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<td>Enfamil</td>
<td>Milk-based</td>
<td>Most babies</td>
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<tr>
<td>Lactofree*</td>
<td>Milk-based; lactose-free (no milk sugar)</td>
<td>Babies with common feeding problems (such as fussiness, gas, diarrhea) when due to lactose sensitivity</td>
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<td>Nutramigen*</td>
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Toddler Formulas

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<td>Next Step*</td>
<td>Milk-based alternative to cow's milk</td>
<td>Most toddlers</td>
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<tr>
<td>Next Step* Soy</td>
<td>Soy-based alternative to cow's milk</td>
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........................................................................................................................................
Proven clinical success* in acute otitis media¹,² due to *H. influenzae*, *M. catarrhalis*, and *S. pneumoniae*

- **91%** BIAxin (n=112) vs **91%** Augmentin® (amoxicillin/clavulanate) (P=NS) (n=121)

- Significantly lower incidence of diarrhea vs Augmentin® (amoxicillin/clavulanate) in two well-controlled studies (P<.001)¹

- Very well tolerated: low incidence of adverse events,¹ including diarrhea 6%, vomiting 6%, abdominal pain 3%, rash 3%, headache 2%

- **Dosing:** 15 mg/kg/day divided BID for 10 days

- **New Improved Flavor**
  125mg/5mL strength bottle now in fruit punch flavor

- **New 50-mL bottle**
  For both the 125 mg/5 mL and 250 mg/5 mL strengths

- **Low cost** vs Augmentin³³

* Clinical success = clinical cure or improvement.

† Based on AWP comparison, which is a published list price and may not represent actual price paid by pharmacies and consumers. Dose based on patient weight per 10-day course of therapy for acute otitis media. Comparison is between BIAxin and Augmentin (amoxicillin/clavulanate), a registered trademark of SmithKline Beecham Pharmaceuticals.

References:

PLEASE SEE BRIEF SUMMARY OF PRESCRIBING INFORMATION ON FOLLOWING PAGE.
CONTRAINDICATIONS: Clarithromycin is contraindicated in patients with a known hypersensitivity to clarithromycin or any of the components in the product. Clarithromycin is contraindicated in patients receiving terfezadine therapy who have preexisting cardiac abnormalities (cardiac arrhythmia, left ventricular failure, proarrhythmia, or prolongation of the QT interval). Cardiac abnormalities associated with heart disease, constrictive pericarditis, or myocardial ischemia may also be observed.

WARNINGS: CLARITHROMYCIN SHOULD NOT BE USED IN PREGNANT WOMEN EXCEPT IN CLINICAL CIRCUMSTANCES WHERE NO ALTERNATIVE THERAPY, IE, PENICILLIN, OCCURS WHILE TAKING THIS DRUG, THE PATIENT IS UNAWARE OF THE POTENTIAL HAZARD TO THE FETUS. CLARITHROMYCIN HAS DEMONSTRATED ADVERSE EFFECTS OF PREGNANCY OUTCOME AND/or EMBRYO-FETAL DEVELOPMENT IN MONKEYS, RATS, MICE, AND RABBITS AT DOSES THAT PRODUCED PLASMA LEVELS 2 TO 10 TIMES THE SERUM LEVELS ACHIEVED IN HUMANS TREATED AT THE MAXIMUM RECOMMENDED HUMAN DOSES. (See PRECAUTIONS - Prenatal).

Pseudomembranous colitis has been reported with nearly all macrolide antibiotics, 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 bacteria not normally resistant to the action of antibiotics. Clarithromycin, like other macrolides, may be associated with a toxin produced by Cladidrium difficile in a primary care setting. When severe, pseudomembranous colitis may be accompanied by the onset of a severe, sometimes fatal, systemic illness described as hypotension and colitis. It is therefore important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Information to Patients: clarithromycin tablets and oral suspension can be taken with or without food and can be taken with milk. Do not receive the tablets in water and then take water with it.

Drug Interactions: Clarithromycin use in patients who are receiving theophylline may be associated with an increase in serum theophylline concentrations. Theophylline concentrations should be monitored carefully and the dose of theophylline may need to be adjusted. Clarithromycin administered to patients receiving high doses of theophylline or with baseline concentrations above 20 mg/L may transiently increase the rate of theophylline elimination and lower the serum theophylline concentration by an average of 30% in the elderly. This effect is seen most frequently in elderly patients with baseline theophylline concentrations higher than 20 mg/L and in patients with heart failure or hepatic impairment. The elderly are particularly sensitive to theophylline accumulation and should be monitored closely for theophylline levels. Clarithromycin administration may be associated with a decrease in serum digoxin levels. When coadministered with digoxin, plasma digoxin levels should be monitored. Due to the potential for digoxin toxicity, dosage adjustment may be required in some patients. Clarithromycin administration has been shown to increase digoxin plasma levels in elderly patients.

Simultaneous oral administration of clarithromycin and zidovudine is associated with an increased risk of myelosuppression when clarithromycin is administered twice daily, steady-state zidovudine concentrations were increased by approximately 2-fold, whereas the AUC was unaffected. Simultaneous administration of Biaxin and didanosine to 12 HIV-infected adult patients resulted in no statistically significant change in didanosine pharmacokinetics. Concomitant administration of fulminocarb 200 mg daily and clarithromycin 500 mg twice daily to 21 healthy volunteers led to small increases in the clarithromycin Cmax and AUC of 33% and 18%, respectively. Steady-state concentrations of 14-OH clarithromycin were not significantly affected by concomitant administration of fulminocarb.

Warnings: Concomitant use of clarithromycin and oral anticoagulants may potentiate the effects of the oral anticoagulants. Prothrombin times should be carefully monitored while patients are receiving clarithromycin and oral anticoagulants simultaneously.

Elevated digoxin serum concentrations in patients receiving clarithromycin and digoxin have also been reported in post-marketing surveillance. Some patients have shown clinical signs consistent with digoxin toxicity, including hypokalemia. Some patients have been observed to have levels of digoxin 3 times normal levels while they are receiving clarithromycin and digoxin simultaneously.

The following drug interactions, other than increased serum concentrations of carbamazepine and active acid metabolite of terfenadine, were seen to be associated with theophyllin, cyclosporine, probenecid, digoxin, indinavir, astemizole, and ergotamine. Serum concentrations of drugs metabolized by the cytochrome P450 system should be monitored closely in patients concurrently receiving these drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility: The following in vitro mutagenicity tests have been performed with clarithromycin:

- Salmonella/Mammalian Microsome Test
- Bacterial Inverse Mutation Test
- In Vitro Chromosome Aberration Test
- Rat Hepatocyte DNA Synthesis Assay
- Mouse Lymphoma
- Mouse Dominant Leital Study
- Mouse Micronucleus Test

All tests have been performed except the In Vitro Chromosome Aberration Test which was weakly positive in one test and negative in another.

In addition, a Bacterial Reverse-Mutation Test (Ames Test) has been performed on clarithromycin metabolites with negative results.

Fertility and reproduction studies have shown that daily doses of up to 160 mg/kg/day (1.3 times the recommended maximum human dose as a percentage of body weight) of clarithromycin to rabbits and rats did not affect fertility or reproductive function. In rabbits, the steady-state levels of Cmax, Cmin, and the area under the serum concentration-time curve (AUC) of theophylline increased about 39%.

Concomitant administration of single doses of clarithromycin and carbamazepine has been shown to result in increased plasma concentrations of carbamazepine. Blood level monitoring of carbamazepine may be considered.

When clarithromycin and theophylline were coadministered, plasma concentrations of the active metabolite of theophylline were increased by 2-fold, on average, the theophylline concentration was level to is likely to be of clinical significance in healthy individuals. Clarithromycin should not be given to patients receiving terfezadine therapy who have preexisting cardiac abnormalities (cardiac arrhythmia, bradycardia, QT interval prolongation, ischemic heart disease, constrictive pericarditis, or myocardial ischemia). Drug interactions of drugs metabolized by the cytochrome P450 system should be monitored closely in patients concurrently receiving these drugs.

Post-Marketing Experience: Allergic reactions ranging from urticaria and mild skin eruption to life-threatening anaphylactic reactions have occurred. Other, rare adverse reactions include Stevens-Johnson syndrome, toxic epidermal necrolysis, and anaphylactic shock. There have been isolated reports of hearing loss, which is usually reversible, occurring chiefly in elderly patients. There have been isolated reports of hepatitis, mostly in patients who receive prolonged courses of therapy. There have been isolated reports of dermatologic reactions in patients who receive prolonged courses of therapy. Clarithromycin has been shown to produce oral or pharyngeal lesions, anorexia, nausea, vomiting, diarrhea, constipation, pseudomembranous colitis, diarrhea, headache, insomnia, dizziness, and an increased incidence of CD4+ lymphocytes in patients with human immunodeficiency virus (HIV) infection.

Hepatic dysfunction, including increased liver enzymes, and hepatoxicity and cholestatic hepatitis, with or without jaundice, has been infrequently reported with clarithromycin. This hepatic dysfunction may be severe and is usually reversible.

In very rare instances, hepatic failure with fatal outcome has been reported and generally has been associated with serious underlying diseases and/or concomitant medications. Hepatic dysfunction is more frequent in patients who are associated with vascular avian infections, including visceral tachypnea (neonatal), and patients receiving clindamycin or clarithromycin who are associated with CD4+ lymphocytes in patients with human immunodeficiency virus (HIV) infection.

