

# NEW FELLOWS

## Dear Academy Fellow:

### In order to fulfill the admission requirements of AAP Bylaws, you are requested to:

Carefully review the following list of new Fellows for Academy membership; and relay your reactions directly to your District Chairperson, whose name and address is at the end of this

list. In submitting these names of board-certified pediatricians to you, it is understood that academic and pediatric credentials are not in question. Comments are requested concerning possible legal and/or ethical situations which you might have personal knowledge.

**Send any comments on the following list of new Fellows to your District Chairperson.**

## UNDISTRICTED

Khaled Salaymeh,  
M.D., FAAP  
Amman  
Jordan

## DISTRICT I NORTHEAST

### Atlantic Provinces

*Anesthesiology Specialty  
Fellow*  
G. Allen Finley, M.D., FAAP  
Halifax, NS B3J 3G9  
Canada

### Connecticut

Matthew Bizzarro,  
M.D., FAAP  
Hamden, CT 06514

Joy Ellen Hong, M.D., FAAP  
Glastonbury, CT 06033

Juan Salazar,  
M.D., M.P.H., FAAP  
Glastonbury, CT 06033

### Maine

John Hickey, M.D., FAAP  
Chesterville, ME 04938

Kathleen Hickey,  
M.D., FAAP  
Chesterville, ME 04938

### Massachusetts

Angela Ciamarra,  
M.D., FAAP  
Shrewsbury, MA 01545

### Rhode Island

Peter Pogacar, M.D., FAAP  
Charlestown, RI 02813

### Uniformed Services-East

William Boleman,  
M.D., FAAP  
Ocean Springs, MS 39564

Kathleen Krejci, M.D., FAAP  
McGuire AFB, NJ 08641

## DISTRICT II NEW YORK STATE

### New York 1

Lori Caruso, M.D., FAAP  
Latham, NY 12110

### New York 2

Kotha Sudharani,  
M.D., FAAP  
New Hyde Park, NY 11040

## DISTRICT III MID ATLANTIC

### Maryland

Michael Fields, M.D., FAAP  
Baltimore, MD 21209

Maria Pane, M.D., FAAP  
Lutherville, MD 21093

Hardin Pantle, M.D., FAAP  
Baltimore, MD 21212

### New Jersey

Ava Cavaliere, D.O., FAAP  
Oceanview, NJ 08230

Madhu Goyal, M.D., FAAP  
Edison, NJ 08820

Robert Jawetz, M.D., FAAP  
Clifton, NJ 07013

Daniel Lapidus, M.D., FAAP  
Lakewood, NJ 08701

Fred Schwartz, M.D., FAAP  
West Orange, NJ 07052

### Pennsylvania

Luca Brunelli, M.D., FAAP  
Ardmore, PA 19003

Alisa Burnham, M.D., FAAP  
Wynnewood, PA 19096

Glen Frick, M.D., FAAP  
Cherry Hill, NJ 08002

Leopoldo Legaspi,  
M.D., FAAP  
Ephrata, PA 17522

Anna Linderman,  
M.D., FAAP  
Allentown, PA 18104

Helen O'Hallaron,  
M.D., FAAP  
Pittsburgh, PA 15202

Pushpa Viswanathan,  
M.D., FAAP  
Transfer, PA 16154

### West Virginia

Farid Hussain, M.D., FAAP  
Matoaka, WV 24736

## DISTRICT IV SOUTH APPALACHIAN

### Kentucky

Mohamad Alnahhas,  
M.D., FAAP  
Prestonsburg, KY 41653

### North Carolina

Felicia Baxter, M.D., FAAP  
Fayetteville, NC 28311

Tara Gaines, M.D., FAAP  
Concord, NC 28027

### South Carolina

Mary Bradley, M.D., FAAP  
Columbia, SC 29201

Beverly Yearwood,  
M.D., FAAP  
Orangeburg, SC 29116

### Tennessee

Joseph Nania, M.D., FAAP  
Nashville, TN 37232

### Virginia

Samantha Ahdoot,  
M.D., FAAP  
Alexandria, VA 22301

Peter Ryan Gaskin,  
M.D., FAAP  
Washington, DC 20060

## DISTRICT V GREAT LAKES

### Indiana

Mualla Akisik, M.D., FAAP  
Carmel, IN 46032

### Michigan

Sharon Berkowitz,  
M.D., FAAP  
Ann Arbor, MI 48103

### Ohio

Jennifer Gigax, M.D., FAAP  
Westerville, OH 43081

Mark Hall, M.D., FAAP  
Columbus, OH 43205

Eleni Lantzouni, M.D., FAAP  
Copley, OH 44321

Mary McMahon,  
M.D., FAAP  
Cincinnati, OH 45229

Matthew Morrison,  
M.D., FAAP  
Columbus, OH 43206

Michael Palcisko,  
M.D., FAAP  
Sandusky, OH 44870

*Neurological Surgery  
Specialty Fellow*  
Shenandoah Robinson,  
M.D., FAAP  
Shaker Heights, OH 44120

