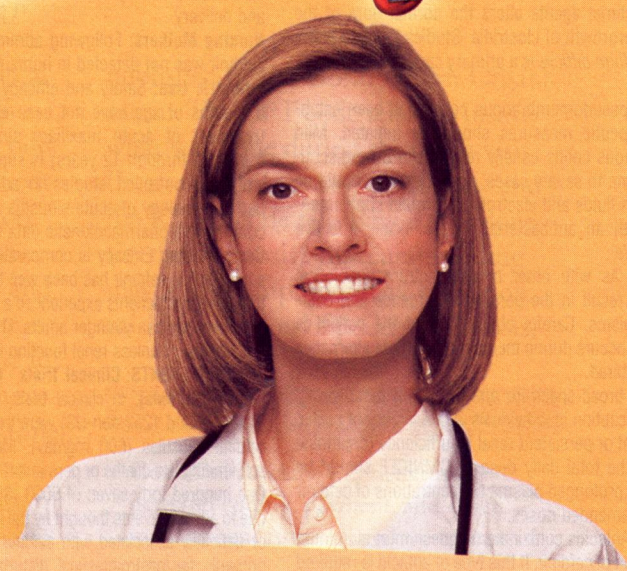

Indications (mild to moderate infections)[1]

Acute bacterial otitis media and **acute maxillary sinusitis** (adults and adolescents) due to *H influenzae* (including ß-lactamase producing strains), *S pneumoniae* (penicillin-susceptible strains only), and *M catarrhalis* (including ß-lactamase producing strains). Use of cefdinir in the treatment of acute maxillary sinusitis in pediatric patients is supported by evidence from adequate and well-controlled studies in adults and adolescents.

Pharyngitis/Tonsillitis due to *S pyogenes*. 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.

Safety information[1]

- OMNICEF is contraindicated in patients with known allergy to the cephalosporin class of antibiotics
- For patients with previous hypersensitivity reaction to penicillins, caution should be exercised because cross-hypersensitivity among ß-lactam antibiotics has been clearly documented. If an allergic reaction to cefdinir occurs, the drug should be discontinued
- Safety and efficacy in neonates and infants less than 6 months have not been established
- 2% of 2,289 pediatric patients discontinued medication due to adverse events in US and ex-US clinical trials. Discontinuations were primarily for gastrointestinal disturbance, usually diarrhea
- The most common reported adverse events occurring in ≥1% of pediatric patients in US clinical trials (N=1,783) were diarrhea (8%), rash (3%), and vomiting (1%)

Reference: 1. OMNICEF® (cefdinir) for Oral Suspension Prescribing Information, Abbott Laboratories.

Please see brief summary of prescribing information on following page.

OMNICEF®
(cefdinir) for oral suspension
125 mg/5 mL

Expert recommended.
Kid preferred.

Abbott Laboratories
Abbott Park, IL 60064

Under License of
Fujisawa Pharmaceutical Co., Ltd.
Osaka, Japan

031-034-9608-1 • September 2003

OMNICEF®
(cefdinir)

BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

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

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: 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: 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 $t_{½}$.

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 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/m^2/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/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.

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.

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 in adult and adolescent patients (N = 3841 cefdinir-treated patients [1733 males and 2108 females]): 1) Incidence ≥1%: diarrhea (15%), vaginal moniliasis (4% of women), nausea (3%), headache (2%), abdominal pain (1%), vaginitis (1% of women); 2) 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%).

