

## **SCHEDULING STATUS 2**

### **PROPRIETARY NAME (AND DOSAGE FORM)**

**PATANOL**<sup>®</sup> Eye Drops, solution

### **COMPOSITION**

Contains 1.11 mg/ml olopatadine hydrochloride equivalent to 1 mg/ml olopatadine, preserved with benzalkonium chloride 0.01% (m/v).

### **PHARMACOLOGICAL CLASSIFICATION**

A.15.4 Ophthalmic preparations, other.  
ATC code: S01EX

### **PHARMACOLOGICAL ACTION**

#### **Pharmacodynamic properties**

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.

#### **Pharmacokinetic properties**

Systemic absorption of topically applied olopatadine is minimal and generally below the limit of quantitation of the assay (<0.5 ng/ml).

### **INDICATIONS**

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

### **CONTRA-INDICATIONS**

Hypersensitivity to PATANOL or any of the excipients.

### **WARNINGS**

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

PATANOL should not be administered while wearing contact lenses. Patients can insert contact lenses 10 minutes after instillation of PATANOL or at any time later.

### **DOSAGE AND DIRECTIONS FOR USE**

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

#### Use in elderly

No dosage alteration in elderly patients is necessary.

#### Use in children

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

#### Use in hepatic and 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. 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.

## **SIDE EFFECTS AND SPECIAL PRECAUTIONS**

### **Undesirable effects**

The following undesirable effects, which were determined to be definitely, probably or possibly related to treatment, have been reported. The incidence was either common (1% to 10%) or uncommon (0.1% to 1%).

#### **Ocular Effects**

Common: ocular discomfort (burning and stinging).

Uncommon: ocular pruritus, ocular hyperaemia, ocular discharge, keratitis, lid oedema, dry eye, foreign body sensation and photophobia.

#### **Systemic Effects**

Uncommon:

Body as a whole: headache, asthenia.

Nervous System: dizziness.

Respiratory system: dry nose.

Special senses: taste perversion.

The following additional undesirable effects have been reported from post marketing experiences with PATANOL: blurred vision, dry mouth, rhinitis and erythema.

### **Interaction with other medicinal products and other forms of interaction**

In case of concomitant therapy with other topical ocular medicines, an interval of 5 minutes should be allowed between successive applications.

No human clinical drug 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 drug 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.

### **Pregnancy and lactation**

#### 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 mothers

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

### **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.

## **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

If overdosage with PATANOL occurs, treatment should be symptomatic.

## **IDENTIFICATION**

Clear, colourless solution.

## **PRESENTATION**

5 ml opaque low-density polyethylene bottles with dispensing plugs and polypropylene screw

caps.

**STORAGE INSTRUCTIONS**

Store below 25°C.

DO NOT USE MORE THAN 30 DAYS AFTER OPENING.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER**

33/15.4/0189

**NAME AND BUSINESS ADDRESS OF THE APPLICANT**

Novartis South Africa (Pty) Ltd  
Magwa Crescent West Waterfall  
City, Jukskei View 2090

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

30 September 2011

Namibia: NS1  
Reg. No.: 06/15.4/0068

Zimbabwe: PIM  
Reg. No.: 2002/19.9/4020