### Ontario

Bandar Al-Mutairi,  
M.D., FAAP  
Calgary, AB T3H2Z6  
Canada

## DISTRICT VI NORTH CENTRAL

### Illinois

Michael Anderson,  
M.D., FAAP  
Rockford, IL 61107

Beth Jo Berkowitz,  
M.D., FAAP  
Chicago, IL 60610

Carla Dyer, M.D., FAAP  
Chicago, IL 60614

Laura Schneiderman,  
M.D., FAAP  
Chicago, IL 60657

Adelina Tseng, M.D., FAAP  
Woodridge, IL 60517

### Minnesota

Janelle Keplinger,  
M.D., FAAP  
Champlin, MN 55316

Brian Moore, M.D., FAAP  
Rochester, MN 55906

### Missouri

*Radiology Specialty Fellow*  
Lisa Lowe, M.D., FAAP  
Kansas City, MO 64108

David Lowry, D.O., FAAP  
Platte City, MO 64079

Jotishna Sharma,  
M.D., FAAP  
Saint Joseph, MO 64506

April Tyus, M.D., FAAP  
Florissant, MO 63033

### Wisconsin

Emilia Arana, M.D., FAAP  
West Allis, WI 53227

Mary Lytle, M.D., FAAP  
New Berlin, WI 53151

James Thompson,  
M.D., FAAP  
Marshfield, WI 54449

## DISTRICT VII SOUTH CENTRAL

### Louisiana

*Surgery Specialty Fellow*  
Faith Hansbrough,  
M.D., FAAP  
Baton Rouge, LA 70808

Catherine Katzenmeyer,  
M.D., FAAP  
Baton Rouge, LA 70808

### Oklahoma

Mary Bradley-LeBoeuf,  
M.D., FAAP  
Idabel, OK 74745

Lisa Owens, D.O., FAAP  
Tulsa, OK 74114

### Texas

Kimberly Edwards,  
M.D., FAAP  
Austin, TX 78749

Faryal Ghaffar, M.D., FAAP  
Irving, TX 75063

Antonieta Gimotea,  
M.D., FAAP  
Mission, TX 78574

Angelica Higgins,  
M.D., FAAP  
Dickinson, TX 77539

William Hogan, M.D., FAAP  
Houston, TX 77098

Grace Hu, M.D., FAAP  
Houston, TX 77030

Tammy Kennedy,  
M.D., FAAP  
Dallas, TX 75225

El Tayeb Massabbal,  
M.D., FAAP  
Houston, TX 77081

Muhammad Mirza,  
M.D., FAAP  
Coppell, TX 75019

Satid Thammasitboon,  
M.D., FAAP  
Houston, TX 77025

## DISTRICT VIII WEST

### Arizona

Asiya Nadeem, M.D., FAAP  
Tucson, AZ 85712

Jayne Sanson-Jaraczewski,  
M.D., FAAP  
Cottonwood, AZ 86326

### Colorado

Noah Makovsky,  
M.D., FAAP  
Denver, CO 80230

Kathleen O'Neal,  
M.D., FAAP  
Colorado Springs,  
CO 80907

### Nevada

Ruben Acherman,  
M.D., FAAP  
Las Vegas, NV 89109

### Oregon

Jill Talik, M.D., FAAP  
Roseburg, OR 97470

### Uniformed Services- West Chapter

Amy Fleming, M.D., FAAP  
Colorado Springs,  
CO 80918

Heather Miller, M.D., FAAP  
Lake Worth, TX 76135

### Utah

Jeffrey Jensen, M.D., FAAP  
Orem, UT 84097

## DISTRICT IX CALIFORNIA

### California 1

Tatiana Goldstein,  
M.D., FAAP  
San Francisco, CA 94115

Grace Martin, M.D., FAAP  
Concord, CA 94521

Allison Schwanda,  
M.D., FAAP  
Cupertino, CA 95014

Dorothy Thompson,  
M.D., FAAP  
Sacramento, CA 95823

Jason Vargas, M.D., FAAP  
Palo Alto, CA 94304

### California 2

Fernando Fan, M.D., FAAP  
Bakersfield, CA 93384

Beatrice Nedjat-Haiem,  
M.D., FAAP  
Los Angeles, CA 90049

Belinda Santos-Senar,  
M.D., FAAP  
Bakersfield, CA 93311

Kristine Thomas,  
M.D., FAAP  
Burbank, CA 91506

Sara Thompson,  
M.D., FAAP  
Hermosa Beach, CA 90254

### California 3

Cara Cohen, M.D., FAAP  
San Diego, CA 92128

Shannon Dawson,  
M.D., FAAP  
La Mesa, CA 91942

Elainie DeVillena,  
M.D., FAAP  
San Diego, CA 91123

Brian Lane, M.D., FAAP  
San Diego, CA 92123

### California 4

*Surgery Specialty Fellow*  
Sherif Emil, M.D., FAAP  
Orange, CA 92868

Robin Steinberg-Epstein,  
M.D., FAAP  
Long Beach, CA 90815

## DISTRICT X SOUTHEAST

### Florida

Anne Egan, M.D., FAAP  
Jacksonville, FL 32204

Julie Ward, D.O., FAAP  
Oviedo, FL 32765

### Georgia

*Surgery Specialty Fellow*  
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Glen Lew, M.D., FAAP  
Atlanta, GA 30342

