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VOLUME 19 NUMBER 4
October 2001

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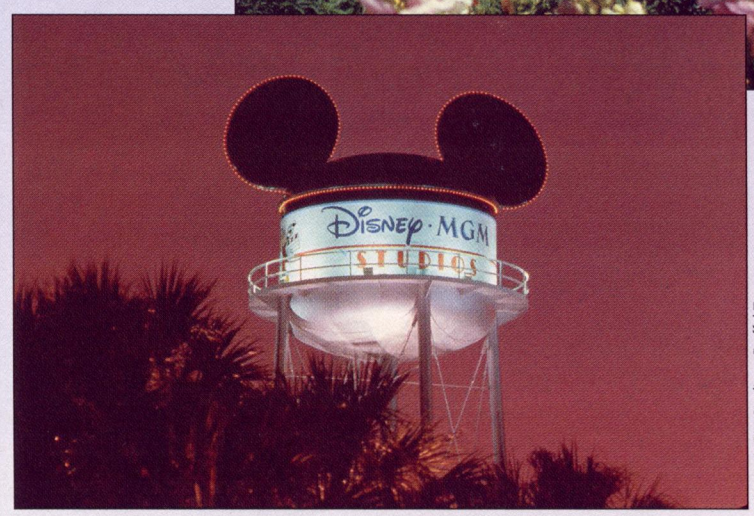

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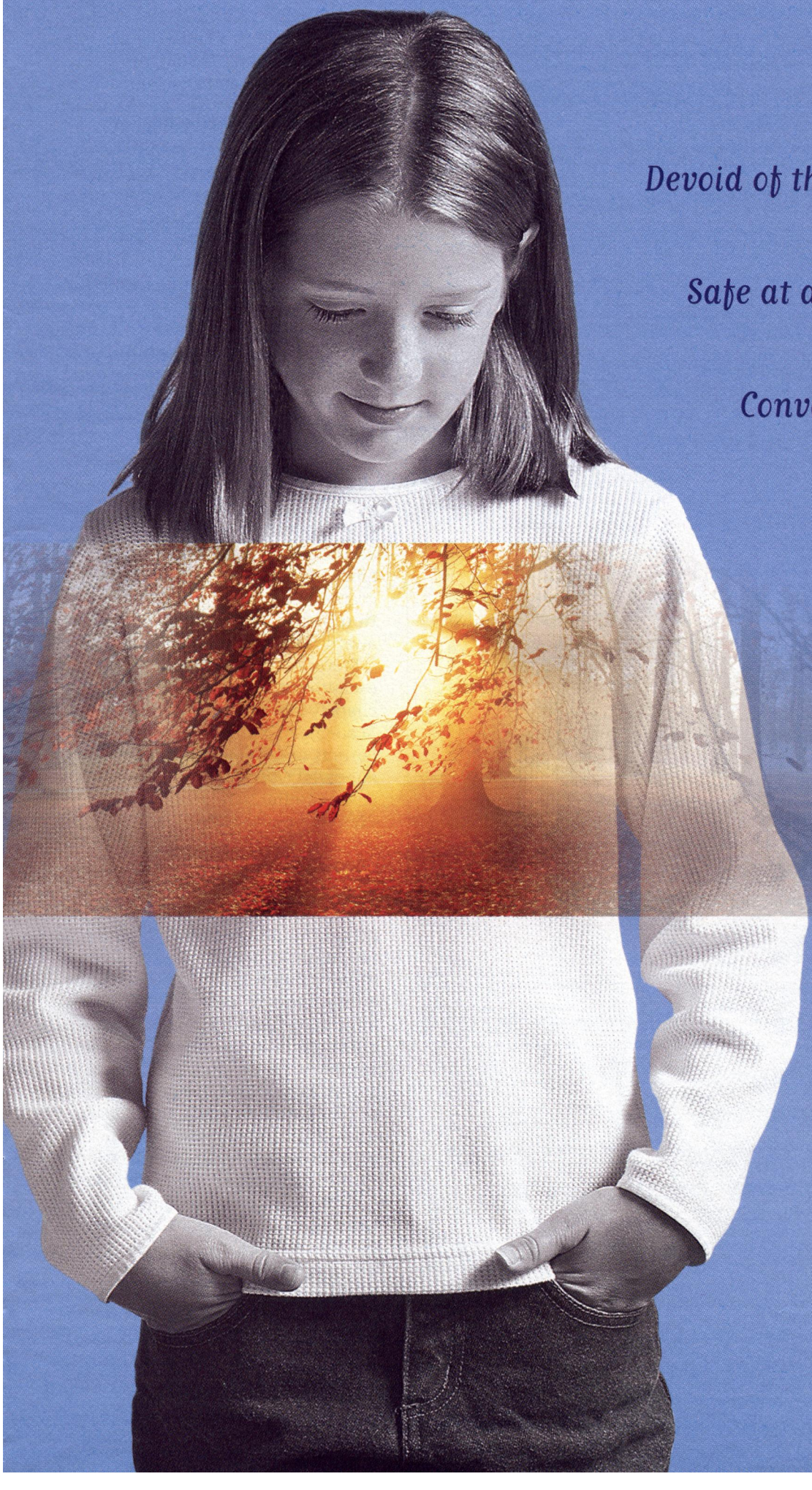

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Xopenex is contraindicated in patients with a history of hypersensitivity to levalbuterol HCl or racemic albuterol.