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 in 3841 adult and adolescent patients: 1) Incidence ≥1%: ↑urine leukocytes (2%), ↑urine protein (2%), ↑gamma-glutamyltransferase[a] (1%), ↓lymphocytes (1%), ↑microhematuria (1%); 2) Incidence <1% but >0.1%: ↑glucose[a] (0.9%), ↑urine glucose (0.9%), ↑white blood cells (0.9%), ↓white blood cells (0.7%), ↑alanine aminotransferase (ALT) (0.7%), ↑eosinophils (0.7%), ↑urine specific gravity (0.6%), ↓urine specific gravity[a] (0.2%), ↓bicarbonate[a] (0.6%), ↑phosphorus (0.6%), ↓phosphorus[a] (0.3%), ↑aspartate aminotransferase (AST) (0.4%), ↑alkaline phosphatase (0.3%), ↑blood urea nitrogen (BUN) (0.3%), ↓hemoglobin (0.3%), ↑polymorphonuclear neutrophils (PMNs) (0.3%), ↓PMNs (0.2%), ↑bilirubin (0.2%), ↑lactate dehydrogenase[a] (0.2%), ↑lymphocytes (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 [977 males and 806 females]): 1) Incidence ≥1%: diarrhea (8%), rash (3%), vomiting (1%); 2) 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%). ([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 in 1783 pediatric patients: 1) Incidence ≥1%: ↑lymphocytes (2%), ↑alkaline phosphatase (1%), ↓bicarbonate[a] (1%), ↑eosinophils (1%), ↑lactate dehydrogenase (1%), ↑platelets (1%), ↑PMNs (1%), ↓PMNs (1%), ↑urine protein (1%); 2) Incidence <1% but >0.1%: ↑phosphorus (0.9%), ↑urine pH (0.8%), ↓ lymphocytes (0.8%), ↓white blood cells (0.7%), ↓ calcium[a] (0.5%), ↓ hemoglobin (0.5%), ↑urine leukocytes (0.5%), ↑monocytes (0.4%), ↓phosphorus (0.4%), ↑AST (0.3%), ↑potassium[a] (0.3%), ↑urine specific gravity (0.3%), ↑white blood cells (0.3%), ↓hematocrit[a] (0.2%), ↓urine specific gravity (0.1%). ([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, 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.

Ref. 03-5157-Rev. October, 2001

03D-034-7894-1 **MASTER**

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VIGAMOX™ solution is indicated for the treatment of bacterial conjunctivitis. VIGAMOX™ solution is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other fluoroquinolones, or to any of the components in this medication. *In vitro* data are not always indicative of clinical success or microbiological eradication in a clinical setting. The dosing of VIGAMOX™ solution is one drop in the affected eye(s) 3 times daily for 7 days.

References

1. Stroman DW, Medoza B, Sukplang P, Berry R, Schlech BA. Kinetics of killing of ocular isolates of *Staphylococcus aureus* and *Staphylococcus epidermidis* by moxifloxacin. Presented at: Association for Research in Vision and Ophthalmology Conference; May 4-9, 2003; Fort Lauderdale, Fla.
2. VIGAMOX™ solution prescribing information.
3. CILOXAN® solution prescribing information.
4. Data on file. Alcon Laboratories, Inc.

Please see brief summary of prescribing information on adjacent page.

Vigamox™
(moxifloxacin HCl ophthalmic solution) 0.5% as base

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ElixSure™. The first spill-resistant children's medicine. Now you can be sure your patients get all the relief you recommend.

