

FYI

Free DVD on ADHD

The "Doctor to Doctor" public awareness campaign is offering free DVDs featuring the latest information about diagnosing and treating attention-deficit hyperactivity disorder. The DVD features Josephine Elia, M.D., of the Children's Hospital of Philadelphia. The DVD is supported by McNeil Consumer and Specialty Pharmaceuticals. Free copies may be obtained by calling 888-265-4115 or by visiting www.healthandfamily.net.

Child Passenger Safety Site

The Children's Hospital of Philadelphia has launched a Web site to provide information to parents about child passenger safety. The site, www.chop.edu/carseat, includes short videos on topics ranging from installing child safety seats to reinforcing safe driving habits in teenagers.

DVDs Fight Childhood Obesity

The U.S. Department of Health and Human Services has released two DVDs to combat childhood obesity. One—"Childhood Obesity: Combating the Epidemic"—is aimed at pediatricians and family physicians. The other—"Max's Magical Delivery: Fit for Kids"—teaches children about fitness. To order, call 800-358-9295 or visit www.ahrq.gov/child/.

Child Medication Safety Guide

The Consumer Healthcare Products Association and the Food and Drug Administration have rereleased the "Kids Aren't

Just Small Adults" pamphlet. The guide provides tips to parents and caregivers about how to administer over-the-counter medicines to children. To order or download the pamphlet, visit www.chpa-info.org, click on "For Consumers" and select "Consumer Publications" from the drop-down menu. A Spanish version also is available.

Promote Hand Washing

The American Society for Microbiology has launched "Take Action: Clean Hands Campaign" to promote hand washing.

The campaign includes educational materials for healthcare professionals and consumers (posters, brochures, stickers). For more information, visit www.washup.org.

Psychiatry Fact Sheets for Families

The American Academy of Child and Adolescent Psychiatry distributes a series of fact sheets to provide information on child and adolescent development, including behavioral, mental, or developmental disorders. The sheets are available in both English and Spanish and can be downloaded from the Internet at www.aacap.org.

Free Allergic Asthma Book

The book "Allergic Asthma for Dummies" is available for free from the Allergy & Asthma Network Mothers of Asthmatics. The book includes tips on asthma management and handling emergencies. To obtain a copy, visit www.breatherville.org.

Web Site Sweetens Kids' Sleep

The National Sleep Foundation has launched a Web site, www.sleepforkids.org, for children aged 7 years and older. The Web site includes information on how important sleep is, what good sleep habits are, and how to combat sleep problems.



Clearly ahead

DESCRIPTION

PATANOL® (olopatadine hydrochloride ophthalmic solution) 0.1% is a sterile ophthalmic solution containing olopatadine, a relatively selective H₁-receptor antagonist and inhibitor of histamine release from the mast cell for topical administration to the eyes.

INDICATIONS AND USAGE

PATANOL® (olopatadine hydrochloride ophthalmic solution) 0.1% is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

CONTRAINDICATIONS

PATANOL® is contraindicated in persons with a known hypersensitivity to olopatadine hydrochloride or any components of PATANOL®.

WARNINGS

PATANOL® is for topical use only and not for injection or oral use.

PRECAUTIONS

Information for Patients: To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

Patients should be advised not to wear a contact lens if their eye is red. PATANOL® should not be used to treat contact lens related irritation. The preservative in PATANOL®, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and **whose eyes are not red** should be instructed to wait at least ten minutes after instilling PATANOL® before they insert their contact lenses.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively. Based on a 40 µL drop size, these doses were 78,125 and 31,250 times higher than the maximum recommended ocular human dose (MROHD). No mutagenic potential was observed when olopatadine was tested in an *in vitro* bacterial reverse mutation (Ames) test, an *in vitro* mammalian chromosome aberration assay, or an *in vivo* mouse micronucleus test. Olopatadine administered to male and female rats at oral doses of 62,500 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of 7,800 times the maximum recommended ocular human use level.

Pregnancy: Pregnancy Category C. Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day or 93,750 times the MROHD and rabbits treated at 400 mg/kg/day or 62,500 times the MROHD during organogenesis showed a decrease in live fetuses. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.

Nursing Mothers: Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when PATANOL® is administered to a nursing mother.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

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

ADVERSE REACTIONS

Headaches have been reported at an incidence of 7%. The following adverse experiences have been reported in less than 5% of patients: Asthenia, blurred vision, burning or stinging, cold syndrome, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, nausea, pharyngitis, pruritus, rhinitis, sinusitis, and taste perversion. Some of these events were similar to the underlying disease being studied.

DOSAGE AND ADMINISTRATION

The recommended dose is one drop in each affected eye two times per day at an interval of 6 to 8 hours.

HOW SUPPLIED

PATANOL® (olopatadine hydrochloride ophthalmic solution) 0.1% is supplied as follows:

- 5 mL in plastic DROP-TAINER® dispenser.
- 5 mL NDC 0065-0271-05.

Rx Only

U.S. Patents Nos. 4,871,865; 4,923,892; 5,116,863; 5,641,805.
Revised: December 2003

References:

1. Lanier BQ, Abelson MB, Berger WE, et al. Comparison of the efficacy of combined fluticasone propionate and olopatadine versus combined fluticasone propionate and fexofenadine for the treatment of allergic rhinoconjunctivitis induced by conjunctival allergen challenge. *Clin Ther*. 2002;24:1161-1174.
2. Berger W, Beck M, Kimura S, Westbrook T, Storms W, Galant S. A multicenter, open-label, crossover, environmental model evaluation of the effect of an adjuvant therapy of Patanol® (olopatadine HCl 0.1%) ophthalmic solution on quality of life of patients with allergic rhinitis using systemic and/or nasal therapy. Submitted for publication.

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