

## POLICY & PRACTICE

### AAP Policy on Pertussis

A new policy statement from the American Academy of Pediatrics (AAP) recommends universal immunization with the tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine at the 11-12 year-age visit, as well as catch-up immunization of older adolescents, to boost individual and herd protection against pertussis. Tdap has replaced the Td (tetanus and reduced diphtheria toxoids) vaccine for adolescents in the childhood immunization schedule. In 2004, more than 25,000 cas-

es of pertussis were reported in the United States—with more than a third occurring in adolescents—up from a low of 1,060 cases in 1976. Additionally, reported pertussis-related deaths among infants increased from about 10 per year in the 1990s to about 20 per year in this decade. “In infants, pertussis can be dangerous, and very severe. Parents need to know how important it is to vaccinate their children on time to prevent a serious and potentially life-threatening disease,” AAP President Dr. Eileen Ouellette said in a statement.

### Vigamox®

(moxifloxacin hydrochloride ophthalmic solution) 0.5% as base

**DESCRIPTION:** VIGAMOX® (moxifloxacin HCl ophthalmic solution) 0.5% is a sterile ophthalmic solution. It is an 8-methoxy fluoroquinolone anti-infective for topical ophthalmic use.

**Clinical Studies:** In two randomized, double-masked, multicenter, controlled clinical trials in which patients were dosed 3 times a day for 4 days, VIGAMOX® solution produced clinical cures on day 5-6 in 66% to 69% of patients treated for bacterial conjunctivitis. Microbiological success rates for the eradication of the baseline pathogens ranged from 84% to 94%. Please note that microbiologic eradication does not always correlate with clinical outcome in anti-infective trials.

**INDICATIONS AND USAGE:** VIGAMOX® solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:

**Aerobic Gram-positive microorganisms:**

*Corynebacterium species\**, *Micrococcus luteus\**, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus hominis*, *Staphylococcus warneri\**, *Streptococcus pneumoniae*, *Streptococcus viridans* group

**Aerobic Gram-negative microorganisms:**

*Acinetobacter lwoffii\**, *Haemophilus influenzae*, *Haemophilus parainfluenzae\**

**Other microorganisms:**

*Chlamydia trachomatis*

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

**CONTRAINDICATIONS:** VIGAMOX® (moxifloxacin HCl ophthalmic solution) is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

**WARNINGS: NOT FOR INJECTION.**

VIGAMOX® solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

**PRECAUTIONS: General:** As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

**Information for Patients:** Avoid contaminating the applicator tip with material from the eye, fingers or other source.

Systemically administered quinolones including moxifloxacin have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

**Drug Interactions:** Drug-drug interaction studies have not been conducted with VIGAMOX® solution. *In vitro* studies indicate that moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2 indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isozymes.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term studies in animals to determine the carcinogenic potential of moxifloxacin have not been performed. However, in an accelerated study with initiators and promoters, moxifloxacin was not carcinogenic in rats following up to 38 weeks of oral dosing at 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose for a 50 kg person, on a mg/kg basis). Moxifloxacin was not mutagenic in four bacterial strains used in the Ames *Salmonella* reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when v79 cells were used. Moxifloxacin was clastogenic in the v79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity *in vivo* in a micronucleus test or a dominant lethal test in mice.

Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 21,700 times the highest recommended total daily human ophthalmic dose. At 500 mg/kg orally, there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

**Pregnancy:**

**Teratogenic Effects. Pregnancy Category C:** Moxifloxacin was not teratogenic when administered to pregnant rats during organogenesis at oral doses as high as 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose); however, decreased fetal body weights and slightly delayed fetal skeletal development were observed. There was no evidence of teratogenicity when pregnant Cynomolgus monkeys were given oral doses as high as 100 mg/kg/day (approximately 4,300 times the highest recommended total daily human ophthalmic dose). An increased incidence of smaller fetuses was observed at 100 mg/kg/day.

Since there are no adequate and well-controlled studies in pregnant women, VIGAMOX® solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers:** Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when VIGAMOX® solution is administered to a nursing mother.

**Pediatric Use:** The safety and effectiveness of VIGAMOX® solution in infants below 1 year of age have not been established.

There is no evidence that the ophthalmic administration of VIGAMOX® has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals.

**Geriatric Use:** No overall differences in safety and effectiveness have been observed between elderly and younger patients.

**ADVERSE REACTIONS:** The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients. Nonocular adverse events reported at a rate of 1-4% were fever, increased cough, infection, otitis media, pharyngitis, rash, and rhinitis.

**Reference:**

1. Data on file. Alcon Laboratories, Inc. 2005.

Rx Only  
Manufactured by  
Alcon Laboratories, Inc.  
Fort Worth, Texas 76134 USA  
Licensed from Bayer AG to Alcon, Inc.  
U.S. PAT. NO. 4,990,517; 5,607,942; 6,716,830  
©2003 Alcon, Inc.