Serious adverse events have been reported in patients treated with clarithromycin. These have included rash, thrombocytopenia, neutropenia, Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatitis, jaundice, and diarrhea. Most of these events have occurred in patients who have been treated with clarithromycin for more than 7 days. In clinical trials, elderly patients have not been found to have an increased incidence of adverse events when compared to younger patients. Dose adjustment should be considered in elderly patients with severe renal impairment.

ADVERSE REACTIONS: The majority of side effects observed in clinical trials were of a mild and transient nature. Fewer than 3% of adult patients treated with clarithromycin have experienced adverse events that were serious or life-threatening, or that required interruption of therapy because of drug-related adverse events. The most frequently reported adverse events in adults were diarrhea (3%), nausea (3%), abdominal distress (3%), dyspepsia (2%), abdominal pain (2%), and diarrhea (2%). Other adverse events reported in 2% of patients with clarithromycin, pseudomembranous colitis, diarrhea, vomiting (6%), abdominal pain (3%), rash (3%), and diarrhea (2%) were usually mild or moderate in severity. Of the reported adverse events, only 1% was described as severe.

Serious adverse events reported in adults comparing clarithromycin to erythromycin base or erythromycin stearate, respectively, were fewer adverse events involving the digestive system in clarithromycin-treated patients compared to erythromycin-treated patients (1% vs 36%; p<0.01). Twenty percent of erythromycin-treated patients discontinued therapy due to adverse events compared to 4% of clarithromycin-treated patients.

In two U.S. studies of acute otitis media comparing clarithromycin to amoxicillin/potassium clavulanate in pediatric patients, there were fewer adverse events involving the digestive system in clarithromycin-treated patients compared to amoxicillin/potassium clavulanate-treated patients (12% vs 40%, p<0.001). One-third as many clarithromycin-treated patients reported adverse events as did amoxicillin/potassium clavulanate-treated patients.

CLARITHROMYCIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (See WARNINGS - Pregnancy.) It is not known whether clarithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when clarithromycin is administered to a nursing mother. Tetracyclines may be secreted in human milk. Pediatirc Use: Safety and effectiveness of clarithromycin in children under 6 months of age have not been established. Clarithromycin is contraindicated in children under 6 months of age. Clarithromycin is similar in efficacy and safety in children and young adults. Children who are similar in age to adults and young adults. Children should be treated with clarithromycin in post-marketing surveillance. Oral clarithromycin were excreted in milk from dams treated with 150 mg/kg/day for 3 weeks, were not adversely affected, despite data indicating higher drug levels in milk. Pediatric Use: Safety and effectiveness of clarithromycin in children under 6 months of age have not been established. Clarithromycin is contraindicated in children under 6 months of age. Clarithromycin is similar in efficacy and safety in children and young adults. Children who are similar in age to adults and young adults. Children should be treated with clarithromycin in post-marketing surveillance. Oral clarithromycin were excreted in milk from dams treated with 150 mg/kg/day for 3 weeks, were not adversely affected, despite data indicating higher drug levels in milk.
BOOKS RECEIVED


PEDIATRICS IN REVIEW: FEBRUARY 1996 CONTENTS

Alcohol Abuse

Leukocyte Disorders: Quantitative and Qualitative Disorders of the Neutrophil (Part 2)—Boxer and Blackwood

Back to Basics: Diagnostic Tests of Lung Function—Voter and McBride

Index of Suspicion—Toledo-Valido, Neal, and Patterson

Consultation With the Specialist: Slipped Capital Femoral Epiphysis—Richards

The Spectrum of Erythema Multiforme and Stevens-Johnson Syndrome—Rauch

Steroid-Dependent Children—Vijayaraghaven and Linder
As surely as the seasons change,

**Chickenpox will be here**

As outside temperatures go down, chickenpox infection rates go up. This simple vaccination schedule allows you to help protect appropriate susceptibles.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 12 months to 12 years</td>
<td>1 subcutaneous dose (0.5 mL)</td>
</tr>
<tr>
<td>Adolescents and adults</td>
<td>2 subcutaneous doses (0.5 mL) each, administered 4 to 8 weeks apart</td>
</tr>
</tbody>
</table>

The American Academy of Pediatrics (AAP) recommends the “vaccine for universal use in early childhood and immunization in susceptible older children and adolescents."

The Advisory Council on Immunization Practices (ACIP) recommends routine immunization of healthy, susceptible children 12 months to 12 years of age. Immunization is also recommended for susceptible individuals 13 years of age and older.

VARIVAX is contraindicated in individuals with a history of hypersensitivity or an anaphylactoid reaction to any component of the vaccine including gelatin or neomycin, or with any immunodeficient condition or receiving immunosuppressive therapy. VARIVAX should not be administered during pregnancy. Pregnancy should be avoided for three months following vaccination.

For details concerning contraindications, warnings, precautions, adverse effects, and dosage and administration, please see the Brief Summary on next page.

It's time to help protect susceptibles with

**VARIVAX®**

[VARICELLA VIRUS VACCINE LIVE (Oka/Merck)]

The First Vaccine Against Chickenpox Available in the U.S.
BRIEF SUMMARY

Please read the full Prescribing Information for complete details.

INDICATIONS AND USAGE

VARIVAX® [Varicella Virus Vaccine Live (Oka/Merck)] is indicated for vaccination against varicella in individuals 12 months of age and older.

Revaccination

The duration of protection of VARIVAX is unknown at present and the need for booster doses is not defined. However, a boost in antibody levels has been observed in vaccinees following exposure to natural varicella as well as following a booster dose of VARIVAX administered four to six years post vaccination.

In a highly vaccinated population, immunity for some individuals may wane due to lack of exposure to natural varicella as a result of shifting epidemiological patterns. Post-marketing surveillance studies are ongoing to evaluate the need and timing for booster vaccination.

Vaccination with VARIVAX may not result in protection of all healthy, susceptible children, adolescents, and adults (see CLINICAL PHARMACOLOGY section of the full Prescribing Information).

CONTRAINDICATIONS

A history of hypersensitivity to any component of the vaccine, including gelatin.

A history of anaphylactoid reaction to neomycin (each dose of reconstituted vaccine contains trace quantities of neomycin).

Individuals with blood dyscrasias, leukemia, lymphomas, or any type of other malignant neoplasms affecting the bone marrow or lymphatic systems.

Individuals receiving immunosuppressive therapy. Individuals who are on immunosuppressants are more susceptible to infections than healthy individuals. Vaccination with live attenuated varicella vaccine can result in a more extensive vaccine-associated rash or disseminated disease in individuals on immunosuppressant doses of corticosteroids.

Individuals with primary and acquired immunodeficiency states, including those who are immunosuppressed in association with AIDS or other clinical manifestations of infection with human immunodeficiency virus; cellular immune deficiencies; and hypogammaglobulinemia and dysgammaglobulinemic states.

A family history of congenital or hereditary immunodeficiency or children with a diminished immune competence of the potential vaccine recipient is demonstrated.

Active untreated tuberculosis.

Any febrile respiratory illness or other active febrile infection.

Pregnancy, the possible effects of the vaccine on fetal development are unknown at this time. However, natural varicella is known to sometimes cause fetal harm. If vaccination of postpartum females is required, vaccination should be avoided for 3 months following vaccination (see PRECAUTIONS, Pregnancy).

WARNINGS

Children and adolescents with acute lymphoblastic leukemia (ALL) in remission can receive the vaccine under an investigational protocol. More information is available by contacting the VARIVAX coordinating center, Bio-Pharm Clinical Services, Inc., 4 Haley Square, Blue Bell, PA 19422, (810) 283-0897.

PRECAUTIONS

General

Acceptable treatment provisions, including epinephrine auto-injectors, should be available in case of an immediate use should an anaphylactoid reaction occur.

The duration of protection from varicella infection after vaccination with VARIVAX is unknown. It is not known whether VARIVAX given immediately after exposure to natural varicella will prevent illness.

Vaccination should be deferred for at least 5 months following blood or plasma transfusions, or administration of immune globulin or varicella zoster immune globulin (VZIG).

Following administration of VARIVAX, any immune globulin, including VZIG, should not be given for 2 months thereafter unless its use outweighs the benefits of vaccination.

Vaccine recipients should avoid use of salicylates for 6 weeks following administration of VARIVAX as Reye's syndrome has been reported following the use of salicylates during natural varicella infection.

Individuals vaccinated with VARIVAX may potentially be capable of transmitting the vaccine virus to close contacts. Therefore, vaccine recipients should avoid close association with susceptible high-risk individuals (e.g., newborns, pregnant women, immunocompromised persons). The potential risk of transmission of vaccine virus should be weighed against the risk of transmission of natural varicella in such circumstances.

The safety and efficacy of VARIVAX have not been established in children and young adults who are known to be infected with human immunodeficiency viruses but who do not have overt clinical manifestations of immunosuppression.

Care should be taken by the healthcare provider for safe and effective use of VARIVAX.

The healthcare provider should question the patient, parent, or guardian about reactions to a previous dose of VARIVAX or a similar product.

The healthcare provider should obtain the previous immunization history of the vaccinee.

VARIVAX should not be injected into a blood vessel.

Vaccination should be deferred in patients with a family history of congenital or hereditary immunodeficiency until the patient's own immune system has been evaluated.