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Macon, GA 31201

Thomas Young, M.D., FAAP  
Augusta, GA 3091



## NEW FELLOWS

### DISTRICT CHAIRPERSONS

#### DISTRICT I

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e-mail: clinder@aap.org

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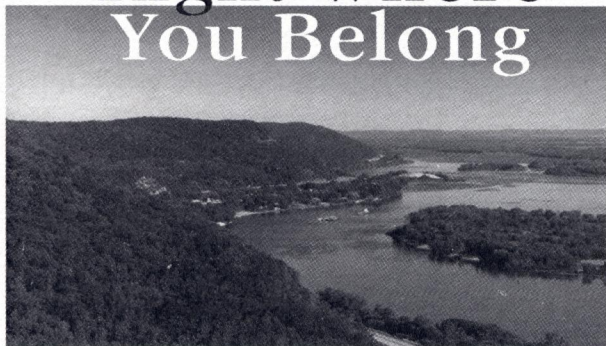
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## Right Where You Belong



### BC/BE Pediatrician BC/BE Pediatric Gastroenterologist BC/BE Neonatologist

Gundersen Lutheran Medical Center in La Crosse, WI, is seeking a BC/BE Pediatrician, a BC/BE Pediatric Gastroenterologist and a BC/BE Neonatologist to join our team of 20 pediatricians, six PNP's, four NNP's and one PA. Our pediatric subspecialty areas include asthma/allergy/immunology, gastroenterology, genetics, hematology/oncology, neonatology, neurodevelopment, neurology, ophthalmology, orthopedics, pulmonology, pediatric ICU and surgery. Gundersen Lutheran includes a state-of-the-art 325-bed acute care hospital with a 20-bed inpatient pediatric ward, a 12-patient NICU and a four-patient pediatric ICU. The position involves outpatient/inpatient care and resident/medical student teaching. Research opportunities are also available. Call for the general position is approximately 1:8.

Gundersen Lutheran is the heart of a 25-clinic network serving a regional population of 530,000. It has been named one of the top 100 health care organizations in the United States and has been designated the western campus of the University of Wisconsin Medical School. Join more than 475 medical, dental and associate staff in a city with a metropolitan population of 100,000 amid the remarkable beauty of the Mississippi River. In La Crosse, safe neighborhoods, affordable housing, and extensive recreational and cultural activities converge for an outstanding professional and personal lifestyle.

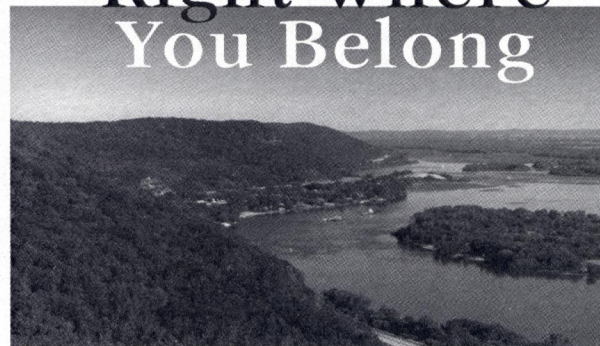
For more information, please contact Dr. Richard Strauss, (800) 362-9567, Ext. 52809, [rstrauss@gundluth.org](mailto:rstrauss@gundluth.org), or Gale Kreibich, Gundersen Lutheran, Medical Staff Development, 1910 South Ave., La Crosse, WI 54601. Phone: (608) 775-6863. E-mail: [gkreibic@gundluth.org](mailto:gkreibic@gundluth.org).

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## Right Where You Belong



### PEDIATRICIAN

Gundersen Lutheran Medical Center in La Crosse, Wisconsin, is seeking a Board Certified/Board Eligible Pediatrician to join our team of 20 general and specialty pediatricians, six PNP's, four NNP's and one PA. Gundersen Lutheran includes a state-of-the-art 325-bed acute care hospital with a 20-bed inpatient pediatric ward, a 12-patient NICU and a four-patient pediatric ICU. The position involves outpatient and inpatient care and resident and medical student teaching. Research opportunities are also available. General call is approximately 1:8.

Gundersen Lutheran is the heart of a 25-clinic network serving a regional population of 530,000. It has been named one of the top 100 health care organizations in the United States and has been designated the western campus of the University of Wisconsin Medical School. Join more than 475 medical, dental and associate staff in a city with a metropolitan population of 100,000 amid the remarkable beauty of the Mississippi River. In La Crosse, safe neighborhoods, affordable housing, and extensive recreational and cultural activities converge for an outstanding professional and personal lifestyle.

