

Pataday™

(olopatadine hydrochloride ophthalmic solution) 0.2%

INDICATIONS AND USAGE

PATADAY™ solution is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

CONTRAINDICATIONS

Hypersensitivity to any components of this product.

WARNINGS

For topical ocular use only. Not for injection or oral use.

PRECAUTIONS

Information for Patients

As with any eye drop, 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. PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% should not be used to treat contact lens related irritation. The preservative in PATADAY™ solution, 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 PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% 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 and a 50 kg person, these doses were approximately 150,000 and 50,000 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 approximately 100,000 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 approximately 15,000 times the MROHD level.

Pregnancy:

Teratogenic effects: Pregnancy Category C

Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 150,000 times the MROHD and rabbits treated at 400 mg/kg/day, or approximately 100,000 times the MROHD, during organogenesis showed a decrease in live fetuses. In addition, rats treated with 600 mg/kg/day of olopatadine during organogenesis showed a decrease in fetal weight. Further, rats treated with 600 mg/kg/day of olopatadine during late gestation through the lactation period showed a decrease in neonatal survival and body weight.

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 PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% 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 and effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS

Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%.

The following adverse experiences have been reported in 5% or less of patients:

Ocular: blurred vision, burning or stinging, conjunctivitis, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, pain and ocular pruritus.

Non-ocular: asthenia, back pain, flu syndrome, headache, increased cough, infection, nausea, 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 once a day.

HOW SUPPLIED

PATADAY™ (olopatadine hydrochloride ophthalmic solution) 0.2% is supplied in a white, oval, low density polyethylene DROP-TAINER® dispenser with a natural low density polyethylene dispensing plug and a white polypropylene cap. Tamper evidence is provided with a shrink band around the closure and neck area of the package.

NDC 0065-0272-25

2.5 mL fill in 4 mL oval bottle

Storage:

Store at 2°C to 25°C (36°F to 77°F)

U.S. Patents Nos. 5,116,863; 5,641,805; 6,995,186; 7,402,609

Rx Only

Alcon

References:

1. *Walters Kluwer Pharma Solutions, Source® Pharmaceutical Audit Suite*, August 2010-September 2010, among all specialties.
2. Abelson MB, Gomes PJ, Pasquine T, Edwards MR, Gross RD, Robertson SM. Efficacy of olopatadine ophthalmic solution 0.2% in reducing signs and symptoms of allergic conjunctivitis. *Allergy Asthma Proc.* 2007;28:427-433.
3. Granet DB, Amin D, Tort MJ. Evaluation of olopatadine 0.2% for the elimination of ocular itching in the conjunctival allergen challenge (CAC) model. Poster presented at: Western Society of Allergy, Asthma and Immunology; January 24-28, 2010; Maui, HI.
4. www.FingertipFormulary.com. Accessed June 17, 2010.

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NEWS FROM THE FDA

Liver Injury With Dronedaronone

The Food and Drug Administration issued a safety announcement about reports of rare but severe liver injury in patients taking dronedaronone, including two patients who had acute liver failure that required transplantation.

Dronedaronone (Multaq) is used to treat abnormal heart rhythm in patients who have those symptoms for the past 6 months, according to FDA.

The announcement warned physicians and patients to be alert for signs and symptoms of liver injury or toxicity, including anorexia, nausea, vomiting, fever, malaise, fatigue, right upper quadrant pain, jaundice, dark urine, or itching. Physicians are encouraged to consider ordering periodic hepatic serum enzymes, particularly during the initial 6 months of treatment with dronedaronone.

The label's adverse reactions and warnings and precautions sections are being updated to include information about the potential risk of liver injury.

Lower Acetaminophen Doses Sought

The FDA has asked manufacturers of prescription pain products containing acetaminophen to include no more than 325 mg of the drug in each capsule, tablet, or other dosage unit.

According to a safety announcement by the agency, the action was taken to address the ongoing problem of acetaminophen overdose, a leading cause of severe liver injury in the United States.

The FDA requests that manufacturers of these combination products – including Vicodin and Percocet – add a boxed warning to product labels about the potential risk of severe liver injury if acetaminophen is taken in excessive doses or with alcohol.

Manufacturers have until January 2014 to comply with the recommendations, so a shortage of these medications is not anticipated, according to the agency.

The FDA is also asking clinicians to educate their patients about the dangers of acetaminophen overdose and to advise patients to take no more than the maximum daily dose of acetaminophen (4,000 mg).

“For physicians and other health care providers, we want to emphasize that it's important to talk to patients and make sure that they are aware of the risks of using prescription pain medicines with acetaminophen,” Dr. Sandra Kweder said during a press briefing.

Currently, prescription acetaminophen products contain up to 750 mg of acetaminophen per dosage unit, but there are no data indicating that more than 325 mg of acetaminophen per unit provides greater pain relief, according to the FDA.

The agency's request does not apply to over-the-counter products, which can contain as much as 500 mg per tablet or capsule in the products marketed as extra strength.

Almost half of acetaminophen-related cases of liver failure in the United

States are caused by overdoses from prescription opioid-acetaminophen products, which are among the most commonly prescribed products in the United States, accounting for almost 200 million prescriptions dispensed per year.

Rules on Tobacco Tightened

Certain tobacco products – including cigarettes, roll-your-own, and smokeless varieties – that were introduced or changed in the United States after Feb. 15, 2007, must be reviewed by the FDA to show that they are “substantially equivalent” to existing products, Dr. Lawrence Deyton, director of the agency's Center for Tobacco Products, said in a press briefing.

The FDA action is driven by the Family Smoking Prevention and Tobacco Control Act, which became law in June 2009. The law allows the FDA to regulate tobacco products with the goal of protecting public health.

The substantial equivalence provisions are “meant to ensure that new tobacco products or changes to existing products are evaluated by the FDA before they enter the marketplace and are consumed by millions of people,” Dr. Deyton said. “Up to now, tobacco products have been the only mass-consumed products for which users do not know what they are consuming,” he said.

The Tobacco Control Act allows tobacco companies to market products that were available after Feb. 15, 2007, if the companies submit at least a preliminary report to the FDA by March 22, 2011, to show that these products are not significantly different from pre-existing products. Products in existence before Feb. 15, 2007, are not subject to the new FDA review, said Ann Simoneau, director of the Center for Tobacco Products' Office of Compliance and Enforcement.

New products introduced after March 22 will follow a different regulatory pathway, Dr. Deyton said.

Physicians should know that the FDA is now examining certain tobacco products and that manufacturers are required to submit information to the FDA about the products and changes to them, “particularly if those changes might raise new questions about public health,” Dr. Deyton said.

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