*Source IMS Health, NPA.

Nebulized inhalation solution market share expressed as a percentage of total prescriptions as of April, 2001.

†Less than 2% reported.

See adjacent page for Xopenex prescribing information and important safety information concerning ß-agonists.

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†Prednisolone base.

*Results of a blinded taste test conducted with 50 children, ages 4–11 years who, after tasting both Orapred and Prelone, were asked to state a preference.

References: 1. (Taste test) Data on file, Ascent Pediatrics, 1999. **2.** Dajani AS. Adherence to physicians' instructions as a factor in managing streptococcal pharyngitis. *Pediatrics.* 1996;97(6, pt 2):976-980. **3.** Matsui DM. Drug compliance in pediatrics. Clinical research and issues. *Pediatr Clin North Am.* 1997;44:1-14. **4.** (Parents survey) Data on file, Ascent Pediatrics, 1997. **5.** (Pediatrician survey) Data on file, Ascent Pediatrics, 1999.

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AD0604 9/01

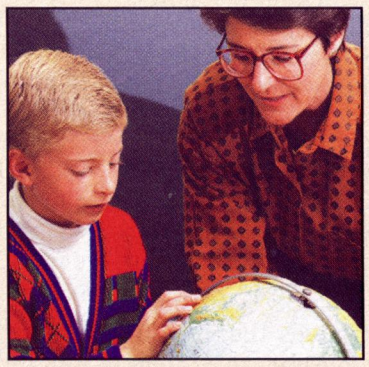
New Understandings in the Neurobiology and Treatment of ADHD

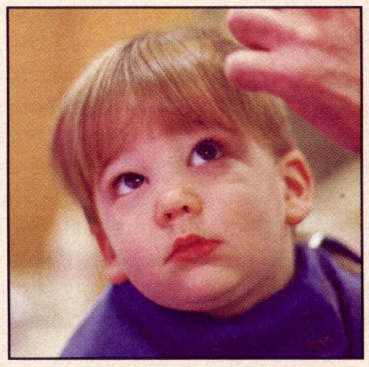
CME Dinner Symposium

Chairman: Joseph Biederman, MD,
Professor of Psychiatry, Harvard Medical School

Friday, October 19, 2001 ◆ 7:00 PM – 10:00 PM

The Argent Hotel San Francisco ◆ Metropolitan Ballroom 1 & 2 ◆ 50 Third Street ◆ San Francisco, California





Learning Objectives

Upon completion of this activity, the participant will be able to:

- Describe new developments in our understanding of the neurobiological basis of attention deficit-hyperactivity disorder (ADHD), especially structural and neurochemical abnormalities associated with the condition
- Review the evidence that ADHD is a disorder with a significant genetic component
- Explain the pharmacologic and nonpharmacologic consequences of viewing ADHD as a genetic disorder
- Review nonpharmacologic interventions, such as education, environmental changes, behavioral modification, and family and school support
- Describe the efficacy and adverse effects of nonstimulant pharmacologic agents in the treatment of ADHD
- Discuss the integration of new and traditional drug therapy with nonpharmacologic treatments

Faculty

CHAIRMAN

JOSEPH BIEDERMAN, MD
Chief, Clinical and Research Program in Pediatric Psychopharmacology
Professor of Psychiatry
Massachusetts General Hospital
Harvard Medical School
Boston, Massachusetts

PRESENTERS

Stephen V. Faraone, PhD
Associate Professor of Psychology in the Department of Psychiatry
Massachusetts General Hospital and Massachusetts Mental Health Center
Harvard Medical School
Boston, Massachusetts

Timothy Edwin Wilens, MD
Associate Professor of Psychiatry
Massachusetts General Hospital
Harvard Medical School
Boston, Massachusetts

Thomas J. Spencer, MD
Associate Professor of Psychiatry
Massachusetts General Hospital
Harvard Medical School
Boston, Massachusetts

Faculty Disclosure Statement

All faculty participating in continuing education activities sponsored by the Postgraduate Institute for Medicine are expected to disclose to the audience any real or apparent commercial financial affiliations related to the content of their presentations/materials.