Interested candidates should contact: Dr. Richard Strauss, Chair, Department of Pediatrics, Gundersen Lutheran, 1910 South Avenue, La Crosse, WI 54601, 800-362-9567, Ext. 52809, [rstrauss@gundluth.org](mailto:rstrauss@gundluth.org) or Gale Kreibich, Medical Staff Development, Gundersen Lutheran, 1910 South Avenue, La Crosse, WI 54601, 608-775-6863, [gkreibic@gundluth.org](mailto:gkreibic@gundluth.org)

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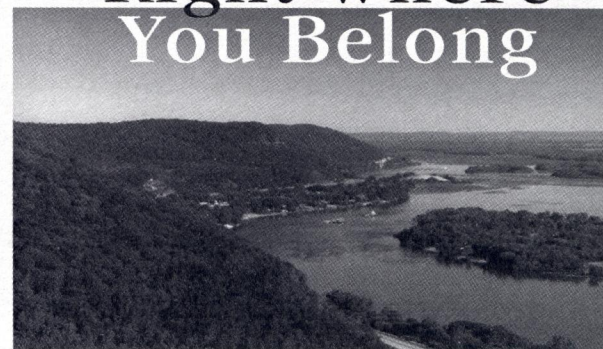
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## Right Where You Belong



### PEDIATRIC GASTROENTEROLOGIST

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The Department of Pediatrics at Gundersen Lutheran is seeking a full-time pediatric gastroenterologist. The GI department has six board-certified adult gastroenterologists and a state-of-the-art GI procedure lab available.

The Department of Pediatrics has 20 pediatricians, six PNP's, four NNP's, and one PA. Our pediatric subspecialty areas include hematology/oncology, orthopedics, asthma/allergy/immunology, ophthalmology, surgery, neonatology, neurodevelopment, neurology, genetics, and pediatric ICU. The pediatric inpatient service also includes a twelve patient NICU, a four patient PICU, and a 20 patient pediatric inpatient service.

We offer an excellent compensation/benefits package, including relocation expenses and continuing education opportunities. Interested candidates should contact Gale Kreibich, Medical Staff Development, Gundersen Lutheran, 1910 South Ave., La Crosse, WI 54601 at (800) 362-9567, Ext. 56863, Email: [gkreibic@gundluth.org](mailto:gkreibic@gundluth.org) or Dr. Richard Strauss, Chair, Dept. of Pediatrics, Gundersen Lutheran, 1836 South Ave., La Crosse, WI 54601 at (800) 362-9567, Ext. 52809, Email: [rstrauss@gundluth.org](mailto:rstrauss@gundluth.org).

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## MID-ATLANTIC

**NEW JERSEY** Ten physician pediatric group in Bergen County seeks qualified BC/BE Associate for part-time and full-time position. Reply with CV and date available to: AAP 11, P.O. Box 996, Abingdon, MD 21009.

## SOUTHEAST

BC/BE pediatrician needed in the underserved area of Bay County Florida. Florida medical license required. Send CV to primary care centre, P.A. to AAP 7, P.O. Box 996, Abingdon, MD 21009.

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Kentucky: BC/BE Pediatrician needed in HPSA location. J-1, H1B permanent resident or U.S. citizen all welcome. Computer literacy preferred. Send CV to: AAP 6, P.O. Box 969, Abingdon, MD 21009.

Growing Pediatric Practice North of Atlanta Harbin Clinic seeks a BC/BE pediatrician to joining a growing practice in Cartersville, GA. Excellent compensation, full benefits, 2-year partnership track. Contact Sarah King at (706) 378-8130; fax (706) 235-3104; e-mail: sking@harbinclinic.com.

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## NORTHWEST

### Neonatologist

The Great Falls Clinic is looking for a BC/BE Neonatologist interested in joining the Neonatology department of a 100+ provider, multi-specialty organization. This position will provide the right candidate with the unique opportunity to work in a progressive level 3 nursery engaged in a multidisciplinary care, tackle challenging neonatal cases, work with conventional/high frequency ventilation and nitric oxide therapy and collaborate with a nationally recognized perinatologist, and a broad base of subspecialty providers and surgeons. The Great Falls Clinic does not qualify for J-1 waiver status. Great Falls is a family-friendly community with excellent schools, low crime, clean air, and a reasonable cost of living. In addition, you will have access to world-class recreational venues, outdoor activities, scenic vistas and regional culture right outside your practice door. Qualified candidates will have excellent clinical and interpersonal skills, be a team player and enjoy working closely with families and other physicians. Great Falls Clinic offers a competitive benefit package and salary leading to partnership. For more information please submit CV and professional goals to Greg Hagfors, Administrator, Great Falls Clinic, P.O. Box 5012, Great Falls, MT 59403 or e-mail: greg.hagfors@gfclinic.com, Web site: www.gfclinic.com.