A separate sterile needle and syringe should be used for administration of each dose of VARIVAX to prevent transfer of infectious diseases.

Needles should be disposed of properly and should not be recapitated.

Information for the recipient.

The healthcare provider should inform the patient, parent, or guardian of the benefits and risks of vaccination.

Patients, parents, or guardians should be instructed to report any adverse reactions to their healthcare provider.

Pregnancy should be avoided for 3 months following vaccination.

Drug Interactions

See PRECAUTIONS, General, regarding the administration of immune globulins, salicylates, and transfusions.

Use with Other Vaccines

Results from clinical studies indicate that VARIVAX can be administered concomitantly with M-M-R® (Measles, Mumps, and Rubella Virus Vaccine Live, MSD).

Limited data from an experimental product containing varicella vaccine suggest that VARIVAX can be administered concomitantly with DTaP (diphtheria, tetanus, acellular pertussis) and PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate), MSD] using separate sites and syringes (see CLINICAL PHARMACOLOGY section for Other Vaccines, the full Prescribing Information). However, there are no data relating to simultaneous administration of VARIVAX with DT or OPV.

Varicella-zoster, Mutagenesis, Impairment of Fertility

VARIVAX has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.

Pregnancy

Category C: Animal reproduction studies have not been conducted with VARIVAX. It is also not known whether VARIVAX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, VARIVAX should not be administered to pregnant females; furthermore, pregnancy should be avoided for 3 months following vaccination (see CONTRAINDICATIONS).

Nursing Mothers

It is not known whether varicella virus vaccine is secreted in human milk. Therefore, because some viruses are secreted in human milk, caution should be exercised if VARIVAX is administered to a nursing woman.

Pediatric Use

No clinical data are available on safety or efficacy of VARIVAX in children less than one year of age, and administration to infants under 12 months of age is not recommended.

ADVERSE REACTIONS

In clinical trials, VARIVAX was administered to 11,102 healthy children and adolescents. VARIVAX was generally well tolerated. In children, adolescents, and adults followed up to 42 days, the adverse effects most frequently reported were as follows: fever (≥101°F [39°C]) oral in children and ≥100°F [37.7°C] oral in adolescents and adults), injection site complaints (pain/ soreness, swelling, and/or redness, rash, pruritus, hematoma, induration, stiffness); and varicella-like rash (injection site and generalized).

In children, adolescents, and adults, adverse experiences reported at ≥1% frequency included, without regard to causality, upper respiratory illness, cough, irritability/nervousness, fatigue, disturbed sleep, diarrhea, loss of appetite, vomiting, otitis, diaper rash/contact rash, headache, teething, malaise, abdominal pain, other rash, nausea, eye complaints, chills, lymphadenopathy, myalgia, stiff neck, arthralgia, lower respiratory illness, allergic reaction (including allergic rash, hives), constipation, itching, heat rash/prickly heat, eczema/dry skin, dermatitis, and cold/canker sore. In children, pneumonitis (<1%) and febrile seizures (<0.1%) have been reported rarely; a causal relationship has not been established.

As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

DOSEAGE AND ADMINISTRATION

FOR SUBCUTANEOUS ADMINISTRATION

Do not inject intravenously.

Children 12 months to 12 years of age should receive a single 0.5 mL dose administered subcutaneously. Adolescents and adults 13 years of age and older should receive a 0.5 mL dose administered subcutaneously at least 24 hours and a second 0.5 mL dose 4 to 8 weeks later.

VARIVAX MUST BE KEPT FROZEN AT AN AVERAGE TEMPERATURE OF -5°C (+23°F) OR COLDER UNTIL IT IS RECONSTITUTED FOR INJECTION. STORAGE IN A FROST-FREE FREEZER WITH AN AVERAGE TEMPERATURE OF +5°F (-15°C) OR COLDER IS ACCEPTABLE. THE DILUENT SHOULD BE STORED SEPARATELY AT ROOM TEMPERATURE OR IN THE REFRIGERATOR. IT IS RECOMMENDED THAT THE VACCINE BE ADMINISTERED IMMEDIATELY AFTER RECONSTITUTION, TO MINIMIZE LOSS OF POTENCY. DISCARD IF RECONSTITUTED VACCINE IS NOT USED WITHIN 24 HOURS. Do not freeze reconstituted vaccine.

Do not give immune globulin including Varicella Zoster Immune Globulin concurrently with VARIVAX (see also PRECAUTIONS).
A MEMBERSHIP BENEFIT.

Only members of The American Academy of Pediatrics are eligible for coverage through Pediatrics Insurance Consultants. Protect your family, your practice, your employees, and yourself. Take advantage of the full range of insurance programs.

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799 W. Roosevelt Road, Bldg. 6, Suite 215
Glen Ellyn, IL 60137-5903

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- Comprehensive Major Medical
- Office Overhead Expense
- Universal Life
- Long Term Care
- Daily Hospital Benefits
- Dental
- Term Life

Name
Birth Date
Spouse Name
Birth Date
Address
Smoker? Q Yes Q No
City/State/Zip

Please call me/Phone: __________
Not a member? Q Check this box for information on AAP Membership: __________
American Academy of Pediatrics
1996 Medical Education Awards
Sponsored by Ross Products Division Abbott Laboratories

The American Academy of Pediatrics is pleased to announce that nominations are now being accepted for the 1996 Medical Education Awards. **Nominations must be submitted by February 29, 1996.** The awards will be presented at the Academy's Annual Meeting in Boston, Massachusetts, October 26–30, 1996.

The AAP Medical Education Awards, sponsored by Ross Products Division Abbott Laboratories, annually recognize excellence in pediatrics education, and are offered in the following categories:

**Lay Education Award**
For programs that educate parents, teachers, children, and others in aspects of child health

**Professional Education Award**
For innovative and effective programs in the education of medical students, residents, nurses, and pediatricians

**Lifetime Achievement Award**
For lifetime achievements in pediatric medical education

The 1995 Award Recipients are as follows:

**Lay Education Award**
Robert B. Mellins, MD

**Professional Education Award**
Thomas G. DeWitt, MD and Kenneth B. Roberts, MD

**Lifetime Achievement Award**
Lewis A. Barness, MD
Julio Meneghello, MD

Criteria for Awards
Selection of awards will be based on originality, educational quality, program/project effectiveness, international/national impact, and the potential for utilization in other programs or practices.

- Nominees are restricted to pediatricians who are members of the American Academy of Pediatrics.
- Nominees for the Professional or Lay Medical Education Awards should be actively involved in the program for which they are being considered. The program should have come to fruition within the last two or three years.
- Previous nominees must be formally resubmitted for consideration.

To obtain nomination forms or additional information, please contact:

Kyle Ann Ostler
AAP Department of Education
141 Northwest Point Boulevard
Elk Grove Village, IL 60007
800/433-9016, Extension 7892
708/228-5097 Facsimile
Take Effective Control of Bed-wetting

- Significant improvement in number of dry nights shown in controlled studies\(^1\)\(^2\)
- Rapid response in children 6 years and older—substantial decrease in wet nights seen in only 1 to 3 nights of therapy\(^3\)
- Desmopressin acetate has a combined 15-year record of safe use in the U.S. and Europe\(^4\)

Nighttime fluid intake should be restricted to decrease the potential occurrence of fluid overload; serum electrolytes should be checked at least once when therapy is continued beyond 7 days.

The most prescribed pharmacologic agent for primary nocturnal enuresis\(^5\)

DDAVP\(^\circledR\) Nasal Spray (desmopressin acetate) 5mL

Dry Nights for Good Mornings

Please see brief summary of prescribing information on adjacent page.
33. Eau Claire Police Department. Bike Helmets: A Study of Their Use by Children of the Eau Claire Area. Eau Claire, WI: Eau Claire Police Department; 1992

WINNERS OF THE 1995 AWARDS FOR EXCELLENCE IN PEDIATRIC RESEARCH

Mary C. Dinauer, MD, PhD, is a pediatric hematologist/oncologist whose research focuses on understanding and treating chronic granulomatous diseases (CGD). Through Dr Dinauer’s research, a detailed understanding of the mutations involved in these diseases have been gained. Her most significant contributions have been the development of myeloid cell lines deficient in the X-linked CGD gene product and the development of the first animal model of CGD using gene targeting technology. The CGD mouse has significant phenotypic similarities with the X-linked human disease. These contributions provide unique opportunities to develop new approaches to this disease, including somatic gene therapy. Dr Dinauer is widely recognized by both physicians and scientists as a prominent leader in the field of phagocyte biology.

A. Thomas Look, MD, is a pediatric hematologist/oncologist who has made major contributions to the understanding of the biology and pathogenesis of childhood cancers, and how such information can be used to improve therapy. Relying first on DNA flow cytometry and then on molecular genetic techniques, he and his colleagues at St Jude Children’s Research Hospital identified disease subtypes whose requirements for therapy supersede those indicated by traditional clinical and pathological evaluation. Beginning to be unraveled are the molecular mechanisms governing the induction of childhood B-lineage leukemias and non-Hodgkin’s lymphomas. Dr Look’s insights into the role of fusion proteins and neoplastic transformation are at the forefront of pediatric molecular oncology.
CONTROLLING ASTHMA CAN BE AN UPHILL BATTLE.

THE STRENGTH OF AEROBID CAN MAKE IT EASIER.

