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SUPER CME 2002

What Every Pediatrician Should Know for the 21st Century

April 17-20, 2002
Orlando, Florida
The Hilton in the Walt Disney World Resort

From the basics to the leading edge
Advance your career with four days of pediatric practice-building education in one super event.

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SuperCME is designed for...
experienced general pediatricians, those just starting their careers, pediatric residents, family physicians and allied health professionals.

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Internet: www.aap.org/profed/cmeCourses.htm, call (866) TheAAP (866) 843-2271, outside the U.S. and Canada call (847) 434-4000 ext. 5830.
STAY TUNED

SOMETHING NEW
IS COMING

SOON

Zithromax®
(azithromycin for oral suspension)
How many hours can one kid spend in “time-out”?

Parents ask their pediatricians all sorts of things.

Teaching kids how to behave and parents how they can guide them—2 of the topics that may not have been covered in your textbooks. Pfizer Pediatric Health, which brought you the highly successful Bright Futures program, introduces the Parent Equation program. Developed with the New York University Child Study Center, Parent Equation materials help you to quickly address tough parenting issues, such as:

- Positive parenting
- Cultivating language and communication
- Raising a well-adjusted child

Contact your Pfizer representative or call 1-800-PED-2323 for complimentary Parent Equation materials. (And make more time for your practice.)
DHA and ARA are vital nutrients, essential for proper infant brain and eye development. Both are naturally found in breast milk and... may soon be added to select U.S. infant formulas!

There have been numerous clinical studies involving the supplementation of infant formulas with DHA (docosahexaenoic acid) and ARA (arachidonic acid) and many have reported significant benefits. In fact, one study concluded that infants fed formula containing Martek's DHA and ARA scored 7 points higher on the Bayley Mental Development Index (MDI) and could see better by one line on the eye chart, compared to infants fed formula without Martek's DHA and ARA.

Infant formulas containing Martek's DHA and ARA are sold in over 60 countries including the United Kingdom and Australia. Martek is the only source for U.S. FDA GRAS reviewed DHA and ARA for use in infant formula.


Breast-feeding is best but if a mother cannot, or chooses not to, breast-feed, then the formula recommended should be as close as possible to breast milk.

To receive a free medical professional's guide to the importance of DHA and ARA, call toll free: 1-888-652-7246
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- for short-term and intermittent long-term therapy
- 0.1% and 0.03% for adults; 0.03% for children aged 2 to 15 years
- for patients who:
  - should avoid the potential risks of conventional therapies
  - are not adequately responsive to conventional therapies
- apply anywhere—including face, neck, sensitive areas

The most common adverse events associated with the use of Protopic Ointment included the sensation of skin burning, pruritus, flu-like symptoms, and headache. Local symptoms are most common during the first few days of application and typically improve as lesions heal.

Protopic Ointment is contraindicated in patients who are hypersensitive to tacrolimus or any of the other ingredients of Protopic.

Please see brief summary of prescribing information on the following page.

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New from the Makers of Ritalin®
(methylphenidate HCl)

Focalin™
Is Now Approved!

New Focalin™
dexmethylphenidate HCl
tablets 15mg, 30mg, 60mg

Contact your local Novartis representative or for customer information call 1-866-4FOCALIN (436-2254)

Please see brief summary of prescribing information on the following page.
**Give your patients a gold star**

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 specified organisms in the specific conditions listed below.

**Acute 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 tympanosclerotic membroanes due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Neutrophilic Influenzae*, *Monaella cattalhia*, 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.**

Sensitization 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 oedema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to ofloxacin is suspected, stop the drug. Sensitization 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 overgrowth of non-susceptible organisms including fungi. If the infection is not improved after one week, cultures should be obtained to guide further treatment. If otitis persists after a full course of therapy, or if two or more episodes of otitis 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 weans 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 solution showed no systemic effects, lesions or erosions of the cartilage in weight-bearing joints, or other signs of arthropathy in immature animals of various species.

**Young growing guinea pigs dosed in the middle ear with 0.3% ofloxacin solution showed no systemic effects, lesions or erosions of the cartilage in weight-bearing joints, or other signs of arthropathy in immature animals of various species.**

**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. 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^1^ and chronic suppurative otitis media with a perforated tympanic membrane^2^:

- 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.\(^1\)\(^\text{3}\)

- 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**\(^\text{1}\) is not effective in eradicating middle ear infections caused by *Pseudomonas aeruginosa*.\(^2\)

### Patients with acute otitis media with tympanostomy tubes^1^

<table>
<thead>
<tr>
<th>Pathogenic Microorganism</th>
<th><strong>ERADICATION RATE</strong></th>
<th><strong>CURE RATE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>95%</td>
<td>84%</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>98%</td>
<td>89%</td>
</tr>
<tr>
<td><em>Streptococcus pneumoniae</em></td>
<td>99%</td>
<td>82%</td>
</tr>
<tr>
<td><em>Moraxella catarrhalis</em></td>
<td>97%</td>
<td>79%</td>
</tr>
<tr>
<td><em>Haemophilus influenzae</em></td>
<td>97%</td>
<td>76%</td>
</tr>
</tbody>
</table>

\(^1\)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 = 650): 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.

<table>
<thead>
<tr>
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<th><strong>ERADICATION RATE</strong></th>
<th><strong>CURE RATE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
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<td>97%</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>100%</td>
<td>90%</td>
</tr>
<tr>
<td><em>Proteus mirabilis</em></td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

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 to two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should be with the affected ear upward, and then the drops should be instilled by holding the bottle at a 90° angle 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 to two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should be with the affected ear upward, and then the drops should be instilled. The dropper 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.

**References:**
2. Based on overall responses of twice-daily ofloxacin-treated patients in Phase III clinical trials (FAO 20-799).

**Orchard**

**FDA**

**DAIICHI PHARMACEUTICAL CORPORATION**
Montvale, NJ 07645

**References:**
2. Based on overall responses of twice-daily ofloxacin-treated patients in Phase III clinical trials (FAO 20-799).
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Devoid of the unnecessary left isomer, (S)-albuterol

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Important Safety Information
Adverse events occurring in ≥2% of patients treated with 0.63 mg and 1.25 mg Xopenex, respectively, included flu syndrome (4.2%; N/A), tachycardia or increased heart rate (2.8%; 2.7%), nervousness (2.8%; 9.6%), tremor (N/A; 6.8%). Xopenex Inhalation Solution at a dose of 1.25 mg produced a slightly higher rate of systemic β-adrenergic adverse effects than 2.5 mg dose of racemic albuterol sulfate inhalation solution.

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

*Storcs IMS Health, NP.

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 β-agonists.