### Pediatric Neurologist

The Great Falls Clinic is looking for a full-time pediatric neurologist to join a Pediatric

department that consists of a pediatric cardiologist, pediatric pulmonologist, 2 developmental pediatricians, pediatric ophthalmologist and 8 general pediatricians. This position will be office-based with hospital consultations, on-call duties limited to neurology consults only, and a desire to develop outreach clinics. Our local hospital has tertiary level NICU and a busy high-risk perinatology service. Great Falls is a warm and safe community perfect for a physician interested in making a home for themselves and/or their family. Access to world-class recreational venues, outdoor activities, scenic vistas and regional culture right outside your practice door. Does not qualify for J-1 waiver status. Contact: Greg Hagfors, Administrator, Great Falls Clinic, P.O. Box 5012, Great Falls, MT 59403; or e-mail: greg.hagfors@gfclinic.com. Web site: www.gfclinic.com.

## GENERAL NOTICES

**HARRIET LANE - REPORT TO DEVELOPING COUNTRIES** — The Children's Health Organization Relief and Educational Services (CHORES) and Sepracor Inc. need your help in collecting used copies of the Harriet Lane Handbook (15th Edition ONLY) so that we may ship them to pediatric practitioners in developing countries. Please ship to: CHORES, 1015 Atlantic Blvd. #155, Atlantic Beach, Florida 32233. We thank you. Check out CHORES - www.chores4kids.org.

"Management of the Tiny Baby" Conference, Feb. 12-15, 2004, at the Walt Disney World Contemporary Resort, Orlando, Florida. 20 hours of Category I AMA/Credit will be awarded. Distinguished

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The Society for Research in Child Development is seeking applications for their AAAS Policy Fellowships. Pediatricians are encouraged to apply. Deadline for applications is December 15, 2003. Visit our Web site at [www.SRCD.org/policyfellowships.html](http://www.SRCD.org/policyfellowships.html) or call (202) 336-5926.

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ZITHROMAX® (azithromycin) is indicated for the treatment of patients with mild to moderate infections (pneumonia; see **WARNINGS**) caused by susceptible strains of the designated microorganisms in the specific conditions listed below. As recommended dosages, durations of therapy and applicable patient populations vary among these infections, please see **DOSAGE AND ADMINISTRATION** for specific dosing recommendations.

**Children:** (See **PRECAUTIONS—Pediatric Use**.)

**Acute otitis media** caused by *Haemophilus influenzae*, *Moraxella catarrhalis* or *Streptococcus pneumoniae*. (For specific dosage recommendation, see **DOSAGE AND ADMINISTRATION**.)

**Community-acquired pneumonia** due to *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae* or *Streptococcus pneumoniae* in patients appropriate for oral therapy. (For specific dosage recommendation, see **DOSAGE AND ADMINISTRATION**.)

**NOTE:** Azithromycin should not be used in pediatric patients with pneumonia who are judged to be inappropriate for oral therapy because of moderate to severe illness or risk factors such as any of the following: patients with cystic fibrosis, patients with nosocomially acquired infections, patients with known or suspected bacteremia, patients requiring hospitalization, or patients with significant underlying health problems that may compromise their ability to respond to their illness (including immunodeficiency or functional asplenia).

**Pharyngitis/tonsillitis** caused by *Streptococcus pyogenes* as an alternative to first-line therapy in individuals who cannot use first-line therapy. (For specific dosage recommendation, see **DOSAGE AND ADMINISTRATION**.)

**NOTE:** Penicillin by the intramuscular route is the usual drug of choice in the treatment of *Streptococcus pyogenes* infection and the prophylaxis of rheumatic fever. ZITHROMAX® is often effective in the eradication of susceptible strains of *Streptococcus pyogenes* from the nasopharynx. Because some strains are resistant to ZITHROMAX®, susceptibility tests should be performed when patients are treated with ZITHROMAX®. Data establishing efficacy of azithromycin in subsequent prevention of rheumatic fever are not available.

Appropriate culture and susceptibility tests should be performed before treatment to determine the causative organism and its susceptibility to azithromycin. Therapy with ZITHROMAX® may be initiated before results of these tests are known; once the results become available, antimicrobial therapy should be adjusted accordingly.

#### CONTRAINDICATIONS

ZITHROMAX® is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin or any macrolide antibiotic.

#### WARNINGS

Serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions including Stevens Johnson Syndrome and toxic epidermal necrolysis have been reported rarely in patients on azithromycin therapy. Although rare, fatalities have been reported. (See **CONTRAINDICATIONS**.) Despite initially successful symptomatic treatment of the allergic symptoms, when symptomatic therapy was discontinued, the allergic symptoms recurred soon thereafter in some patients without further azithromycin exposure. These patients required prolonged periods of observation and symptomatic treatment. The relationship of these episodes to the long tissue half-life of azithromycin and subsequent prolonged exposure to antigen is unknown at present.

If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

In the treatment of pneumonia, azithromycin has only been shown to be safe and effective in the treatment of community-acquired pneumonia due to *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae* or *Streptococcus pneumoniae* in patients appropriate for oral therapy. Azithromycin should not be used in patients with pneumonia who are judged to be inappropriate for oral therapy because of moderate to severe illness or risk factors such as any of the following: patients with cystic fibrosis, patients with nosocomially acquired infections, patients with known or suspected bacteremia, patients requiring hospitalization, elderly or debilitated patients, or patients with significant underlying health problems that may compromise their ability to respond to their illness (including immunodeficiency or functional asplenia).

