

CLINICAL CAPSULES

Salmonella From Turtles

Small pet turtles were linked to four cases of salmonella in children in 2004, according to the Centers for Disease Control and Prevention and the public health departments of Wisconsin and Wyoming (MMWR 2005;54:223-6). A 4-year-old girl from Kansas developed diarrhea and a 4-day fever shortly after vacationing in Wisconsin and purchasing a small turtle at a souvenir store. The girl was treated with trimethoprim/sulfamethoxazole for 3 days and had recovered after 5 days. A 2-year-old boy and a 10-year-old boy in Wisconsin de-

veloped similar symptoms, including diarrhea and fever, which were traced to pet turtles purchased from different souvenir shops in Wisconsin. In addition, a 6-year-old boy in Wyoming presented with nausea, diarrhea, vomiting, and a persistent fever. A stool sample yielded *S. typhimurium*, which was traced to the boy's two pet turtles. Although salmonella infections generally resolve after mild gastroenteritis, they can develop into serious illnesses. Despite an FDA ban on the sale of turtles with a carapace less than 4 inches, local health and environmental officials must consider the po-

tential for infections transmitted by turtles that are sold illegally.

Oseltamivir Eases Asthma During Flu

Treatment with oseltamivir (Tamiflu) within 24 hours of the onset of flu symptoms reduced exacerbations of asthma in children aged 6-12 years, wrote Sebastian L. Johnston, M.D., of Imperial College, London, and his associates (Pediatr. Infect. Dis. J. 2005;24:225-32). In a randomized, double-blind, placebo-controlled 4-week study, the asthmatic children received either 2 mg/kg of oseltamivir or a placebo twice daily as an oral syrup (6 mg/mL). The primary end point—median time to

freedom from flu illness—was not significantly different within the intent-to-treat infected population of 179 children; the median was 124 hours in the treatment group, compared with 134 hours in the placebo group. A greater difference appeared in the per protocol population, in which 170 children who took oseltamivir had a 17% reduction in the median length of illness (24 hours). However, children treated with oseltamivir within 24 hours of symptom onset experienced rapid improvement in asthma exacerbation, whereas those in the placebo group initially showed worse symptoms, then improved gradually. Children who presented later than 24 hours after symptom onset recovered steadily regardless of randomization, although the treated children had a higher rate of improvement of asthma. Although oseltamivir generally was well tolerated, approximately half of all the children reported at least one adverse event. Gastrointestinal problems were the most common problem, reported by 16% on oseltamivir and 11% on placebo. In addition, improvement in pulmonary function (FEV1) was significantly greater among the oseltamivir group, compared with the placebo group, after 6 days of treatment (10% vs. 5%).

Bacterial Infections Rare With Flu

Serious bacterial illness occurred in only 16 of 163 (9.8%) children with influenza, compared with 153 of 542 (28.2%) children without flu in a retrospective study of 705 infants aged 0-36 months, according to Hannah F. Smitherman, M.D., and her colleagues at Baylor College of Medicine in Houston. The evaluation of febrile children consumes much office time, and the relatively low prevalence of serious bacterial infections suggests that febrile children with the flu may not need to have blood drawn for cultures, the investigators wrote (Pediatrics 2005;115:710-8). The study included four flu seasons, and children who presented with fever underwent viral testing and blood cultures. Bacteremia was 86% less likely among the children with the flu, compared with those who did not have the flu. In addition, of the 110 children with the flu who underwent urine cultures, only 2 (1.8%) tested positive for urinary tract infections.

Teens Unaware of Hepatitis Risk

Adolescents showed a significant lack of understanding of the risk of hepatitis B from contaminated piercing and tattoo tools, as well as from infected needles and risky sexual behaviors, wrote Amy B. Slonim, Ph.D., of the Michigan Public Health Institute in Okemos, and her associates. In a survey of 17,063 adolescents and young adults aged 13-21 years, 47% could not provide any correct information about hepatitis B vaccination, including 27% who gave no information and 20% who gave incorrect information. Nearly half of those who gave incorrect information thought a vaccination was "something bad." Clinic staff members who conducted the surveys suggested a strategy for educating teens about hepatitis including examples of how it is contracted, emphasis of the possible severity of the illness (liver cirrhosis) and the safety and effectiveness of the vaccine (J. Adolesc. Health 2005;36:178-86).

—Heidi Splete



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.
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References:

- 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.
- 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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ALCON LABORATORIES, INC.
Fort Worth, Texas 76134
www.alconlabs.com