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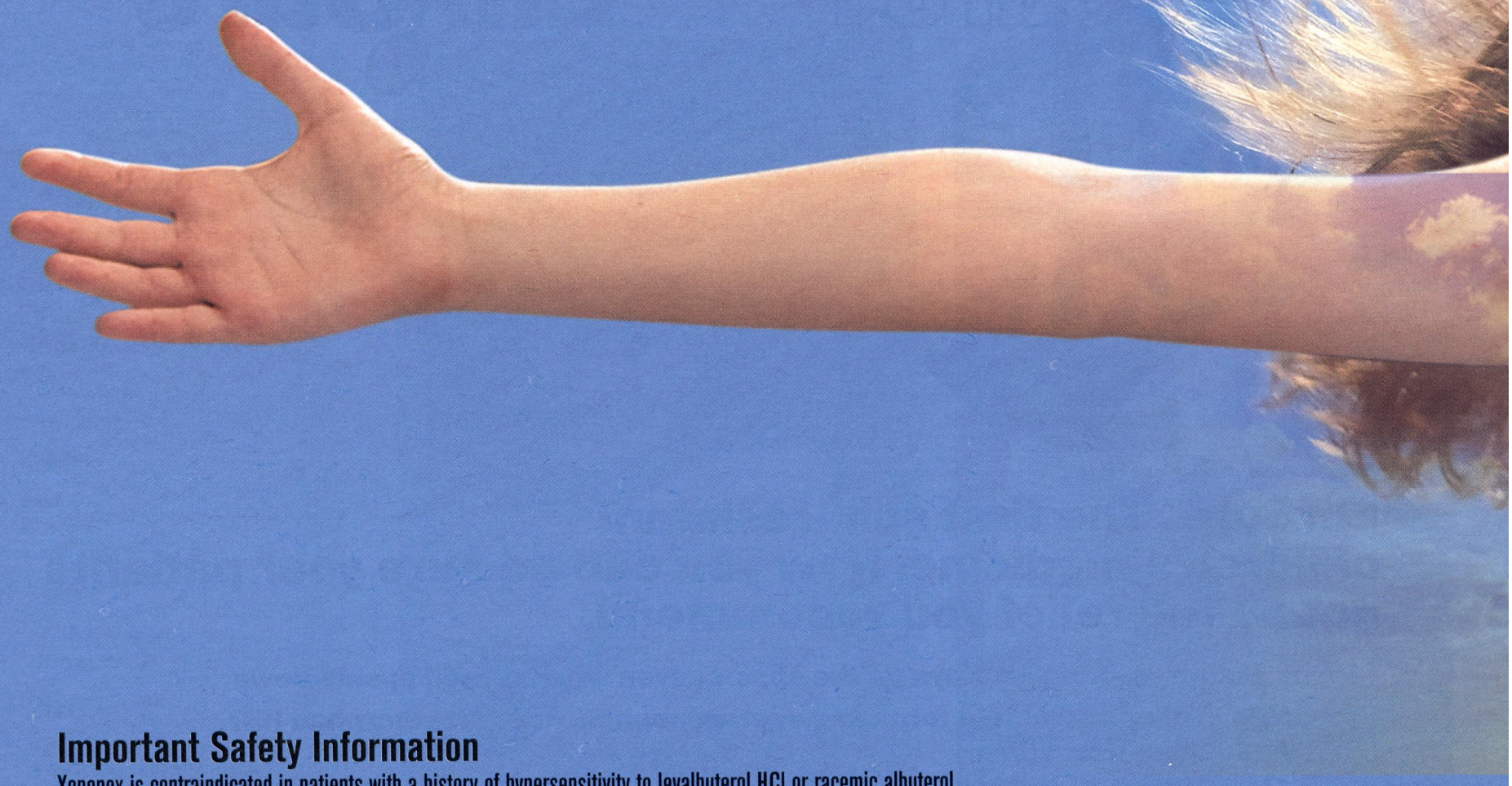

Important Safety Information

Xopenex is contraindicated in patients with a history of hypersensitivity to levalbuterol HCl or racemic albuterol. Patients receiving the highest dose of Xopenex Inhalation Solution should be monitored closely for adverse effects and the risks of such effects should be balanced against the potential for improved efficacy.

In patients aged 6 to 11 years, the adverse events occurring in ≥2% of patients and more frequently than with patients receiving placebo, were (0.31 mg Xopenex; 0.63 mg Xopenex; and placebo, respectively): headache (7.6%; 11.9%; 8.5%), pharyngitis (3%; 10.4%; 6.8%), rhinitis (6.1%; 10.4%; 1.7%), asthma (9.1%; 9%; 5.1%), fever (9.1%; 3%; 5.1%), viral infection (7.6%; 9%; 5.1%), rash (NR‡; 7.5%; NR‡), accidental injury (6.1%; 4.5%; 3.4%), diarrhea (1.5%; 6%; NR‡), pain (3%; 1.5%; 3.4%), asthenia (3%; 3%; NR‡), lymphadenopathy (3%; NR‡; NR‡), and urticaria (NR‡; 3%; NR‡).

In patients aged 12 years and older, the adverse events occurring in ≥2% of patients and more frequently than with patients receiving placebo, were (0.63 mg Xopenex; 1.25 mg Xopenex; and placebo, respectively): nervousness (2.8%; 9.6%; NR‡), tremor (NR‡; 6.8%; NR‡), flu syndrome (4.2%; NR‡; NR‡), and tachycardia or increased heart rate (2.8%; 2.7%; NR‡).

†The mean duration of effect, as measured by a >15% increase from baseline FEV_1, was approximately 5 hours after administration of 0.63 mg of levalbuterol and approximately 6 hours after administration of 1.25 mg of levalbuterol after 4 weeks of treatment. In some patients, the duration of effect was as long as 8 hours.
‡Less than 2% reported.

Please see brief summary of prescribing information on adjacent page.