**Pseudomembranous colitis** has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of "antibiotic-associated colitis."

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to discontinuation of the drug alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis.

#### PRECAUTIONS

**General:** Because azithromycin is principally eliminated via the liver, caution should be exercised when azithromycin is administered to patients with impaired hepatic function. Due to the limited data in subjects with GFR <10 mL/min, caution should be exercised when prescribing azithromycin in these patients.

The following adverse events have been reported with macrolide products: ventricular arrhythmias, including ventricular tachycardia and *torsade de pointes*, in individuals with prolonged QT intervals.

There has been a spontaneous report from the post-marketing experience of a patient with previous history of arrhythmias who experienced *torsade de pointes* and subsequent myocardial infarction following a course of azithromycin therapy.

**Information for Patients:** ZITHROMAX® oral suspension can be taken with or without food.

Patients should also be cautioned not to take aluminum- and magnesium-containing antacids and azithromycin simultaneously.

The patient should be directed to discontinue azithromycin immediately and contact a physician if any signs of an allergic reaction occur.

**Drug Interactions:** Co-administration of nelfinavir at steady-state with a single oral dose of azithromycin resulted in increased azithromycin serum concentrations. Although a dose adjustment of azithromycin is not recommended when administered in combination with nelfinavir, close monitoring for known side effects of azithromycin, such as liver enzyme abnormalities and hearing impairment, is warranted. (See **ADVERSE REACTIONS**.)

Azithromycin did not affect the prothrombin time response to a single dose of warfarin. However, prudent medical practice dictates careful monitoring of prothrombin time in all patients treated with azithromycin and warfarin concomitantly. Concurrent use of macrolides and warfarin in clinical practice has been associated with increased anticoagulant effects.

Drug interaction studies were performed with azithromycin and other drugs likely to be co-administered. When used in therapeutic doses, azithromycin had a modest effect on the pharmacokinetics of atorvastatin, carbamazepine, ceftriaxone, didanosine, efavirenz, fluconazole, indinavir, midazolam, rifabutin, sildenafil, theophylline (intravenous and oral), triazolam, trimethoprim/sulfamethoxazole or zidovudine. Co-administration with efavirenz, or fluconazole had a modest effect on the pharmacokinetics of azithromycin. No dosage adjustment of either drug is recommended when azithromycin is coadministered with any of the above agents.

Interactions with the drugs listed below have not been reported in clinical trials with azithromycin; however, no specific drug interaction studies have been performed to evaluate potential drug-drug interaction. Nonetheless, they have been observed with macrolide products. Until further data are developed regarding drug interactions when azithromycin and these drugs are used concomitantly, careful monitoring of patients is advised:

Digoxin—elevated digoxin concentrations.  
Ergotamine or dihydroergotamine—acute ergot toxicity characterized by severe peripheral vasospasm and dysesthesia.  
Terfenadine, cyclosporine, hexobarbital and phenytoin concentrations.

**Laboratory Test Interactions:** There are no reported laboratory test interactions.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term studies in animals have not been performed to evaluate carcinogenic potential. Azithromycin has shown no mutagenic potential in standard laboratory tests: mouse lymphoma assay, human lymphocyte clastogenic assay, and mouse bone marrow clastogenic assay. No evidence of impaired fertility due to azithromycin was found.

**Pregnancy:** Teratogenic Effects. Pregnancy Category B: Reproduction studies have been performed in rats and mice at doses up to moderately maternally toxic dose concentrations (i.e., 200 mg/kg/day). These doses, based on a mg/m<sup>2</sup> basis, are estimated to be 4 and 2 times, respectively, the human daily dose of 500 mg. In the animal studies, no evidence of harm to the fetus due to azithromycin was found. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed.

**Nursing Mothers:** It is not known whether azithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when azithromycin is administered to a nursing woman.

**Pediatric Use:** (See **INDICATIONS AND USAGE** and **DOSAGE AND ADMINISTRATION**.)

**Acute Otitis Media** (total dosage regimen: 30 mg/kg, see **DOSAGE AND ADMINISTRATION**): Safety and effectiveness in the treatment of children with otitis media under 6 months of age have not been established.

**Community-Acquired Pneumonia** (dosage regimen: 10 mg/kg on Day 1 followed by 5 mg/kg on Days 2-5): Safety and effectiveness in the treatment of children with community-acquired pneumonia under 6 months of age have not been established. Safety and effectiveness for pneumonia due to *Chlamydia pneumoniae* and *Mycoplasma pneumoniae* were documented in pediatric clinical trials. Safety and effectiveness for pneumonia due to *Haemophilus influenzae* and *Streptococcus pneumoniae* were not documented bacteriologically in the pediatric clinical trial due to difficulty in obtaining specimens. Use of azithromycin for these two microorganisms is supported, however, by evidence from adequate and well-controlled studies in adults.

**Pharyngitis/Tonsillitis** (dosage regimen: 12 mg/kg on Days 1-5): Safety and effectiveness in the treatment of children with pharyngitis/tonsillitis under 2 years of age have not been established.