### Food Allergen Labeling

All food labels now must clearly state if a product contains any ingredients with protein derived from the eight major allergenic foods. Under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), manufacturers are required to identify in plain English the presence of ingredients that contain protein derived from milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, or soybeans in the list of ingredients or to say “contains” followed by the name of the source of the food allergen after or adjacent to the list of ingredients. It is estimated that 2% of adults and about 5% of infants and young children in the United States suffer from food allergies. Approximately 30,000 consumers require emergency department treatment and 150 Americans die each year because of allergic reactions to food. “The eight major food allergens account for 90% of all documented food allergic reactions, and some reactions may be severe or life threatening,” said Robert E. Brackett, Ph.D., director of the Food and Drug Administration’s Center for Food Safety and Applied Nutrition. “Consumers will benefit from improved food labels for products that contain food allergens.” The statute, however, does not require manufacturers or retailers to relabel or remove products that don’t have the labeling, because they were labeled before the effective date. For that reason, there will be a period of time where consumers will see packaged food on store shelves and in their homes without the revised allergen labeling, the FDA cautioned.

### Improving Food Marketing

Food and beverage marketing targeted to children aged 12 years and under encourages them to consume high-calorie, non-nutritious products, according to a report from the Institute of Medicine. Although some companies and restaurants have begun to develop and promote healthier choices, overall, food industries spend most of their resources on products with high amounts of added sugar, fat, and salt, and a lack of essential nutrients, the report said. The IOM recommended that these industries shift their resources to developing a wider array of products that are “nutritious, appealing, and affordable.” Lawmakers should look at the IOM report as a road map to help improve children’s diets and address childhood obesity, said Center for Science in the Public Interest Nutrition Policy Director Margo G. Wootan, D.Sc. “Getting junk food out of schools, promoting fruits and vegetables, putting nutrition information on chain restaurant menus, and scrutinizing food ads on children’s television programming are four things Congress could consider right now to advance the IOM’s recommendations,” she said.

### Mental Health Screening Snapshot

More than half the states provide education or information to primary care providers to help them focus on young children’s mental health development, according to a survey from the National Academy for State Health Policy (NASHP). As part of the Assuring Better Child Health and Development (ABCD II) program, NASHP surveyed Medicaid, maternal and child health, and children’s

mental health agencies in all 50 states and the District of Columbia to gather information on how states were addressing the healthy mental development of children aged birth to 3 years. Mental health consultation was mentioned most frequently (48%), followed by state-funded care coordinators (33%), public health nursing consultation (30%), and lists of organizations for physician referrals (27%). However, “these low percentages suggest that none of these resources are readily available,” the survey indicated. States reported that providers raised a number of concerns regarding screening for social emotional development, such as a lack of referral resources, insufficient payment, and a lack of expertise.

### Big Apple Tackles Obesity

New York City’s Department of Health and Mental Hygiene (DOHMH) has launched a series of physical activity and education campaigns to prevent childhood obesity. Training has begun for close to 500 pre-kindergarten teachers in the SPARK program (Sport, Play and Active Recreation for Kids), which provides skills and equipment for structuring physical activity into a child’s day. “Nearly half of the city’s elementary school students are either overweight or obese, and 21% are obese as early as kindergarten,” said Dr. Thomas R. Frieden, the department’s commissioner. “Our initiative makes healthy ideas and practices accessible for kids, because even a small increase in physical activity can help prevent excess weight gain and reduce risks later in life.”

### Data on Youth Suicide Attempts

About 900,000 children aged 12-17 planned to commit suicide during their worst or most recent episode of major depression, according to data from the Substance Abuse and Mental Health Services Administration. Of those who planned suicide, 712,000 attempted it. The report, which was compiled using data from the 2004 National Survey on Drug Use and Health, defined a “major depressive episode” as a period of at least 2 weeks in which a person experienced a depressed mood or loss of interest or pleasure in daily activities, and had at least five of nine symptoms of depression listed in the DSM-IV.

### Video-Induced Seizure Risks

The Epilepsy Foundation has released recommendations for reducing seizures triggered by flashing images and other patterns on television and in video games and computers. The guidelines, which appeared in the September issue of *Epilepsia* and on the foundation’s Web site, address light intensity, flicker, contrast, duration, and pattern and define the technical parameters within these factors that are most likely to provoke seizures in people who are susceptible to them. Although no numbers are available on how many people experience seizures while watching television or surfing the Internet, some epileptologists say they have noticed an increase in the number of young people coming to them with this complaint. “Children and young adults 7-19 years of age are especially susceptible to visually induced seizures,” the journal said in a statement

—Jennifer Lubell