Program Agenda

7:00 PM	RECEPTION AND DINNER
7:30 PM	INTRODUCTION Joseph Biederman, MD
7:35 PM	AN OVERVIEW OF ADHD AND ITS NEUROBIOLOGIC BASIS Joseph Biederman, MD
8:00 PM	THE GENETICS OF ADHD Stephen V. Faraone, PhD
8:20 PM	TREATMENT OF PEDIATRIC ADHD: THE ARMAMENTARIUM OF STIMULANTS Thomas J. Spencer, MD
8:50 PM	NEW THERAPEUTIC OPTIONS FOR ADHD: NOW AND INTO THE FUTURE Timothy Edwin Wilens, MD
9:10 PM	QUESTION AND ANSWER SESSION
9:30 PM	CONCLUSION Joseph Biederman, MD

Sponsored by Postgraduate Institute for Medicine

Accreditation

This activity has been 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 the Postgraduate Institute for Medicine (PIM) and IntraMed Educational Group. PIM is accredited by the ACCME to provide continuing medical education for physicians and takes responsibility for the content, quality, and scientific integrity of this CME activity.

Designation

Postgraduate Institute for Medicine designates this educational activity for a maximum of 2.0 hours 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.

Audience

The program is intended for pediatricians and allied health professionals interested in ADHD. Enrollment for this dinner symposium is complimentary and reservations are recommended. Because enrollment for this program is limited, registration will be accepted on a first-come, first-served basis. Please e-mail your registration information to ADHD@intramedgroup.com to enroll in advance.

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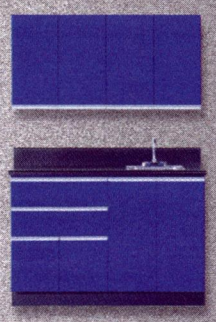
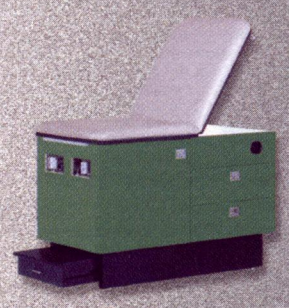


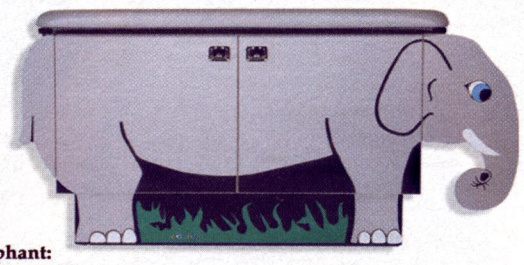
Casework

Infant Table & Scale

School Bus



Pro Series



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H 35" W 24" L 70"
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Safari 4x4:
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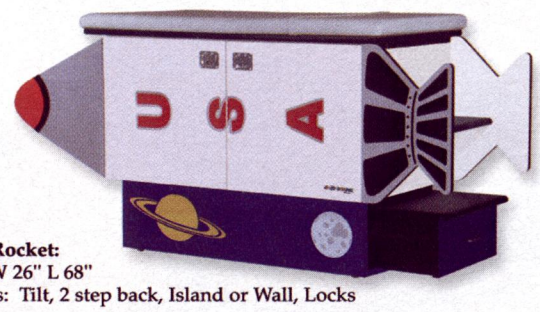

Space Rocket:
H 33" W 26" L 68"
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Blast off your exams with the Space Rocket. A two step walk up back with a retractable bottom step makes boarding fun and efficient. Lockable doors open to expose the large cargo bay equipped with adjustable shelves.

Submarine:
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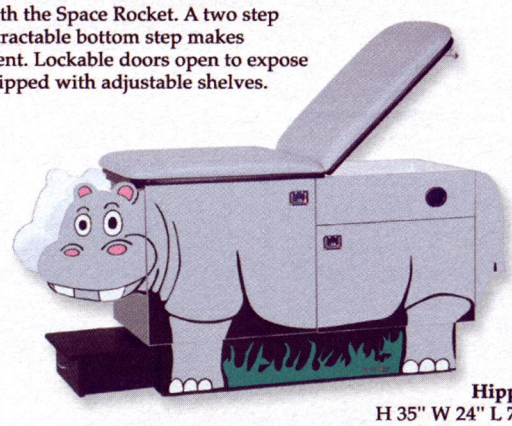
Your patients will feel like a captain aboard the Submarine. It features a two step walk up back that will reduce lifting and save you time. Below the 2" thick comfort pad are large cabinets with adjustable shelves.



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Brief Summary. Please see product insert for complete prescribing information.
For otic use only.

INDICATIONS AND USAGE
FLOXIN® Otic (ofloxacin otic solution) 0.3% is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:
Otitis Externa in adults and pediatric patients, one year and older, due to *Staphylococcus aureus and Pseudomonas aeruginosa.*
Chronic Suppurative Otitis Media in patients 12 years and older with perforated tympanic membranes due to *Staphylococcus aureus, Proteus mirabilis, and Pseudomonas aeruginosa.*
Acute Otitis Media in pediatric patients one year and older with tympanostomy tubes due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, and Pseudomonas aeruginosa.*

CONTRAINDICATIONS
FLOXIN® Otic (ofloxacin otic solution) 0.3% is contraindicated in patients with a history of hypersensitivity to ofloxacin, to other quinolones, or to any of the components in this medication.