When bronchodilators alone can’t control asthma...

AEROBID®

(flunisolide) 250 mcg/puff

THE STRENGTH TO CONTROL ASTHMA. WITH FEWER PUFFS PER DAY.
AEROBID 250 mcg/puff. The strength to control asthma, with fewer puffs per day.

Only AEROBID delivers 250 mcg of medication with every puff. So when patients require 800 to 2000 mcg/day—as recommended by the National Heart, Lung and Blood Institute and World Health Organization¹—AEROBID delivers the dose with fewer puffs per day. That's why AEROBID is so convenient whether patients are young or old with moderate or severe asthma.

A strong record of safety—up to 2000 mcg/day.

AEROBID also delivers a strong record of safety. In studies of adults treated with AEROBID for 2 years or more, no significant adrenal suppression was reported, even at doses of up to 2000 mcg/day.² What's more, in the same studies, no significant adrenal suppression was reported in children who received 1000 mcg/day of AEROBID for up to 2 years.²

AEROBID is indicated for use in adults and in children aged 6 and older. AEROBID may cause nausea and/or vomiting, headache, and sore throat in some patients.


Not recommended for chronic use with alternate prednisone regimens.

CAUTION: ADRENAL INSUFFICIENCY MAY OCCUR WHEN TRANSFERRING PATIENTS FROM SYSTEMIC STEROIDS (SEE WARNINGS).

Please see brief summary of prescribing information on adjacent page.

When bronchodilators alone can't control asthma...

AEROBID (flunisolide) 250 mcg/puff

AEROBID-M (flunisolide) 250 mcg/puff

The strength to control asthma. With fewer puffs per day.

© 1995 Forest Pharmaceuticals, Inc.
CONTRAINDICATIONS
AERODIS® and AERODIS®-M (flunisolide)
Inhaler system for oral inhalation only
Brief summary of prescribing information

WARNINGS
Loosely veiled: One danger of patients who are transferred from previously active corticosteroids to AERODIS® and AERODIS®-M (flunisolide) because deaths due to adrenal insufficiency have occurred in patients on corticosteroids and after withdrawal of corticosteroids. After withdrawal of corticosteroids, number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function. During this period of HPA suppression, patients may exhibit symptoms of adrenal insufficiency when exposed to stress (surgery, infection, particularly gastrointestinal). Although AERODIS® and AERODIS®-M (flunisolide) may provide control of asthmatic symptoms during these episodes, it does not provide the systemic steroid function necessary for coping with these emergencies.

During periods of stress or a severe asthmatic attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume systemic steroids in large initial doses immediately and to contact their physician for further clarification. These patients should also be instructed to carry a warning card indicating that they need supplementation of systemic steroids during periods of stress or a severe asthmatic attack. To assess the risk of adrenal insufficiency in emergency situations, routine tests of adrenal cortical function, withholding of all systemic steroids, should be performed periodically in all patients. An early morning cortisol level may be accepted as normal if it is at or near the normal mean level.

PRECAUTIONS
General: Observation of the presence of some adverse effect in the patient's condition, and the observation of the effect of this adverse effect on the patient's condition, is the responsibility of the prescribing physician.

During the period of HPA suppression, patients may exhibit symptoms of adrenal insufficiency when exposed to stress (surgery, infection, particularly gastrointestinal). Although AERODIS® and AERODIS®-M (flunisolide) may provide control of asthmatic symptoms during these episodes, it does not provide the systemic steroid function necessary for coping with these emergencies.

During periods of stress or a severe asthmatic attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume systemic steroids in large initial doses immediately and to contact their physician for further clarification. These patients should also be instructed to carry a warning card indicating that they need supplementation of systemic steroids during periods of stress or a severe asthmatic attack. To assess the risk of adrenal insufficiency in emergency situations, routine tests of adrenal cortical function, withholding of all systemic steroids, should be performed periodically in all patients. An early morning cortisol level may be accepted as normal if it is at or near the normal mean level.

Loosely veiled: One danger of patients who are transferred from previously active corticosteroids to AERODIS® and AERODIS®-M (flunisolide) because deaths due to adrenal insufficiency have occurred in patients on corticosteroids and after withdrawal of corticosteroids. After withdrawal of corticosteroids, number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function. During this period of HPA suppression, patients may exhibit symptoms of adrenal insufficiency when exposed to stress (surgery, infection, particularly gastrointestinal). Although AERODIS® and AERODIS®-M (flunisolide) may provide control of asthmatic symptoms during these episodes, it does not provide the systemic steroid function necessary for coping with these emergencies.

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When symptoms to acute otitis media*...

choose

with unsurpassed efficacy

and now

dose daily

ONCE-A-DAY
Vantin® Oral Suspension
cefpodoxime proxetil for oral suspension

*For the treatment of acute otitis media in children (aged 5 months to 12 years) caused by Streptococcus pneumoniae, Haemophilus influenzae (including β-lactamase–producing strains), or Moraxella (Branhamella) catarrhalis.
Prescribe Vantin 10 mg/kg/qd for 10 days for acute otitis media*

Now Vantin qd for greater convenience

- 10 mg/kg qd may help enhance compliance
- Vantin is generally well tolerated by children—the most frequent adverse reactions during clinical trials using multiple doses of oral suspension were diarrhea (7.0%), diaper rash (3.5%), other skin rashes (1.8%), and vomiting (1.7%).

Vantin qd provides unsurpassed efficacy

- Vantin qd proven comparable to qd Suprax® in a clinical trial of patients with acute otitis media
- Vantin effectively kills β-lactamase-producing H influenzae

* For the treatment of acute otitis media in children (aged 5 months to 12 years) caused by β-lactamase-producing strains of H influenzae (including β-lactamase-producing strains of M catarrhalis).

- Suprax® is a registered trademark of Lederle Laboratories.

Reference


ONCE-A-DAY Vantin Oral Suspension
cefpodoxime proxetil for oral suspension

50mg/5mL
100mg/5mL

THE MORE YOU PRESCRIBE IT, THE MORE YOU’LL SEE WHY

VANTIN Tablets and Oral Suspension
brand of cepodoxime proxetil tablets and cepodoxime proxetil for oral suspension

CONTRAINDICATIONS

- Known allergy to cepodoxime or to cephalosporins.

WARNING

- Before starting therapy with VANTIN, carefully inquire whether the patient has had previous hypersensitivity reactions to cepodoxime, other cephalosporins, penicillins, or other drugs. CROSS-SENSITIVITY 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 VANTIN OCCURS, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSensitivity REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, IF INDICATED.

PSEUDOMEMBRANOUS COLITIS has been reported with nearly all antibiotics, including cepodoxime, and may range from mild to life threatening. This diagnosis must be considered in patients who present with diarrhea subsequent to the use of antibacterial agents.

Observe extreme caution when using this product in patients at increased risk for antibiotic-induced pseudomembranous colitis because of exposure to institutional settings, such as nursing homes or hospitals with endemic Clostridium difficile.

VANTIN can alter normal colonic flora and may permit overgrowth of clostridia, a toxin produced by C difficile is the primary cause of antibiotic associated colitis.” Initial therapeutic measures once the diagnosis of pseudomembranous colitis has been established. Most cases usually respond to drug discontinuation alone. Moderate to severe cases may require management with fluids and electrolytes, protein supplementation, and treatment with an oral antibiotic effective against C difficile.

C difficile organisms or toxin was reported in 10% of adult patients treated with VANTIN who had diarrhea; however, no specific diagnosis of pseudomembranous colitis was made. Postmarketing experience outside the United States includes reports of pseudomembranous colitis associated with use of VANTIN.

PRECAUTIONS

- General: Reduce total daily doses of VANTIN in patients with transient or permanent reduction in renal output due to renal insufficiency because high and prolonged serum levels can occur following usual doses. Administer with caution to patients taking potent diuretics. Prolonged use may cause overgrowth of nonsusceptible organisms. Take appropriate measures if superinfection occurs during therapy. Drug Interactions: High doses of antacids or sucralfate reduce peak blood levels and extent of cepodoxime absorption; rate of absorption is not altered. Oral antacids bismuth subcitrate delays peak blood levels but does not affect extent of absorption. Disopyramide inhibits renal excretion of cepodoxime, resulting in increased absorption and peak plasma levels of cepodoxime. Close monitoring is required when VANTIN is administered concurrently with known nephrotoxic agents. Drug/Laboratory Test Interactions. A positive direct Coombs test may be induced. Carcinogenesis, Mutagenesis, Fertility Impairment. Long term carcinogenesis studies have not been done. Mutagenesis studies were negative. No untoward effects on fertility or reproduction in rats. Pregnancy - Teratogenic Effects: Pregnancy Category B/Labor and Delivery. There has not been used; use only if clearly needed. Nursing Mothers. Cepodoxime is excreted in human milk. Because of the potential for serious reactions in nursing infants, discontinue VANTIN or breastfeed with caution. Nursing mothers should be apprised of the potential hazards. Pediatric Use. Safety and efficacy in infants less than 3 months old have not been established. Geriatric Use. There were no unusual adverse reactions in elderly patients. Pediatric Use. No unusual adverse reactions in elderly patients with normal renal function are not necessary.

ADVERSE REACTIONS

- General: The following adverse reactions were considered possibly or probably related to VANTIN.