**Studies evaluating the use of repeated courses of therapy have not been conducted.**

**Geriatric Use:** Pharmacokinetic parameters in older volunteers (65-85 years old) were similar to those in younger volunteers (18-40 years old) for the 5-day therapeutic regimen. Dosage adjustment does not appear to be necessary for older patients with normal renal and hepatic function receiving treatment with this dosage regimen.

In multiple-dose clinical trials of oral azithromycin, 9% of patients were at least 65 years of age (458/4949) and 3% of patients (144/4949) were at least 75 years of age. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in response between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ZITHROMAX® for oral suspension 100 mg/5 mL contains 3.7 mg of sodium per 5 mL of constituted solution. ZITHROMAX® for oral suspension 200 mg/5 mL contains 7.4 mg of sodium per 5 mL of constituted solution.

#### ADVERSE REACTIONS

In clinical trials, most of the reported side effects were mild to moderate in severity and were reversible upon discontinuation of the drug. Potentially serious side effects of angioedema and cholestatic jaundice were reported rarely. Approximately 0.7% of the patients (adults and children) from the 5-day multiple-dose clinical trials discontinued ZITHROMAX® (azithromycin) therapy because of treatment-related side effects. In adults given 500 mg/day for 3 days, the discontinuation rate due to treatment-related side effects was 0.4%. In clinical trials in children given 30 mg/kg, either as a single dose or over 3 days, discontinuation from the trials due to treatment-related side effects was approximately 1%. (See **DOSAGE AND ADMINISTRATION**.) Most of the side effects leading to discontinuation were related to the gastrointestinal tract, e.g., nausea, vomiting, diarrhea, or abdominal pain.

#### Children:

**Single and Multiple-dose regimens:** The types of side effects in children were comparable to those seen in adults, with different incidence rates for the dosage regimens recommended in children.

**Acute Otitis Media:** For the recommended total dosage regimen of 30 mg/kg, the most frequent side effects (≥1%) attributed to treatment were diarrhea, abdominal pain, vomiting, nausea and rash. (See **DOSAGE AND ADMINISTRATION**.) The incidence, based on dosing regimen, is described in the table below:

Dosage Regimen	Diarrhea, %	Abdominal Pain, %	Vomiting, %	Nausea, %	Rash, %
1-day	4.3%	1.4%	4.9%	1.0%	1.0%
3-day	2.6%	1.7%	2.3%	0.4%	0.6%
5-day	1.8%	1.2%	1.1%	0.5%	0.4%

**Community-Acquired Pneumonia:** For the recommended dosage regimen of 10 mg/kg on Day 1 followed by 5 mg/kg on Days 2-5, the most frequent side effects attributed to treatment were diarrhea/loose stools (5.8%), abdominal pain, vomiting, nausea (1.9% each), and rash (1.6%).

**Pharyngitis/Tonsillitis:** For the recommended dosage regimen of 12 mg/kg on Days 1-5, the most frequent side effects attributed to treatment were diarrhea (5.4%), vomiting (5.6%), abdominal pain (3.4%), nausea (1.8%), rash (0.7%), and headache (1.1%).

With any of the treatment regimens, no other treatment-related side effects occurred in children treated with ZITHROMAX® with a frequency greater than 1%. Side effects that occurred with a frequency of 1% or less included the following:

**Gastrointestinal:** Chest pain.

**Gastrointestinal:** Dyspepsia, constipation, anorexia, enteritis, flatulence, gastritis, jaundice, loose stools and oral moniliasis.

**Hematologic and Lymphatic:** Anemia and leukopenia.

**Nervous System:** Headache (otitis media dosage), hyperkinesia, dizziness, agitation, nervousness and insomnia.

**General:** Fever, face edema, fatigue, fungal infection, malaise and pain.

**Allergic:** Rash and allergic reaction.

**Respiratory:** Cough increased, pharyngitis, pleural effusion and rhinitis.

**Skin and Appendages:** Eczema, fungal dermatitis, pruritus, sweating, urticaria and vesiculobullous rash.

**Special Senses:** Conjunctivitis.

**Post-Marketing Experience:**

Adverse events reported with azithromycin during the post-marketing period in adult and/or pediatric patients for which a causal relationship may not be established include:

**Allergic:** Arthralgia, edema, urticaria and angioedema.

**Cardiovascular:** Arrhythmias including ventricular tachycardia and hypotension.

**Gastrointestinal:** Anorexia, constipation, dyspepsia, flatulence, vomiting/diarrhea rarely resulting in dehydration, pseudomembranous colitis, pancreatitis, oral candidiasis and rare reports of tongue discoloration.

**General:** Asthenia, paresthesia, fatigue, malaise and anaphylaxis (rarely fatal).

**Genitourinary:** Interstitial nephritis and acute renal failure and vaginitis.

**Hematopoietic:** Thrombocytopenia.

**Liver/Biliary:** Abnormal liver function including hepatitis and cholestatic jaundice, as well as rare cases of hepatic necrosis and hepatic failure, some of which have resulted in death.