WARNINGS
NOT FOR OPHTHALMIC USE.
NOT FOR INJECTION.
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been *reported in patients* receiving systemic quinolones, including ofloxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to ofloxacin is suspected, stop the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management, including intubation, should be administered as clinically indicated.

PRECAUTIONS
General: As with other anti-infective preparations, prolonged use may result in over-growth of nonsusceptible organisms including fungi. If the infection is not improved after one week, cultures should be obtained to guide further treatment. If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumor.
The systemic administration of quinolones, including ofloxacin at doses much higher than given or absorbed by the otic route, has led to lesions or erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species.
Young growing guinea pigs dosed in the middle ear with 0.3% ofloxacin otic solution showed no systemic effects, lesions or erosions of the cartilage in weight-bearing joints, or other signs of arthropathy. No drug-related structural or functional changes of the cochlea and no lesions in the ossicles were noted in the guinea pig following otic administration of 0.3% ofloxacin for one month.
No signs of local irritation were found when 0.3% ofloxacin was applied topically in the rabbit eye. Ofloxacin was also shown to lack dermal sensitizing potential in the guinea pig maximization study.
Information for Patients: Avoid contaminating the application tip with material from the fingers or other sources. This precaution is necessary if the sterility of the drops is to be preserved.Systemic quinolones, including ofloxacin, have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

Otitis Externa
Prior to administration of FLOXIN® Otic in patients with otitis externa, the solution should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. This position should be maintained for five minutes to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear (see DOSAGE AND ADMINISTRATION).
Acute Otitis Media and Chronic Suppurative Otitis Media
In pediatric patients (from 1 to 12 years old) with acute otitis media with tympanostomy tubes and in patients with chronic suppurative otitis media with perforated tympanic membranes, prior to administration, the solution should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. The tragus should then be pumped 4 times by pushing inward to facilitate penetration of the drops into the middle ear. This position should be maintained for five minutes. Repeat, if necessary, for the opposite ear (see **DOSAGE AND ADMINISTRATION**).
Drug Interactions: Specific drug interaction studies have not been conducted with FLOXIN® Otic.
Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term studies to determine the carcinogenic potential of ofloxacin have not been conducted. Ofloxacin was not mutagenic in the Ames test, the sister chromatid exchange assay (Chinese hamster and human cell lines), the unscheduled DNA synthesis (UDS) assay using human fibroblasts, the dominant lethal assay, or the mouse micro-nucleus assay. Ofloxacin was positive in the rat hepatocyte UDS assay, and in the mouse lymphoma assay. In rats, ofloxacin did not affect male or female reproductive performance at oral doses up to 360 mg/kg/day. This would be over 1000 times the maximum recommended clinical dose, based upon body surface area, assuming total absorption of ofloxacin from the ear of a patient treated with FLOXIN® Otic twice per day.
Pregnancy
Teratogenic effects: Pregnancy Category C. Ofloxacin has been shown to have an embryocidal effect in rats at a dose of 810 mg/kg/day and in rabbits at 160 mg/kg/day.
These dosages resulted in decreased fetal body weights and increased fetal mortality in rats and rabbits, respectively. Minor fetal skeletal variations were reported in rats receiving doses of 810 mg/kg/day. Ofloxacin has not been shown to be teratogenic at doses as high as 810 mg/kg/day and 160 mg/kg/day when administered to pregnant rats and rabbits, respectively.
Ofloxacin has not been shown to have any adverse effects on the developing embryo or fetus at doses relevant to the amount of ofloxacin that will be delivered ototopically at the recommended clinical doses.
Nonteratogenic Effects: Additional studies in the rat demonstrated that doses up to 360 mg/kg/day during late gestation had no adverse effects on late fetal development, labor, delivery, lactation, neonatal viability, or growth of the newborn. There are, however, no adequate and well-controlled studies in pregnant women. FLOXIN® Otic should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nursing Mothers: In nursing women, a single 200 mg oral dose resulted in concentrations of ofloxacin in milk which were similar to those found in plasma. It is not known whether ofloxacin is excreted in human milk following topical otic administration. Because of the potential for serious adverse reactions from ofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric Use: No changes in hearing function occurred in 30 pediatric subjects treated with ofloxacin otic and tested for audiometric parameters. Although safety and efficacy have been demonstrated in pediatric patients one year and older,

For middle ear infections with otorrhea†‡...