References: 1. Nelson HS, Bensch G, Pleskow WW, et al. Improved bronchodilation with levalbuterol compared with racemic albuterol in patients with asthma. *J Allergy Clin Immunol.* 1998;102:943-952. **2.** Xopenex Prescribing Information. **3.** Milgrom H, Skoner DP, Bensch G, et al. Low-dose levalbuterol in children with asthma: safety and efficacy in comparison with placebo and racemic albuterol. *J Allergy Clin Immunol.* 2001;108:938-945. **4.** *IMS* DDD Class of Trade Database, April 1999-May 2003.

IMPORTANT DATA VALIDATE THE VALUE OF XOPENEX

- **Greater peak mean % change** in FEV_1 in severe asthmatics with Xopenex 1.25 mg*[1]
- **Long duration of action:** TID dosing for greater patient convenience†[1,2]
- **Well-established safety profile across the dosing range, supported by over 250 million doses prescribed**[1-4]

*FEV_1 <60% of predicted.

Xopenex®
(levalbuterol HCl)

Inhalation Solution, 0.31 mg, 0.63 mg and 1.25 mg*

Breathing is Believing

*Potency expressed as levalbuterol.

Great Minds Think Alike

Think Taste. Think Guidelines. Think OMNICEF.

Indications (mild to moderate infections)[1]

Acute bacterial otitis media and **acute maxillary sinusitis** (adults and adolescents) due to *H influenzae* (including ß-lactamase producing strains), *S pneumoniae* (penicillin-susceptible strains only), and *M catarrhalis* (including ß-lactamase producing strains). Use of cefdinir in the treatment of acute maxillary sinusitis in pediatric patients is supported by evidence from adequate and well-controlled studies in adults and adolescents.

Pharyngitis/Tonsillitis due to *S pyogenes*. 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.

Safety information[1]

- OMNICEF is contraindicated in patients with known allergy to the cephalosporin class of antibiotics
- For patients with previous hypersensitivity reaction to penicillins, caution should be exercised because cross-hypersensitivity among ß-lactam antibiotics has been clearly documented. If an allergic reaction to cefdinir occurs, the drug should be discontinued
- Safety and efficacy in neonates and infants less than 6 months have not been established
- 2% of 2,289 pediatric patients discontinued medication due to adverse events in US and ex-US clinical trials. Discontinuations were primarily for gastrointestinal disturbance, usually diarrhea
- The most common reported adverse events occurring in ≥1% of pediatric patients in US clinical trials (N=1,783) were diarrhea (8%), rash (3%), and vomiting (1%)

Reference: 1. OMNICEF® (cefdinir) for Oral Suspension Prescribing Information, Abbott Laboratories.

Please see brief summary of prescribing information on following page.

OMNICEF®
(cefdinir) for oral suspension
125 mg/5 mL

Expert recommended.
Kid preferred.

Abbott Laboratories
Abbott Park, IL 60064

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031-034-9608-1 • September 2003

New ACIP Influenza Vaccination Recommendation for Infants and Children*

Universal Influenza Vaccination for All Healthy Infants and Children 6 to 23 Months of Age and Their Caregivers**

—

Effective Fall 2004

The National Foundation for Infectious Diseases (NFID) applauds CDC's Advisory Committee for Immunization Practices (ACIP) for its unanimous vote to recommend universal influenza vaccination for all healthy infants and children 6 to 23 months of age and their caregivers.

Children in this age group are at increased risk for influenza-related hospitalizations similar to rates among persons 65 years and older.

NFID encourages health care providers to plan pediatric influenza immunization programs for the 2004–2005 season.

Strategies to help pediatricians and family practitioners implement the new pediatric influenza recommendation are highlighted in a new NFID publication. Please visit our Web site: http://www.nfid.org/publications

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* ACIP recommendations are forwarded to the CDC director and secretary of Health and Human Services for review. If the ACIP recommendations are accepted by the CDC director and HHS secretary, they are published in the *Morbidity and Mortality Weekly Report* and become recommendations of the CDC.

**Two doses of inactivated influenza vaccine administered more than one month apart are recommended for previously unvaccinated children less than 9 years of age. If possible, the second dose should be administered before December. All subsequent annual influenza vaccinations require only one dose of vaccine.

Made possible by an unrestricted educational grant to the National Foundation for Infectious Diseases from Aventis Pasteur.

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