Table:<

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Clinical Data</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>7.3%</td>
<td>0-5%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1.2%</td>
<td>0-1%</td>
</tr>
<tr>
<td>Rash</td>
<td>1.6%</td>
<td>0-1%</td>
</tr>
<tr>
<td>Headache</td>
<td>1.1%</td>
<td>0-1%</td>
</tr>
<tr>
<td>Other skin rashes</td>
<td>1%</td>
<td>0-1%</td>
</tr>
</tbody>
</table>

DOSAGE AND ADMINISTRATION: VANTIN Tablets should be given with food to enhance absorption. VANTIN Oral Suspension may be given without regard to food. Tablet and oral suspension: 5 and 10 mg/kg/day (not to exceed 500 mg/day) for 10 days. Patients With Renal Dysfunction. See full prescribing information for dosage adjustments recommended for patients with severe renal impairment (≤40 mL/min) or maintenance hemodialysis. If urine output is increased, reduce dosage to 1/2 the usual dosage. If urine output is decreased, discontinue the drug.

CAUTION: Federal law prohibits dispensing without a prescription.
POLYTRIM® Solution eradicates the most common causative pathogens of bacterial conjunctivitis. And it has proven efficacy against H. influenzae.¹

Eliminating H. flu is critical, because it causes 3-4 times more cases of bacterial conjunctivitis in children than any other ocular pathogen.²

Yet for all its bactericidal activity, POLYTRIM® is safe and effective for children 2 months and over. It’s comfortable on instillation, and contains no neomycin or sulfa.

All good reasons why POLYTRIM® makes an excellent pinkeye solution. Especially for those baby blues.
**POLYTRIM® Ophthalmic Solution Sterile**

(trimethoprim sulfate 0.1% and polymyxin B sulfate 10,000 units/mL)

**INDICATIONS AND USAGE:** POLYTRIM® Ophthalmic Solution is indicated in the treatment of surface ocular bacterial infections, including acute bacterial conjunctivitis, and blepharoconjunctivitis, caused by susceptible strains of the following microorganisms: *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus viridans, Haemophilus influenzae* and *Pseudomonas aeruginosa.*

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

**CONTRAINDICATIONS:** POLYTRIM® Ophthalmic Solution is contraindicated in patients with known hypersensitivity to any of its components.

**WARNINGS:** NOT FOR INJECTION INTO THE EYE. If a sensitivity reaction to POLYTRIM® occurs, discontinue use. POLYTRIM® Ophthalmic Solution is not indicated for the prophylaxis or treatment of ophthalmia neonatorum.

**PRECAUTIONS:**

**General:** As with other antimicrobial preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated.

**Information for Patients:** Avoid contaminating the applicator tip with material from the eye, fingers, or other source. This precaution is necessary if the sterility of the drops is to be maintained. If redness, irritation, swelling or pain persists or increases, discontinue use immediately and contact your physician.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Carcinogenesis: Long-term studies in animals to evaluate carcinogenic potential have not been conducted with polymyxin B sulfate or trimethoprim. Mutagenesis: Trimethoprim has been demonstrated to be non-mutagenic in the Ames assay. In studies at two laboratories, no chromosomal damage was detected in cultured Chinese hamster ovary cells at concentrations approximately 500 times human plasma levels after oral administration; at concentrations approximately 1000 times human plasma levels after oral administration in these same cells a low level of chromosomal damage was induced at one of the laboratories. Studies to evaluate mutagenic potential have not been conducted with polymyxin B sulfate. Impairment of Fertility: Polymyxin B sulfate has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown. No adverse effects on fertility were noted in the study by Brummitt and Pursell.

**Pregnancy:** Teratogenic Effects: Pregnancy Category C. Animal reproduction studies have not been conducted with polymyxin B sulfate. It is not known whether polymyxin B sulfate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Trimethoprim has been shown to be teratogenic in the rat when given in oral doses 40 times the human dose. In some rabbit studies, the overall increase in fetal loss (dead and resorbed and malformed conceptuses) was associated with oral doses 6 times the human therapeutic dose. While there are no large well-controlled studies on the use of trimethoprim in pregnant women, Brummitt and Pursell, in a retrospective study, reported the outcome of 186 pregnancies during which the mother received either placebo or oral trimethoprim in combination with sulfamethoxazole. The incidence of congenital abnormalities was 4.5% (3 of 66) in those who received placebo and 3.3% (4 of 120) in those receiving trimethoprim and sulfamethoxazole. There were no abnormalities in the 10 children whose mothers received the drug during the first trimester. In a separate survey, Brummitt and Pursell also found no congenital abnormalities in 35 children whose mothers had received oral trimethoprim and sulfamethoxazole at the time of conception or shortly thereafter. Because trimethoprim may interfere with folic acid metabolism, trimethoprim should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nonteratogenic Effects:** The oral administration of trimethoprim to rats at a dose of 70 mg/kg/day commencing with the last third of gestation and continuing through parturition and lactation caused no deleterious effects on gestation or pup growth and survival. Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when POLYTRIM® Ophthalmic Solution is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in children below the age of 2 months have not been established (see WARNINGS).

**ADVERSE REACTIONS:** The most frequent adverse reaction to POLYTRIM® Ophthalmic Solution is local irritation consisting of increased redness, burning, stinging, and/or itching. This may occur on instillation, within 48 hours, or at any time with extended use. There are also multiple reports of hypersensitivity reactions consisting of lid edema, itching, increased redness, tearing, and/or circumocular rash. Photosensitivity has been reported in patients taking oral trimethoprim.


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Introducing non-staining Triaminic® Infant Oral Decongestant Drops

No dyes. No stains. Nothing but relief.

Recommend non-staining Triaminic Infant Oral Decongestant Drops—the newest clear product from Triaminic.

- Relieves nasal congestion
- Won’t stain clothes (contains no dyes)
- Terrific grape flavor

For older children, recommend non-staining Triaminic AM...available in a single active ingredient decongestant formula or in a cough and decongestant formula.

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Triaminic cough/cold medicines are the sponsors of The Injury Prevention Program (IPP™) developed by the American Academy of Pediatrics.
Life Is A Journey, Filled With Hopes And Dreams

As children embark on the journey, give them guidance and good health.

PERSPECTIVES ON PEDIATRICS:

A comprehensive edition of The Cutting Edge Medical Report™ that no parent, child care professional or pediatrician should miss. Perspectives On Pediatrics will examine the latest developments in pediatric medicine.

Join Dr. Jerome Klein, Director of Pediatric Infectious Diseases, Boston City Hospital and Dr. George McCracken, Professor of Pediatrics, University of Texas Southwestern Medical Center for a thorough examination of

Otitis-Pneumococcus:
- Who Gets It
- What Are The Symptoms
- How Is It Treated

The Cutting Edge Medical Report™ is a 30 minute TV magazine dedicated to showcasing the latest developments in medical technology. For more information on air dates and times, and how to obtain a video library of "Perspectives On Pediatrics", call 1-800-INFO-ITV (800-463-6488). To access current media releases on the Internet: http://www.prnewswire.com go to Information Television Network.

Tomorrow’s Medicine... Today.

Pediatric Infectious Diseases Society

This program is made possible through an educational grant to The Pediatric Infectious Diseases Society by Pfizer, Inc.

Photo by Lisa Nalven
problem. Health care providers must work to remove barriers identified in this study by means of patient education and peer and family counseling so that young patients who wish to avoid pregnancy will view Norplant as a contraceptive alternative.

REFERENCES
8. Tanter K. Knowledge, attitudes and intentions of American women regarding the hormonal implant. Fam Plann Perspect. 1994;26:60–66

UPCOMING CONFERENCE

The First International Congress of the European Club for Pediatric Burns
“Current Concepts in Pediatric Burn Care”
A Three-Day Conference and Workshop in Zurich, Switzerland
October 16–18, 1996

Information:
Martin Meuli, MD, Director, Pediatric Burn Center, and J. Mohaci and M. Breisacher, Congress Secretaries
Tel. 266 71 11, Fax 266 71 71 or 266 71 70
You tell Timmy that once his medicine’s all gone, he won’t be “down in the dumps” anymore...
Timmy Ford, aged 2
Orson, 12 weeks
Future civil engineer
and his location scout

* Due to Haemophilus influenzae, Streptococcus pneumoniae, or Moraxella catarrhalis.

1 Randomized, double-blind, double dummy, multicenter study in which 553 children with acute otitis media received powder for oral suspension forms of Zithromax® (azithromycin) (10 mg/kg on day 1, 5 mg/kg qd on days 2–5) or Augmentin (40 mg/kg/day in three divided doses for 10 days) and were evaluated for clinical efficacy and safety.
New 5-Day, Once-Daily Therapy for Acute Otitis Media*

The antibiotic solution with predictable results in unpredictable patients

Predictable Coverage of Key Pathogens:
H influenzae, S pneumoniae, and M catarrhalis

Predictable Results:
Proven as effective as Augmentin†,‡,§

Predictable Convenience:
The only 5-day, once-daily treatment

Predictably Well Tolerated:
Only 0.3% discontinuation due to side effects

The most frequent side effects are diarrhea/loose stools (2%), abdominal pain (2%), vomiting (1%), and nausea (1%). Zithromax® (azithromycin) is contraindicated in patients with known hypersensitivity to macrolides.

Please see brief summary of prescribing information on adjacent page.