★ FLOXIN® Otic is the first-and-only FDA-approved treatment for acute otitis media with tympanostomy tubes† and chronic suppurative otitis media with a perforated tympanic membrane‡:

†Acute otitis media (AOM TT) in pediatric patients ≥1 year of age with tympanostomy tubes due to *Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus pneumoniae, Moraxella catarrhalis*, and *Haemophilus influenzae*

‡Chronic suppurative otitis media (CSOM) in patients ≥12 years of age with a perforated tympanic membrane due to *Pseudomonas aeruginosa, Staphylococcus aureus*, and *Proteus mirabilis*

★ FLOXIN Otic achieves excellent eradication and cure rates of the most common pathogens.[1-3]

- **Acute middle ear infection with otorrhea in patients with tympanostomy tubes is most often caused by *Pseudomonas aeruginosa* and requires a distinct treatment.**
- **FLOXIN Otic is the *only* ototopical drop indicated for *Pseudomonas aeruginosa* infection of the middle ear.**
- **Augmentin® is not effective in eradicating middle ear infections caused by *Pseudomonas aeruginosa*.[§4]**

Patients with acute otitis media with tympanostomy tubes[2]

	ERADICATION RATE	CURE RATE
Pseudomonas aeruginosa	95%	84%
Staphylococcus aureus	98%	89%
Streptococcus pneumoniae	99%	82%
Moraxella catarrhalis	97%	79%
Haemophilus influenzae	97%	76%

Patients with chronic suppurative otitis media[2]

	ERADICATION RATE	CURE RATE
Pseudomonas aeruginosa	100%	97%
Staphylococcus aureus	100%	90%
Proteus mirabilis	100%	100%

[§]Augmentin is a registered trademark of SmithKline Beecham Corp.

Most commonly reported adverse reactions in clinical trials in patients treated with FLOXIN® Otic for acute otitis media with tympanostomy tubes and for chronic suppurative otitis media with a perforated tympanic membrane (n=656): taste perversion (7%), earache (1%), pruritus (1%), paraesthesia (1%), rash (1%), and dizziness (1%).

FLOXIN Otic is contraindicated in patients with a history of hypersensitivity to ofloxacin, other quinolones, or other ingredients of the medication, and should be discontinued at the first sign of allergic reaction. Patients who have not improved after 1 week of treatment should be evaluated by their doctor.

Safety and efficacy have not been established in patients <1 year of age with acute otitis media with tympanostomy tubes, or in patients <12 years of age with chronic suppurative otitis media.

Please see brief summary below, including adverse events and contraindications.

First-line therapy

FLOXIN® (ofloxacin otic solution) 0.3% OTIC B.I.D.

the power drop™

safety and effectiveness in infants below the age of one year have not been established. Although quinolones, including ofloxacin, have been shown to cause arthropathy in immature animals after systemic administration, young growing guinea pigs dosed in the middle ear with 0.3% ofloxacin otic solution for one month showed no systemic effects, quinolone-induced lesions, erosions of the cartilage in weight-bearing joints, or other signs of arthropathy.

ADVERSE REACTIONS

In the Phase III registration trials, a total of 885 subjects were treated with ofloxacin otic solution. This included 229 subjects with otitis externa (with intact tympanic membranes) and 656 subjects with acute otitis media with tympanostomy tubes or chronic suppurative otitis media with perforated tympanic membranes. The reported treatment-related adverse events are listed below:

Subjects with Otitis Externa

The following treatment-related adverse events occurred in 1% or more of the subjects with intact tympanic membranes.

Adverse Event	Frequency (n = 229)
Pruritus	4%
Application Site Reaction	3%
Dizziness	1%
Earache	1%
Vertigo	1%

The following treatment-related adverse events were each reported in a single subject: dermatitis, eczema, erythematous rash, follicular rash, rash, hypoaesthesia, tinnitus, dyspepsia, hot flushes, flushing, and otorrhagia.

Subjects with Acute Otitis Media with Tympanostomy Tubes and Subjects with Chronic Suppurative Otitis Media with Perforated Tympanic Membranes

The following treatment-related adverse events occurred in 1% or more of the subjects with non-intact tympanic membranes.

Adverse Event	Frequency (n = 656)
Taste Perversion	7%
Earache	1%
Pruritus	1%
Paraesthesia	1%
Rash	1%
Dizziness	1%

Other treatment-related adverse reactions reported in subjects with non-intact tympanic membranes included: diarrhea (0.6%), nausea (0.3%), vomiting (0.3%), dry mouth (0.5%), headache (0.3%), vertigo (0.5%), otorrhagia (0.6%), tinnitus (0.3%), fever (0.3%). The following treatment-related adverse events were each reported in a single subject: application site reaction, otitis externa, urticaria, abdominal pain, dysaesthesia, hyperkinesia, halitosis, inflammation, pain, insomnia, coughing, pharyngitis, rhinitis, sinusitis, and tachycardia.

