NOVARTIS

PATANOL®

(olopatadine hydrochloride)

1 mg/ml, Eye Drops, Solution

Professional Information

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SCHEDULING STATUS **S2**

1 NAME OF THE MEDICINE

PATANOL® 1 mg/ml Eye Drops, solution

2 QUALITIVE AND QUANTITIVE COMPOSITION

Contains 1,11 mg/ml olopatadine hydrochloride equivalent to 1 mg/ml olopatadine.

Excipients with known effect:

Benzalkonium chloride 0.1 mg/ml

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution

Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

PATANOL is indicated for the temporary prevention of itching of the eye due to allergic conjunctivitis.

4.2 Posology and method of administration Posology

Instill one drop of PATANOL in the conjunctival sac of the affected eye(s) twice daily.

Special populations

Use in elderly.

No dosage alteration in elderly patients is necessary.

Use in renal impairment

PATANOL eye drops has not been studied in patients with renal or hepatic disease. However, a renal impairment study after oral dosing of olopatadine in patients with severe renal impairment indicates that a higher plasma concentration can be expected with PATANOL in this population. However, because of the low plasma exposure following topical ocular administration, no dose adjustment is necessary.

Use in hepatic impairment

Hepatic metabolism represents a small fraction of olopatadine elimination. Therefore, hepatic impairment is not expected to alter the pharmacokinetics of olopatadine and no dose adjustment is necessary.

Paediatric population

PATANOL may be used in paediatric patients (3 years of age and older) at the same posology as in adults.

Method of administration

- For ocular use only.

- 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.

4.3 Contraindications

Hypersensitivity to PATANOL or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Benzalkonium chloride, which is commonly used as a preservative in ophthalmic products, has been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy. Close monitoring is required with frequent or prolonged use in dry eye patients, or in conditions where the cornea is compromised.
- *Contact lenses*

  Benzalkonium is known to discolour soft contact lenses. Avoid contact with soft contact lenses. PATANOL should not be administered while wearing contact lenses. Patients can insert contact lenses 15 minutes after instillation of PATANOL or at any time later.

4.5 Interaction with other medicines and other forms of interaction

No human clinical medicine interaction studies were performed with PATANOL.

Experimental studies have shown that olopatadine did not inhibit metabolic reactions, which involve cytochrome P-450 isozymes.

No significant medicine interaction was noted following systemic administration of olopatadine and the CYP3A4 inhibitor itraconazole in studies evaluating pro-arrhythmic potential. These results indicate that olopatadine is unlikely to result in metabolic interactions with other concomitantly administered active substances.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/ Contraception in males and females

Not applicable.

Pregnancy

No adequate and well-controlled studies were performed in pregnant women. Studies in animals have shown reproductive toxicity at systemic doses well in excess of the maximal level recommended for human ocular use. Because animal studies are not always predictive of human responses, the use of PATANOL in pregnancy is not recommended.

Breastfeeding

It is not known whether topical administration to humans could result in sufficient systemic absorption to produce detectable quantities in human breastmilk. PATANOL is not recommended for breastfeeding mothers.

Fertility

Studies have not been performed to evaluate the effect of topical ocular administration of olopatadine on human fertility.

4.7 Effects on ability to drive and use machines

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

a. Summary of the safety profile

Tabulated list of adverse reactions

The following adverse reactions have been reported during clinical studies and post-marketing data and 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 <1/1000) very rare (<1/10,000) or not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	**Frequency**	**Adverse Reactions**
Infections and infestations	Uncommon	rhinitis
Immune system disorders	Not known	hypersensitivity, swelling face
Nervous system disorders	Common	headache, dysgeusia
	Uncommon	dizziness, hypoaesthesia
	Not known	somnolence

Eye disorders	Common	eye pain, eye irritation, dry eye, abnormal sensation in eyes
	Uncommon	corneal erosion, corneal epithelium defect, corneal epithelium disorder, punctate keratitis, keratitis, corneal staining, eye discharge, photophobia, vision blurred, visual acuity reduced, blepharospasm, ocular discomfort, eye pruritus, conjunctival follicles, conjunctival disorder, foreign body sensation in eyes, lacrimation increased, erythema of eyelid, eyelid oedema, eyelid disorder, ocular hyperaemia
	Not known	corneal oedema, eye oedema, eye swelling, conjunctivitis, mydriasis, visual disturbance, eyelid margin crusting
Respiratory, thoracic, and mediastinal disorders	Common	nasal dryness
	Not known	dyspnoea, sinusitis

Gastrointestinal disorders	Not known	nausea, vomiting,
Skin and subcutaneous tissue disorders	Uncommon	dermatitis contact, skin burning sensation, dry skin
	Not known	dermatitis, erythema
General disorders and administration site conditions	Common	fatigue
	Not known	asthenia, malaise

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). If overdosage with PATANOL occurs, treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.15.4 Ophthalmic preparations, other.

Pharmacotherapeutic group: ophthalmologicals; decongestant and antiallergics; other antiallergics, ATC code: S01GX 09

Olopatadine is a selective and topically active anti-histaminic and mast-cell stabilising agent. Olopatadine prevents histamine-induced inflammatory cytokine production by human conjunctival epithelial cells.

5.2 Pharmacokinetic properties

Systemic absorption of topically applied olopatadine is minimal and generally below the limit of quantitation of the assay (< 0,5 ng/ml).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Sodium chloride

Disodium phosphate dodecahydrate

Purified water

Hydrochloric acid and/or sodium hydroxide (pH adjuster)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

DO NOT USE MORE THAN 30 DAYS AFTER OPENING.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

5 ml opaque low–density polyethylene bottles with dispensing plugs and polypropylene screw caps.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Novartis South Africa (Pty) Ltd.

Magwa Crescent West

Waterfall City,

Jukskei View

2090

+27 10 347 6600

8 REGISTRATION NUMBER(S)

33/15.4/0189

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30 September 2011

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