THE PREDICTABILITY YOU NEED IN PEDIATRICS.
Predictable in vitro activity against important pathogens1

<table>
<thead>
<tr>
<th>Gram-positive aerobic bacteria</th>
<th>Gram-negative bacilli</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>Haemophilus influenzae</td>
</tr>
<tr>
<td>Streptococcus pneumonia</td>
<td>Moraxella catarrhalis</td>
</tr>
<tr>
<td>(group A)</td>
<td>Legionella pneumophila</td>
</tr>
</tbody>
</table>

In vitro susceptibility does not necessarily correlate with in vivo results.


*Note: See product literature for full prescribing information.*

1. ZITHROMAX® (azithromycin) is a registered trademark of SmithKline Beecham Pharmaceuticals.
INTRODUCING

Children’s SUDAFED®

Antihistamine-free congestion relief enters a new age

• Formulated with pseudoephedrine hydrochloride, a time-honored standard for nasal decongestant efficacy: Pediatric Oral Drops (7.5 mg/dropper), Nasal Decongestant Liquid (15 mg/5 mL)
• Free of antihistamine and its anticholinergic and sedative effects
• Alcohol-free and sugar-free
• Great-tasting flavors kids love
• Also available in Cold & Cough Liquid

The only line of children’s cold medicines that are always antihistamine-free

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Consumer HealthCare
Morristown, N.J. 07960 USA

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S-094521-1 (01-99)
In pediatric asthma...

A choice of the NHLBI for first-line maintenance therapy

The National Heart, Lung, and Blood Institute recommends cromolyn sodium as first-line maintenance therapy for pediatric asthma. They also recommend it for the prevention of exercise-induced asthma (EIA). That's because INTAL has been demonstrated to control symptoms, reduce emergency room visits, and has a remarkable safety profile. The most frequently reported adverse events attributed to INTAL Inhaler in controlled clinical studies were throat irritation or dryness, bad taste, cough, wheeze, and nausea.

Fisons, the maker of INTAL, is proud to sponsor Asthma Explorers—an educational program providing children aged 6-12 with fun and informative materials that help them understand and deal with asthma. This program is free to both physicians and patients. For information, call 1-800-982-3902.

Usual starting dose: 2 inhalations qid at regular intervals
In EIA, 2 inhalations 10-15 minutes before exercise
**INTAL Inhaler**
(cromolyn sodium inhalation aerosol)

**Brief Summary**

**INDICATIONS AND USAGE:** INTAL Inhaler is a prophylactic agent indicated in the management of patients with bronchial asthma.

**CONTRAINDICATIONS:** INTAL Inhaler is contraindicated in those patients who have shown hypersensitivity to cromolyn sodium or other components in this preparation.

**WARNINGS:** INTAL Inhaler has no role in the treatment of an acute attack of asthma, especially status asthmaticus. Severe anaphylactic reactions can occur after cromolyn sodium administration. The recommended dosage should be decreased in patients with decreased renal or hepatic function. INTAL Inhaler should not be discontinued if the patient develops eosinophilic pneumonia (or pulmonary infiltrates with eosinophilia). Because of the prophylaxis in this preparation, it should be used with caution in patients with coronary artery disease or a history of cardiac arrhythmia.

**PRECAUTIONS:** General. In view of the biliary and renal routes of excretion for cromolyn sodium, consideration should be given to decreasing the dosage or discontinuing the administration of the drug in patients with impaired renal or hepatic function.

Occasionally, patients may experience cough and/or bronchospasm following cromolyn sodium inhalation. At times, patients who develop bronchospasm may not be able to continue administration despite bronchodilator administration. Rarely, very severe bronchospasm has been encountered.

Carcinogenicity, Mutagenicity, Impairment of Fertility. Long-term studies in mice (12 months intraperitoneal treatment followed by 6 months observation), hamsters (12 months intraperitoneal treatment followed by 12 months observation), and rats (18 months subcutaneous treatment) showed no reproductive effect of cromolyn sodium. No evidence of chromosomal damage or cytotoxicity was obtained in various mutagenesis studies.

**WARNINGS:** Bronchitis

**INDICATIONS**

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 5 years have not been established. For young pediatric patients unable to obey the Inhaler, INTAL Nebulizer System cromolyn sodium inhalation solution, USP is recommended. Because of the possibility that adverse effects of the drug could become apparent only after many years, a benefit-risk consideration of the long-term use of INTAL Inhaler is particularly important in pediatric patients.

**ADVERSE REACTIONS:** In controlled clinical studies of INTAL Inhaler, the most frequently reported adverse reactions attributed to cromolyn sodium treatment were:

- Throat irritation or dryness
- Cough
- Nasal stuffiness or sneezing
- Headache
- Nausea

The most frequently reported adverse reactions attributed to other forms of cromolyn sodium (in the absence of recollection following washout) involve the respiratory tract and are bronchospasm (sometimes severe), associated with a persistent fall in pulmonary function (FEV1), cough, angioedema (urticaria), nasal congestion (sometimes severe), pharyngitis, irritation, and wheezing.

Adverse reactions which occur infrequently and are associated with administration of the drug are: anaphylaxis, angioedema, dyspnea (including laryngospasm), edema (urticaria), exfoliative dermatitis, phototoxicity, and rash; angioedema, eosinophilia, hematoma, hypoglycemia, interstitial nephritis, leukopenia, lymphadenopathy, myalgia, myopathy, pericarditis, pericardial effusion, pleurisy, pruritus, purpura, pulmonary edema, rash, rashes, rash, respiratory distress, urticaria, bronchospasm, and wheezing.

Adverse reactions which may be associated with the use of INTAL Inhaler, and which have been reported as rare events and it is unclear whether they are attributable to the drug, anaphylaxis, angioedema, bronchospasm, cough, angioedema (urticaria), nasal congestion (sometimes severe), pharyngitis, irritation, and wheezing.

**OVERDOSAGE:** No action other than medical observation should be necessary.

Note: The indented section below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFCs).

**WARNINGS:** Contains CFC-12 and CFC-114 substances which harm public health and environment by destroying ozone in the upper atmosphere.

**CAUTION:** Federal law prohibits dispensing without prescription.

**Marketed by:**

**Fisons Pharmaceuticals**
34 Health Care Specialists Drive
Loughborough, England LE11 1EP

**INTAL Inhaler:** The blue and white colors applied to the inhaler are registered trademarks of Fisons Ltd.

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156-1135

**References:**


**American Academy of Pediatrics**
141 Northwest Point Blvd.
Elk Grove Village, IL 60007

**As an AAP member, you may join one or more of 41 sections, designed solely to meet your unique needs as a subspecialist. AAP sections offer:**

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While some subspecialty organizations tend to focus on adult-based care, the American Academy of Pediatrics (AAP) is the only medical organization that focuses exclusively on the needs of children and their health care providers.

**Our Focus is YOU.**
For your patients with no patience

CEFZIL®
(CEFPROZIL)
Fights Infections* Fast!

*Mild to moderate pediatric respiratory tract infections.
Oral suspension has great-tasting, bubblegum flavor
Well tolerated in pediatric patients
Broad-spectrum in vitro activity for greater therapeutic assurance
BID dosing schedule

*Although a useful guide, in vitro activity does not necessarily correlate with clinical response.


**BRIEF SUMMARY**

The following is a brief summary. Please consult complete prescribing information

**INTERIM NARRATIVE**

**CEFPROZIL** (ciprofloxacin) is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated miicroorganisms in the conditions listed below.

**UPPER RESPIRATORY TRACT**

Pharyngitis/Tonsillitis caused by Streptococcus pneumoniae

**Note:** The usual dose of orally administered streptococcal infections, including the prophylaxis of rheumatic fever, is a single oral dose of cefprozil. Cefprozil is generally effective in the eradication of Streptococcus pneumoniae from the respiratory tract. However, substantial cross-resistance to amoxicillin and to oral penicillin V has been observed in some patients. The mechanism of resistance is believed to be by production of an inadequate amount of penicillin-binding protein. Cefprozil could be an alternative in patients with resistance to these oral antibiotics.

**Skin and Skin Structure Infections**

Cefprozil has been used to treat skin and skin structure infections caused by Staphylococcus aureus (including methicillin-resistant strains) and Streptococcus pyogenes. Abnormal results usually require surgical drainage. Culture and susceptibility testing should be performed when appropriate to determine susceptibility of the causative organism to cefprozil.

**CONTRAINDICATIONS**

Cefprozil is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

**WARNINGS**

- **Before Therapy with Cefprozil is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefprozil, cephalosporins, penicillin, or other drugs.** If this product is given to a patient known to be allergic to penicillin, the risk of a similar reaction with cefprozil cannot be determined. Patients with a history of penicillin allergy should be observed for an allergic reaction.

- **During Therapy**
  - **Hypersensitivity Reactions:** Unusual sensitivity to this antibiotic may occur. In such instances, the patient should be observed by a physician with the ability to institute appropriate therapy. If a reaction occurs, the treatment should be discontinued and an alternative antibiotic should be administered.
  - **Skin Reactions:** If skin eruptions occur during therapy, appropriate measures should be taken. Cefprozil should be prescribed cautiously in patients with a history of drug allergy.
  - **Superinfections:** Cefprozil is capable of causing superinfections by the most susceptible pathogens. The management of patients with superinfections due to local tissue infections is difficult and may require surgical treatment. The treatment of such infections should be supervised by a physician with appropriate training and expertise.