DOSAGE AND ADMINISTRATION

Otitis Externa: The recommended dosage regimen for the treatment of otitis externa is: For pediatric patients (from 1 to 12 years old): Five drops (0.25 mL, 0.75 mg ofloxacin) instilled into the affected ear twice daily for ten days. For patients 12 years and older: Ten drops (0.5 mL, 1.5 mg ofloxacin) instilled into the affected ear twice daily for ten days. The solution should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. This position should be maintained for five minutes to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear.

Acute Otitis Media in pediatric patients with tympanostomy tubes: The recommended dosage regimen for the treatment of acute otitis media in pediatric patients (from one to 12 years old) with tympanostomy tubes is: Five drops (0.25 mL, 0.75 mg ofloxacin) instilled into the affected ear twice daily for ten days.

The solution should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. The tragus should then be pumped 4 times by pushing inward to facilitate penetration of the drops into the middle ear. This position should be maintained for five minutes. Repeat, if necessary, for the opposite ear.

Chronic Suppurative Otitis Media with perforated tympanic membranes: The recommended dosage regimen for the treatment of chronic suppurative otitis media with perforated tympanic membranes in patients 12 years or older is: Ten drops (0.5 mL, 1.5 mg ofloxacin) instilled into the affected ear twice daily for fourteen days.

The solution should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, before instilling the drops. The tragus should then be pumped 4 times by pushing inward to facilitate penetration into the middle ear. This position should be maintained for five minutes. Repeat, if necessary, for the opposite ear.

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(FPI April 20, 1999)

References:

1. Goldblatt EL, Dohar J, Nozza RJ, Nielsen RW, et al. Topical ofloxacin versus systemic amoxicillin/clavulanate in purulent otorrhea in children with tympanostomy tubes. *Int J Pediatr Otorhinolaryngol.* 1999;46:91-101.
2. Based on overall responses of twice-daily ofloxacin-treated patients in Phase III clinical trials (NDA 20-799).
3. Agro AS, Garner ET, Wright III JW, Caballeros de Escobar I, et al. Clinical trial of ototopical ofloxacin for treatment of chronic suppurative otitis media. *Clin Ther.* 1998;20:744-759.
4. *Physicians' Desk Reference.* Montvale, NJ: Medical Economics Co; 2001:3069.

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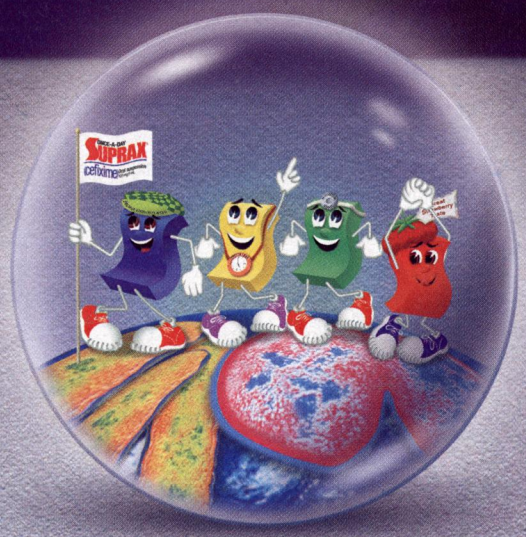
FO-101-175 08/01

REDISCOVER SUPRAX®

In the changing microbiological environment of AOM, increasing resistance of *Haemophilus influenzae* and *Moraxella catarrhalis* should be a concern.[1,2]*

SUPRAX demonstrates excellent activity against beta-lactamase± strains of both *H. influenzae* and *M. catarrhalis*.[3]

Rediscover potency against gram-negative pathogens.
Rediscover SUPRAX.



*SUPRAX is indicated for acute otitis media due to susceptible strains of *H. influenzae* (ß-lactamase±), *M. catarrhalis* (most of which are ß-lactamase+), and *Streptococcus pyogenes*.

Please see brief summary of Prescribing Information on adjacent page for WARNINGS, ADVERSE REACTIONS, and CONTRAINDICATIONS. GI UPSET IS THE MOST FREQUENTLY REPORTED SIDE EFFECT.

SUPRAX is administered as a single dose, once a day, or if preferred, in equally divided doses twice a day.

References: 1. Jorgensen JH, Doern GV, Maher LA, et al. Antimicrobial resistance among respiratory isolates of *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Streptococcus pneumoniae* in the United States. *Antimicrob Agents Chemother.* 1990;34:2075-2080. **2.** Doern GV, Jones RN, Pfaller MA, et al. *Haemophilus influenzae* and *Moraxella catarrhalis* from patients with community-acquired respiratory tract infections: antimicrobial susceptibility patterns from the SENTRY Antimicrobial Surveillance Program (United States and Canada, 1997). *Antimicrob Agents Chemother.* 1999;43:385-389. **3.** Barry AL, Pfaller MA, Fuchs PC, et al. In vitro activities of 12 orally administered antimicrobial agents against four species of bacterial respiratory pathogens from U.S. medical centers in 1992 and 1993. *Antimicrob Agents Chemother.* 1994;38:2419-2425.

