NOVARTIS

PATANOL (olopatadine 0.1%)

1mg/mL sterile ophthalmic solution

Basic Succinct Statement

CODE: BSS RD MAR 18; APPR 25 SEP 18

This material is only meant for Healthcare Professionals

PATANOL*

Important note: Before prescribing, consult full prescribing information.

Presentation: DROP-TAINER* dispenser. Each ml of solution contains 1 mg olopatadine and 0.1 mg Benzalkonium Chloride as a preservative.

Indications: Treatment of the signs and symptoms of allergic conjunctivitis**.**

Dosage and administration: ♦1 drop in each affected eye 2 times per day. ♦Safety and effectiveness in paediatric patients and patients with hepatic or renal impairment have yet to be established.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions: ♦**General:** For topical use only. Not for injection or oral use. ♦After the bottle cap is removed, if the tamper evident snap collar is loose, remove before using the product. ♦To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas, or other surfaces with the dropper tip of the bottle. ♦Keep the bottle tightly closed when not in use. ♦In case of concomitant therapy with other topical ocular medicines, an interval of 5 minutes should be allowed between successive applications. Eye ointments should be administered last. ♦Patients should be advised not to wear a contact lens if their eye is red. ♦Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. ♦**Fertility:** Studies have not been performed to evaluate the effect of administration of Olopatadine on human fertility. Effects in non-clinical fertility studies in male and female animals were observed only at dosages considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. No effects on human fertility are anticipated since systemic exposure to Olopatadine is negligible by the topical ocular route (AUC_{0-6} of 9.7 ng* hr/mL in humans administered 1 drop of 0.77% Olopatadine in both eyes once daily for 6.5 days). Olopatadine can be used by women of childbearing potential. ♦**Pregnancy:** There are no or limited amount of data from the use of Olopatadine in pregnant women. Effects in nonclinical reproduction and developmental toxicity studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use. No effects during pregnancy are anticipated since systemic exposure to Olopatadine is negligible by the topical ocular route (AUC_{0-6} of 9.7 ng*hr/mL in humans administered 1 drop of 0.77% Olopatadine in both eyes once daily for 6.5 days). Before prescribing Olopatadine to a pregnant woman, a physician should weigh the benefit of administration to the woman to the risk of the fetus. ♦**Breast-feeding:** Available pharmacodynamic/toxicological data in animals have shown excretion of Olopatadine/metabolites in milk following high dose systemic Olopatadine administration. Radioactivity has been identified in the milk of nursing rats at concentrations of 0.33 to 4.28 times that of plasma concentrations (1,184 ng*hr/mL AUC_{0-24} in lactating rat plasma) following a 1 mg/kg oral administration of ^{14}C-Olopatadine. Based upon the low level of Olopatadine present in human plasma following topical ocular administration (AUC_{0-6} of 9.7 ng*hr/mL in humans administered 1 drop of 0.77% Olopatadine in both eyes once daily for 6.5 days), the concentration of Olopatadine potentially present in breast milk is expected to be negligible. However, as there is no data available on the concentration of Olopatadine/metabolites in human milk following topical ocular administration, a risk to the suckling child cannot be

excluded. Patients should be informed that antihistamines may affect the milk production of a nursing mother. Before prescribing Olopatadine to a nursing mother, a physician should weigh the benefit of administration to the mother to the risk of the breastfeeding child. ♦**Contact lenses:** Contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to application of PATANOL eye drops and wait at least 15 minutes before reinsertion. ♦**Ability to drive and use machines:** Temporary blurred vision after drop use or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after instillation, the patient must wait until the vision clears before driving or using machinery.

Adverse drug reactions: The following adverse reactions are classified according to the following convention: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) and very rare (<1/10,000). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness.♦**Uncommon:** headache, dysguesia, punctate keratitis, keratitis, eye pain, dry eye, eyelid oedema, eye pruritus, eye discharge, ocular hyperaemia, eyelid margin crusting, ocular discomfort, nasal dryness, fatigue. ♦**Rare:** dizziness, photophobia, vision blurred, erythema of eyelid, dry mouth, dermatitis contact. ♦**Post-Marketing Surveillance:** *in order of decreasing seriousness:* hypersensitivity, lacrimation increased, nausea.

* a tradename of Novartis