**PRECAUTIONS**

General

- **Evaluation of Renal Status Before and During Therapy:** The risk of interstitial nephritis, which has been reported with cephalosporins, should be carefully monitored in patients receiving cefprozil.

**Drug Laboratory Test Interactions**

- **Cephalosporin antibiotics may produce a false-positive reaction for glucose in the urine with copper reduction tests (i.e., Clinitest or Tes-Tape).** False positive results may also be obtained with glucose oxidase tests (i.e., Tes-Tape). False negative reaction may occur in the fenugreek test for blood glucose. The presence of cefprozil in the urine may result in a false-positive or negative result of urine or cerebrospinal fluid by the akaline picrate method.

- **Gastrointestinal, Management, and Impairment of Fertility**
  - **Nausea and Vomiting:** Nausea and vomiting have been reported in patients receiving cefprozil. It is not known whether the risk of nausea and vomiting is greater with cefprozil than with other cephalosporins. When nausea and vomiting occur, it usually is self-limited and brief. Discontinuation of therapy is usually not necessary.

**Pregnancy**

**Cephalosporin Pregnancy Category B**

Reproduction Studies: Studies have been performed in mice, rats, and rabbits at doses of 15, 47, and 0.7 times the maximum human dose of 1000 mg/day, and have revealed no evidence of harm to the fetus due to cefprozil. 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**

Cefprozil has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.

**Nursing Mothers**

It is not known whether cefprozil is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when cefprozil is administered to a nursing mother.

**Pediatric Use**

Safety and effectiveness in pediatric patients who are age 6 months or younger have not been established. However, accumu-
Is her cough dry or loose?

Recommend Naldecon® Pediatric Drops for Infants

- Pediatric drops with cough suppressant for infants under 2 years old.
- Also available as Children's Syrup.
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Infant Dosage Recommendations

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\[
\begin{align*}
& \frac{1}{4} \text{ mL} \text{ for infants 1 to 3 months (8-12 lbs)} \\
& \frac{1}{2} \text{ mL} \text{ for infants 4 to 6 months (13-17 lbs)} \\
& \frac{3}{4} \text{ mL} \text{ for infants 7 to 9 months (18-20 lbs)} \\
& 1 \text{ mL} \text{ for infants 10 months or more (21 lbs or more)}
\end{align*}
\]

Usual dosage schedule is every 4 hours, not to exceed 6 doses in 24 hours.

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Naldecon® Cough Formulas for Infants and Children
"I'm supposed to keep putting it on until the itching stops... right?"

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ELIMITE® (permethrin) 5% Cream

INDICATIONS AND USAGE: ELIMITE® (permethrin) 5% Cream is indicated for the treatment of infestation with Sarcoptes scabiei (scabies). CONTRAINDICATIONS: ELIMITE® is contraindicated in patients with known hypersensitivity to any of its components, to any synthetic pyrethroid, or pyrethrin. WARNINGS: If hypersensitivity to ELIMITE® occurs, discontinue use. PRECAUTIONS: General: Scabies infestation is often accompanied by pruritus, edema, and erythema. Treatment with ELIMITE® may temporarily exacerbate these conditions. Information for Patients: Patients with scabies should be advised that itching, mild burning and/or stinging may occur after application of ELIMITE®. In clinical trials, approximately 75% of patients treated with ELIMITE® who continued to manifest pruritus at 2 weeks after cessation by 4 weeks. If irritation persists, they should consult their physician. ELIMITE® may be very mildly irritating to the eyes. Patients should be advised to avoid contact with eyes during application and to flush with water immediately if ELIMITE® gets in the eyes. Carcinogenesis, Mutagenesis, Impairment of Fertility: Six carcinogenicity bioassays were evaluated with permethrin, three each in rats and mice. No tumorigenicity was seen in the rat studies. However, species-specific increases in pulmonary adenomas, a common benign tumor of mice of high spontaneous background incidence, were seen in the three mouse studies. In one of these studies there was an increased incidence of pulmonary alveolar-cell carcinomas and benign liver adenomas only in female rats when permethrin was given in their food at a concentration of 200 ppm. Mutagenicity assays, which give useful correlative data for interpreting results from carcinogenicity bioassays in rodents, were negative. Permethrin showed no evidence of mutagenic potential in a battery of in vitro and in vivo genetic toxicity studies. Permethrin did not have any adverse effect on reproductive function at a dose of 180 mg/kg/day orally in a three-generation rat study. Pregnancy: Teratogenic Effects: Pregnancy Category B: Reproduction studies have been performed in mice, rats, and rabbits (200 to 400 mg/kg/day orally) and have revealed no evidence of impaired fertility or harm to the fetus due to permethrin. 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. Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the evidence for tumorigenic potential of permethrin in animal studies, consideration should be given to discontinuing nursing temporarily or withholding the drug while the mother is nursing. Pediatric Use: ELIMITE® is safe and effective in children two months of age and older. Safety and effectiveness in children less than two months of age have not been established. ADVERSE REACTIONS: In clinical trials, generally mild and transient burning and stinging followed application with ELIMITE® in 10% of patients and was associated with the severity of infestation. Pruritus was reported in 7% of patients at various times post-application. Erythema, numbness, tingling, and rash were reported in 1 to 2% or less of patients (see PRECAUTIONS: General). OVERDOSAGE: No instance of accidental ingestion of ELIMITE® has been reported. If ingested, gastric lavage and general supportive measures should be employed. DOSAGE AND ADMINISTRATION: Adults and children: Thoroughly massage ELIMITE® into the skin from the head to the soles of the feet. Scabies rarely infests the scalp of adults, although the hairline, neck, temple, and forehead may be infested in infants and geriatric patients. Usually 30 grams is sufficient for an average adult. The cream should be removed by washing (shower or bath) after 8 to 14 hours. Infants should be treated on the scalp, temple and forehead. ONE APPLICATION IS GENERALLY CURATIVE. Patients may experience persistent pruritus after treatment. This is rarely a sign of treatment failure and is not an indication for retreatment. Demonstrate living mites after 14 days indicate that retreatment is necessary.

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Irvine, CA 92715, U.S.A.
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So if you treat one, you may need to treat them all.

Highly contagious, t. capitis is reaching epidemic proportions among African-American children. And family epidemics are common. So when you diagnose t. capitis in one child, examine the brothers and sisters, and other family members as well.

GRifulvin V® is the only suspension. Its easy-to-swallow solution helps encourage compliance while providing broad-spectrum activity against a wide variety of pathogens.

The most commonly reported adverse reaction is of the hypersensitivity type, such as skin rashes, urticaria, and, rarely, angioneurotic edema.
GRIFULVIN V®
[grůf'ulvin]
griseofulvin oral suspension

Microsize Suspension 125mg/5mL
griseofulvin tablets

Microsize Tablets 250mg or 500mg

Indications and Usage

Major indications for GRIFULVIN V (griseofulvin microsize) are:

Tinea capitis (ringworm of the scalp)
Tinea corporis (ringworm of the body)
Tinea pedis (athlete's foot)
Tinea unguum (onychomycosis, ringworm of the nails)
Tinea cruris (ringworm of the thigh)
Tinea barbae (barber's itch)

GRIFULVIN V (griseofulvin microsize) inhibits the growth of those genera of fungi that commonly cause ringworm infections of the hair, skin, and nails, such as:

- Trichophyton rubrum
- Microsporum audouini
- Microsporum canis
- Microsporum gypseum
- Trichophyton mentagrophytes
- Epidermophyton floccosum
- Trichophyton verrucosum
- Trichophyton schoenleini
- Trichophyton griseum
- Trichophyton tonsurans

Note: Prior to therapy, the type of fungus responsible for the infection should be identified. The use of the drug is not justified in minor or trivial infections which will respond to topical antifungal agents alone.

It is not effective in:
- Bacterial infections
- Cerebral (Mycotic) infections
- Histoplasmosis
- Acanthamoebiasis
- Actinomycosis
- Tinea versicolor
- Sporotrichosis
- Nocardioides

Contraindications

This drug is contraindicated in patients with porphyria, hepatic failure, and in individuals with a history of hypersensitivity to griseofulvin.

Two cases of conjoined twins have been reported in patients taking griseofulvin during the first trimester of pregnancy. Griseofulvin should not be prescribed to pregnant patients.

Warnings

Prophylactic Usage: Safety and efficacy of prophylactic use of this drug have not been established.

Chronic feeding of griseofulvin at levels ranging from 0.5-2.5% of the diet resulted in the development of liver tumors in several strains of mice, particularly in males. Smaller particle sizes result in an enhanced effect. Lower oral dosage levels have not been tested. Subcutaneous administration of relatively small doses of griseofulvin once a week during the first three weeks of life has also been reported to induce hepatomas in mice. Although studies in other animal species have not yielded evidence of tumorigencity, these studies were not of adequate design to draw conclusions in this regard.

In subacute toxicity studies, orally administered griseofulvin produced hepatoxic necrosis in mice, but this has not been seen in other species. Disturbances in porphyrin metabolism have been reported in griseofulvin-treated laboratory animals. Griseofulvin has been reported to have a colchicine-like effect on mitosis and colarcoagulation with meytochrome c in cutaneous tumor induction in laboratory animals.