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ONCE-A-DAY
SUPRAX®
(cefixime) Oral suspension
100 mg/5 mL

Potent. Proven. Practical.

SUPRAX®

(cefixime) Oral suspension 100 mg/5 mL

BRIEF SUMMARY FOR THE PHYSICIAN
See package insert for full Prescribing Information

INDICATIONS AND USAGE:
SUPRAX (cefixime) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms: ***Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis***, caused by ***Streptococcus pneumoniae*** and ***Haemophilus influenzae*** (beta-lactamase positive and negative strains). ***Otitis Media*** caused by ***H. influenzae*** (beta-lactamase positive and negative strains), ***Moraxella (Branhamella) catarrhalis*** (most of which are beta-lactamase positive), and ***Streptococcus pyogenes*. Pharyngitis and Tonsillitis,*** caused by ***S. pyogenes.*** Note: Penicillin is the usual drug of choice in the treatment of ***S. pyogenes*** infections, including the prophylaxis of rheumatic fever. SUPRAX is generally effective in the eradication of ***S. pyogenes*** from the nasopharynx; however, data establishing the efficacy of SUPRAX in the subsequent prevention of rheumatic fever are not available. ***Uncomplicated Urinary Tract Infections*** caused by ***Escherichia coli*** and ***Proteus mirabilis. Uncomplicated gonorrhea*** **(cervical/urethral)** caused by ***Neisseria gonorrhoeae*** (penicillinase- and nonpenicillinase-producing strains). Appropriate cultures and susceptibility studies should be performed to determine the causative organism and its susceptibility to SUPRAX; however, therapy may be started while awaiting the results of these studies. Therapy should be adjusted, if necessary, once these results are known.

*Efficacy for this organism in this organ system was studied in fewer than 10 infections.

CONTRAINDICATIONS:
In patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS:
BEFORE THERAPY WITH SUPRAX IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS HYPERSENSITIVITY AMONG BETA-LACTAM ANTIBIOTICS HAS BEEN CLEARLY DOCUMENTED AND MAY OCCUR IN UP TO 10% OF PATIENTS WITH A HISTORY OF PENICILLIN ALLERGY. IF AN ALLERGIC REACTION TO SUPRAX OCCURS, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, AS CLINICALLY INDICATED.

Administer antibiotics, including SUPRAX, cautiously to any patient who has demonstrated some form of allergy, particularly to drugs. Treatment with broad-spectrum antibiotics, including SUPRAX, 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 severe antibiotic-associated diarrhea including pseudomembranous colitis.

Pseudomembranous colitis has been reported with the use of SUPRAX and other broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider this diagnosis in patients who develop diarrhea in association with the use of antibiotics. Symptoms of pseudomembranous colitis may occur during or after antibiotic treatment and may range in severity from mild to life-threatening. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, management should include fluids, electrolytes, and protein supplementation. If the colitis does not improve after the drug has been discontinued, or if the symptoms are severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be excluded.

PRECAUTIONS:
General: The possibility of the emergence of resistant organisms which might result in overgrowth should be kept in mind, particularly during prolonged treatment. In such use, careful observation of the patient is essential. Take appropriate measures if superinfection occurs during therapy. Adjust the SUPRAX dose in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Monitor patients on dialysis carefully. (See **DOSAGE AND ADMINISTRATION** in full Prescribing Information.) Prescribe SUPRAX with caution in individuals with a history of gastrointestinal (GI) disease, particularly colitis. **Drug Interactions:** *Carbamazepine*—Elevated carbamazepine levels have been reported when SUPRAX is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations. **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 SUPRAX may result in a false-positive reaction for glucose in the 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. A false-positive direct Coombs test has been reported during treatment with other cephalosporin antibiotics; it should be recognized that a positive Coombs test may be due to the drug. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** Lifetime studies in animals to evaluate carcinogenic potential have not been conducted. SUPRAX did not cause point mutations in bacteria or mammalian cells, DNA damage, or chromosome damage *in vitro* and did not exhibit clastogenic potential *in vivo* in the mouse micronucleus test. In rats, fertility and reproductive performance were not affected by cefixime at doses up to 125 times the adult therapeutic dose. **Usage in Pregnancy:** Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 400 times the human dose and have revealed no evidence of harm to the fetus due to SUPRAX. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. **Labor and Delivery:** SUPRAX has not been studied for use during labor and delivery. Give only if clearly needed. **Nursing Mothers:** It is not known whether SUPRAX is excreted in human milk. Consider discontinuing nursing temporarily during treatment. **Pediatric Use:** Safety and effectiveness of SUPRAX in children aged less than six months old have not been established. The incidence of GI adverse reactions, including diarrhea and loose stools, in pediatric patients receiving the suspension, was comparable to the incidence seen in adult patients receiving tablets.