**Nervous System:** Convulsions, dizziness/vertigo, headache, somnolence, hyperactivity, nervousness, agitation and syncope.

**Psychiatric:** Aggressive reaction and anxiety.

**Skin/Appendages:** Pruritus, rarely serious skin reactions including erythema multiforme, Stevens Johnson Syndrome and toxic epidermal necrolysis.

**Special Senses:** Hearing disturbances including hearing loss, deafness and/or tinnitus and rare reports of taste perversion.

**Laboratory Abnormalities:**

**Children: One, Three and Five Day Regimens:** Laboratory data collected from comparative clinical trials employing two 3-day regimens (30 mg/kg or 60 mg/kg in divided doses over 3 days), or two 5-day regimens (30 mg/kg or 60 mg/kg in divided doses over 5 days) were similar for regimens of azithromycin and all comparators combined, with most clinically significant laboratory abnormalities occurring at incidences of 1-5%. Laboratory data for patients receiving 30 mg/kg as a single dose were collected in one single center trial. In that trial, an absolute neutrophil count between 500-1500 cells/mm<sup>3</sup> was observed in 10/64 patients receiving 30 mg/kg as a single dose, 9/62 patients receiving 30 mg/kg given over 3 days, and 8/63 comparator patients. No patient had an absolute neutrophil count <500 cells/mm<sup>3</sup>. (See **DOSAGE AND ADMINISTRATION**.)

In multiple-dose clinical trials involving approximately 4700 pediatric patients, no patients discontinued therapy because of treatment-related laboratory abnormalities.

#### DOSAGE AND ADMINISTRATION (See **INDICATIONS AND USAGE**.)

ZITHROMAX® for oral suspension can be taken with or without food.

**Acute Otitis Media:** The recommended dose of ZITHROMAX® for oral suspension for the treatment of children with acute otitis media is 30 mg/kg given as a single dose or 10 mg/kg once daily for 3 days or 10 mg/kg as a single dose on the first day followed by 5 mg/kg/day on Days 2 through 5. The safety of re-dosing azithromycin in children who vomit after receiving 30 mg/kg as a single dose has not been established. In clinical studies involving 487 patients with acute otitis media given a single 30 mg/kg dose of azithromycin, eight patients who vomited within 30 minutes of dosing were re-dosed at the same total dose.

**Community-Acquired Pneumonia:** The recommended dose of ZITHROMAX® for oral suspension for the treatment of children with community-acquired pneumonia is 10 mg/kg as a single dose on the first day followed by 5 mg/kg on Days 2 through 5.

**Pharyngitis/Tonsillitis:** The recommended dose of ZITHROMAX® for children with pharyngitis/tonsillitis is 12 mg/kg once daily for 5 days.


For more detailed product information please refer to the full prescribing information or call 1-800-879-3477.

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 U.S. Pharmaceuticals





**With Single Dose  
Zithromax, you'll  
have to find a new  
use for all those  
extra spoons.**

**One 30-mg/kg dose of Zithromax delivers the efficacy of 20 doses of Augmentin® in acute otitis media<sup>1</sup>**

- Single Dose Zithromax has efficacy comparable with Augmentin at end of therapy (87% vs 88%) and test of cure (75% vs 75%)<sup>1</sup>
- A subset analysis also revealed comparable clinical success rates between Zithromax and Augmentin in patients aged 6 months to 2 years<sup>1</sup>
- Zithromax is well tolerated  
—The overall incidence of adverse events was 16.8% for Zithromax compared with 22.5% for Augmentin<sup>1</sup>

**Simply effective.**

Single Dose Zithromax is indicated for acute otitis media in children 6 months and older due to *Haemophilus influenzae*, *Moraxella catarrhalis*, or *Streptococcus pneumoniae*.

The most common side effects of Single Dose Zithromax are diarrhea (4.3%), vomiting (4.9%), abdominal pain (1.4%), rash (1.0%), and nausea (1.0%). Zithromax is contraindicated in patients with known hypersensitivity to any macrolide antibiotic.

If an allergic reaction occurs, discontinue drug and institute appropriate therapy. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy for the allergic reaction is discontinued.

Pseudomembranous colitis has been reported with nearly all antibacterial agents. It is important to consider this diagnosis in patients who present with diarrhea.

**Reference:** 1. Block SL, Arrieta A, Seibel M, McLinn S, Eppes SC, Murphy MJ. Single-dose (30 mg/kg) azithromycin compared with amoxicillin/clavulanate for the treatment of uncomplicated acute otitis media. *Curr Ther Res*.<sup>\*</sup> In press.

Healthcare professionals in the US may obtain a copy of the article free of charge by request to the Pfizer Medical Information Hotline at 1-800-438-1985. The article is also available on [www.KidsEars.com](http://www.KidsEars.com), a Pfizer Web site.

<sup>\*</sup>Peer-reviewed publication. This study was funded by Pfizer Inc.

Please see brief summary of prescribing information on adjacent page.



**Single Dose  
Zithromax<sup>®</sup>**  
(azithromycin for oral suspension)