Reports of animal studies in the Soviet literature state that a griseofulvin preparation was found to be embryotoxic and teratogenic on oral administration to pregnant Wistar rats. Rat reproduction studies done thus far in the United States and Great Britain have been inconclusive in this regard, and additional animal reproduction studies are underway. Patients with abnormalities have been reported in the litter of a few bitches treated with griseofulvin.

Suppression of spermatogenesis has been reported to occur in rats but investigation in man failed to confirm this.

Precautions

Patients on prolonged therapy with any potent medication should be under close observation. Periodic monitoring of organ system function, including renal, hepatic and hematopoietic, should be done.

Since griseofulvin is derived from species of penicillin, the possibility of cross sensitivity with penicillin exists. However, known penicillin-sensitive patients have been treated without difficulty.

Since a photosensitivity reaction is occasionally associated with griseofulvin therapy, patients should be warned to avoid exposure to intense natural or artificial sunlight. Should a photosensitivity reaction occur lupus erythematosus may be aggravated.

Drug Interactions: Patients on warfarin-type anticoagulant therapy may require dosage adjustment of the anticoagulant during and after griseofulvin therapy. Concomitant use of barbiturates usually depresses griseofulvin activity and may necessitate raising the dosage.

The concomitant administration of griseofulvin has been reported to reduce the efficacy of oral contraceptives and to increase the incidence of breakthrough bleeding.

Adverse Reactions

When adverse reactions occur, they are most commonly of the hypersensitivity type such as skin rash, urticaria and rarely, anorexia, nausea, vomiting, epigastric distress, diarrhea, headache, fatigue, dizziness, insomnia, mental confusion and impairment of performance of routine activities.

Proctitis, and leukopenia have been reported rarely. Administration of the drug should be discontinued if granulocytopenia occurs.

When rare, serious reactions occur with griseofulvin, they are usually associated with high dosages and/or long periods of therapy.

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**Only Children's Motrin® (ibuprofen) Suspension offers the efficacy of pediatric ibuprofen without a prescription.**

Children's Motrin is the **only** pediatric ibuprofen available OTC. And clinical studies show the OTC dosing of 7.5mg/kg effectively relieves a wide range of fevers as well as pain in children.

In fact, Children's Motrin cools them down longer (6 to 8 hours) than any OTC pediatric antipyretic.² Pretty cool!

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**Pediatric fever relief that starts fast and lasts.**

Peak plasma levels usually occurred within 1 to 2 hours. The clinical significance of this is unknown. Duration demonstrated between 6 and 8 hours.

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* Paralytic disease following ingestion of live poliovirus vaccines has been reported on rare occasions in individuals receiving the vaccine or in their close contacts.

Please see brief summary of Prescribing Information on the following page.
Orimune®
Poliovirus Vaccine Live
Oral Trivalent

Brief Summary
Poliovirus Vaccine
Live Oral Trivalent
ORIMUNE
SAFETY STRAINS TYPES 1, 2 AND 3

Please see package insert for full description, directions for use, and references.

INDICATIONS AND USAGE
For prevention of poliomyelitis caused by polioviruses Types 1, 2 and 3.

Infants from 6 to 12 weeks of age, all nonimmunized children, and adolescents up to age 18 are the usual candidates for routine prophylaxis.

CONTRAINDICATIONS
Under no circumstances should this vaccine be administered parenterally.
ORIMUNE must not be administered to patients with immune deficiency diseases such as combined immunodeficiency, hypogammaglobulinemia, and agammaglobulinemia. Further, ORIMUNE must not be administered to patients with altered immune states, such as those occurring in human immunodeficiency virus (HIV) infection, systemic lupus erythematosus, leukemia, lymphoma, generalized malignancy, or advanced debilitating conditions, as by severe resistance from therapy with corticosteroids, cytotoxic drugs, antineoplastic agents, or radiation. Because vaccine viruses are excreted by the vaccinee, and may spread to contacts, ORIMUNE should not be used in families with immunocompetent members, or with a history of immunodeficiency until the immune states of all members are determined to be normal. Recipients of ORIMUNE should have been type-specific and combined contacts with altered immune states for at least 6 to 8 weeks. Inactivated poliovirus vaccine (IPV) is preferred for immunizing all persons in the above described circumstances.

WARNINGS
Under no circumstances should this vaccine be administered parenterally.
Administration of the vaccine should be deferred during the course of any febrile illness or acute infection, and also in the presence of persistent vomiting or diarrhea, or suspected gastrointestinal infection. Other recipients (including those with HIV and other enteroviruses) may compromise the desired response to this vaccine, since their presence in the intestinal tract may interfere with the replication of the attenuated strains of poliovirus.

PRECAUTIONS
The vaccine is not effective in modifying or preventing cases of existing and/or incubating poliomyelitis.

Records Required by the National Childhood Vaccine Injury Act: Manufacturer and lot number of vaccine administered must be recorded by health care providers in vaccine recipient’s permanent record, along with date of administration and name, address, and title of person administering vaccine.

Health care provider must report to a health department or to the FDA the occurrence, following immunization, of any event set forth in the Vaccine Injury Table, including: paralysis; poliomyelitis; in a nonimmunized recipient within 3 days of administration; in an immunized recipient within 6 months of vaccination; any vaccine-associated community case of paralytic poliomyelitis; or any acute complication or sequelae (including death) of above events.

Use in Pregnancy: Category C: Animal reproduction studies have not been conducted with Poliovirus Vaccine Live Oral Trivalent. It is also not known whether OPV can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Although there is no convincing evidence documenting adverse effects of either OPV or IPV on the developing fetus or pregnant women, it is prudent for the health care provider to avoid vaccinating pregnant women. However, if immediate protection against poliomyelitis is needed, IPV is recommended. (See CONTRAINDICATIONS AND ADVERSE REACTIONS.)

ADVERSE REACTIONS
Paralytic disease following the inoculation of live poliovirus vaccines has been, on rare occasions, reported in infants or children who were in close contact with vaccinees. The vaccine viruses are shed in the vaccinee’s stools up to 6 to 8 weeks as well as via the respiratory tract. Most reports of paralytic disease following inoculation of the vaccine or contact with a recent vaccinee are based on epidemiological analysis and temporal associations between vaccination or contact and the onset of symptoms. Most authorities believe that a causal relationship exists. A large retrospective study suggests that paralytic disease with poliovirus vaccine is up to 10 times more likely to occur in recipients with serum antibodies to poliovirus. A causal relationship has not been established. Persons administering the vaccine must stress that vaccinees should be aware of or directly inform potential contacts that their vaccine is not contraindicated, but that individuals known to be vaccinated should be excluded for an additional period of time.

The Centers for Disease Control report that during the years 1973 through 1984 approximately 24,350 of the 7 million cases in the U.S. During this same period, 113,066 vaccine-associated cases were reported (1 case per 2.5 million doses distributed). Of these 113,066 cases, 26 occurred in vaccine recipients (1 case per 1.0 million doses distributed), 50 occurred in household members (1 case per 5.2 million doses distributed), 54 occurred in immunodeficient recipients or contacts, and 8 occurred in persons with no history of vaccine exposure, from whom vaccine-like viruses were isolated. The 30% (94%) of the recipient cases, 41 (82%) of the contact cases, and 7 (30%) of the household cases were associated with the recipient’s first dose of OPV. Because most cases of vaccine-associated paralytic disease have been associated with the first dose, the CDC has estimated the likelihood of paralysis in association with first dose subsequent doses of OPV, using the number of children born during 1973-1984 to estimate the number of first doses distributed, and subtracting this from the total distribution to estimate the number of subsequent doses distributed. (This method assumes the frequency of paralysis for recipients at one case per 1.2 million first doses and one case per 116.3 million subsequent doses; for contacts, one case per 1.0 million first doses and one case per 25.0 million subsequent doses; and for all vaccine-associated paralytic disease, one case per 720,000 first doses and one case per 12.5 million subsequent doses.

Other methods of estimating the likelihood of paralysis in association with OPV have been described. Because the number of vaccine recipients or contacts of recipients to whom the vaccine has been given is not known, the true risk of vaccine-associated poliomyelitis is impossible to determine precisely.

When the attenuated vaccine strains are to be introduced into a household with adults who are not immunized or whose immune status cannot be determined, the risk of vaccine-associated paralytic disease can be reduced by giving these adults 2 doses of enhanced potency (EPI) a month apart before the children receive ORIMUNE. The children may receive the first dose of ORIMUNE at the same visit that the adults receive the second dose of enhanced potency. If a booster dose of OPV is given to partially immunized adult cases at the same visit that the first dose of OPV is given to the child, the responsible adult should be referred to the Centers for Disease Control for counseling on changing adult habits.

The AAP states: "Because of the overriding importance of insuring prompt and complete immunization of the child and the extreme rarity of OPV-associated disease in contacts, the Committee recommends the administration of OPV to a child regardless of the poliovirus status of adult household contacts. This is the usual practice in the United States. The responsible adult should be informed of the risks. An acceptable alternative, if there is strong assurance that vaccine, full immunization of the child will not be jeopardized and unless desired by the immunized adult...for IPV...before giving OPV to the child.'"

The American Academy of Pediatrics and the American College of Physicians have made similar recommendations.

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• COCO develops resources to link women leaders to opportunities within committees, councils, and chapters.
• The Academy recently issued a policy statement on Sexual Harassment in the Workplace.

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