ADVERSE REACTIONS:
Most adverse reactions observed in clinical trials were of a mild and transient nature. Five percent of patients in the U.S. trials discontinued therapy because of drug-related adverse reactions. The most common adverse reactions in U.S. trials of the tablet formulation were GI events, which were reported in 30% of adult patients on either the BID or the QD regimen. Clinically mild GI side effects occurred in 20% of all patients, moderate events in 9%, and severe adverse reactions occurred in 2% of all patients. Individual event rates included diarrhea 16%, loose or frequent stools 6%, abdominal pain 3%, nausea 7%, dyspepsia 3%, and flatulence 4%. The incidence of GI adverse reactions, including diarrhea and loose stools, in pediatric patients receiving the suspension was comparable to that seen in adult patients receiving tablets. Symptoms usually responded to symptomatic therapy or ceased when SUPRAX was discontinued. Several patients developed severe diarrhea and/or documented pseudomembranous colitis, and a few required hospitalization.

The following adverse reactions have been reported following the use of SUPRAX. Incidence rates were less than 1 in 50 (less than 2%), except as noted above for GI events. *GI* (see above): Diarrhea, loose stools, abdominal pain, dyspepsia, nausea, and vomiting. Several cases of documented pseudomembranous colitis were identified during the studies; onset of symptoms may occur during or after therapy. *Hypersensitivity Reactions*: Skin rashes, urticaria, drug fever, and pruritus. Erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have been reported. *Hepatic*: Transient elevations in SGPT, SGOT, and alkaline phosphatase. *Renal*: Transient elevations in BUN or creatinine. *Central Nervous System*: Headaches or dizziness. *Hemic and Lymphatic Systems*: Transient thrombocytopenia, leukopenia, and eosinophilia. Prolongation in prothrombin time was seen rarely. *Other*: Genital pruritus, vaginitis, candidiasis.

In addition to the adverse reactions listed above which have been observed in patients treated with SUPRAX, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics: *Adverse Reactions*: Allergic reactions including anaphylaxis, toxic epidermal necrolysis, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage, and colitis.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. (See **DOSAGE AND ADMINISTRATION** in full Prescribing Information, and **OVERDOSAGE**.) If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated. *Abnormal Laboratory Tests*: Positive direct Coombs test, elevated bilirubin, elevated LDH, pancytopenia, neutropenia, agranulocytosis.

OVERDOSAGE:
Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2 g of SUPRAX did not differ from the profile seen in patients treated at the recommended doses.

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This Brief Summary is based on the current circular CI 4468-3, Revised October 22, 1998.

For years, doctors have been saying what a baby's skin really needs is **air.**

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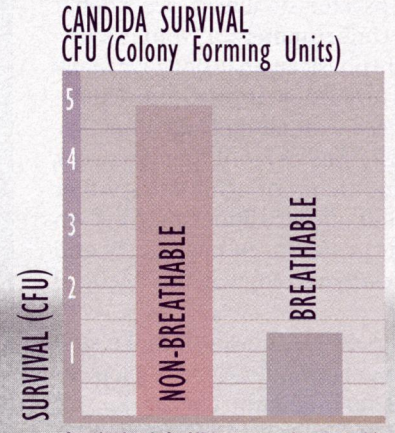
Huggies® diapers have an outer cover that's especially permeable, a unique inner structure that promotes air-flow, and two solid reasons to recommend them.

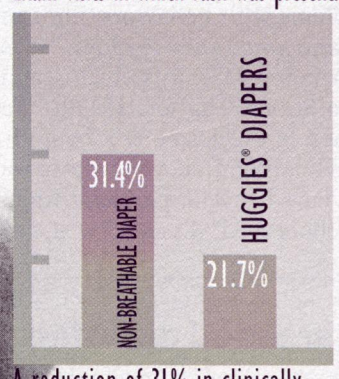
1 Huggies® inhibits growth of Candida Albicans cells by 75%.



Survival of C. Albicans on human skin was reduced by 75% with Huggies® breathable diapers covers.

2 Huggies® reduces the prevalence of Diaper Dermatitis by nearly one-third.

Double blind clinical study results. Exam visits in which rash was present.



A reduction of 31% in clinically diagnosed cases of Diaper Dermatitis for babies wearing Huggies® Supreme Diapers.

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* Withdrawals would be subject to income tax and may be subject to an additional 10% federal income tax penalty.

AC-00-013 (3/01)

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- Low frequency of adverse events in actual use[1]

* Tylenol is a registered trademark of McNeil Consumer Products Company.
† Based on reducing temperature to <100°F; liquid formulations only.

Reference: 1. Clinical study: Children's analgesic medicine project (CAMP). Unpublished study. Medical Department, Whitehall-Robins Healthcare.

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