125 mm

200 mm

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory
OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION USP 0.1%
ALERCHEK 0.1%

## COMPOSITION
**Each ml contains:**
Active:Olopatadine Hydrochloride USP 1.11mg,
equivalent to Olopatadine 1mg.
Preservative: Benzalkonium Chloride 0.01%
Inactive: Dibasic Sodium Phosphate, Sodium
Chloride, Hydrochloric acid and / or Sodium
Hydroxide (to adjust pH) and Water for Injection

## DOSAGE FORM
Ophthalmic Solution

## PHARMACOLOGY
### Pharmacodynamics
Pharmacotherapeutic group: Decongestants and antiallergics; other antiallergics.
ATC code: S01GX09

Olopatadine is a multiple-action molecule: an inhibitor of the release of histamine from the mast cell and a relatively selective histamine H1-antagonist that inhibits the in vivo and in vitro type 1 immediate hypersensitivity reaction including inhibition of histamine induced effects on human conjunctival epithelial cells and an inhibitor of cytokine secretion. Olopatadine is devoid of effects on alpha- adrenergic, dopamine, muscarinic Type 1 and 2 receptors.

Results from conjunctival antigen challenge studies demonstrated that ALERCHEK 0.1% when subjects were challenged with antigen both initially and up to 8 hours after dosing, was significantly more effective than its vehicle in preventing ocular itching associated with allergic conjunctivitis. Results from an environmental study demonstrated that ALERCHEK 0.1% was effective in the treatment of the signs and symptoms of allergic conjunctivitis when dosed twice daily for up to 6 weeks.

### Pharmacokinetics
### Ocular pharmacokinetics
Following topical ocular administration of radiolabeled olopatadine in rabbits, absorption occurred with the highest amount of radioactivity in cornea, followed by the conjunctiva, iris-ciliary body and aqueous humour. Low systemic exposure was observed after topical ocular administration in rabbits. The degree of melanin binding in pigmented ocular tissues occurred but was minimal.

In man, following topical ocular administration, olopatadine was also shown to have low systemic exposure. Two studies in normal volunteers (totalling 24 subjects) dosed bilaterally with olopatadine 0.15 % eye drops solution once every 12 hours for 2 weeks demonstrated plasma concentrations to be generally below the quantitation limit of the assay (<0.5 ng/ml). Samples in which olopatadine was quantifiable were typically found within 2 hours of dosing and ranged from 0.5 to 1.3 ng/ml.

### Systemic pharmacokinetics
After oral administration, the half- life in plasma was approximately 7 hours in fasting subjects, which increased to approximately 10 hours with the ingestion of food. This was accompanied by a small delay in the $T_{max}$ as well as a small and minimal decrease in systemic exposure. Elimination after oral administration of olopatadine in humans was predominantly through renal excretion. Approximately 60 - 70 % of the dose was recovered in the urine as parent drug. Two metabolites, the mono-desmethyl and the N-oxide, were detected at low concentrations in the urine. In rat studies after oral administration of radiolabeled olopatadine, radioactivity was principally distributed to the site of absorption and eliminating organs. There was no evidence of drug retention in most of the tissues with half-lives that typically followed the plasma half-life. Longer half-lives were observed for kidney, liver and fat tissues; however, no radioactivity was observed at 48 hours.

### Preclinical safety data
Non-clinical data reveal no special hazard for humans treated with ALERCHEK 0.1% eye drops based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.
Studies in animals have shown reduced growth of nursing pups of dams receiving systemic doses of olopatadine well in excess of the maximum level recommended for human ocular use. Olopatadine has been detected in the milk of nursing rats following oral administration.

## INDICATIONS
**ALERCHEK 0.1%** (olopatadine hydrochloride ophthalmic solution 0.1%) is indicated for the treatment of the signs and symptoms of allergic conjunctivitis.

## DOSAGE AND ADMINISTRATION
### Dosage
The recommended dose is 1 drop in each affected eye 2 times per day.

Use in children
Safety and effectiveness in paediatric patients below the age of 3 years have not been established.

Use in patients with hepatic or renal impairment
No clinical studies with ALERCHEK 0.1% eye drops have been conducted in patients with renal or hepatic impairment; therefore the efficacy and safety of ALERCHEK 0.1% eye drops in these patients have yet to be established.

### Method of administration
For ocular use.
After cap is removed, if tamper evident snap collar is loose, remove before using 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. Keep the bottle tightly closed when not in use.
Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reactions.
If more than one topical ophthalmic product is being used, the products must be administered at least 5 minutes apart. Eye ointments should be administered last.

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10 mm
5 mm

Pharma Code

125 mm

200 mm

## CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the excipients.

## SPECIAL WARNINGS AND PRECAUTIONS FOR USE
- For topical use only. Not for injection.
- Do not use if tamper evident seal is damaged or broken at time of purchase.
- ALERCHEK 0.1% eye drops 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 ALERCHEK 0.1% eye drops and wait at least 15 minutes before reinsertion.

## INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
No clinically relevant interactions have been described.

## FERTILITY, PREGNANCY AND LACTATION
### Pregnancy
There are no or limited amount of data from the use of ophthalmic olopatadine in pregnant women.
Studies in animals with olopatadine have shown reproductive toxicity following systemic administration.
ALERCHEK 0.1% eye drops is not recommended during pregnancy.
### Breast-feeding
Studies in animals have shown that olopatadine is excreted in breast milk following oral administration.
However, it is unknown whether olopatadine or its metabolites are excreted in human milk following topical ocular administration.
ALERCHEK 0.1% eye drops should not be used during breast-feeding.
### Fertility
Studies have not been performed to evaluate the effect of topical ocular administration of olopatadine on human fertility.

## EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
ALERCHEK 0.1% eye drops has no or negligible influence on the ability to drive and use machines.
Olopatadine is a non-sedating anti-histamine. 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.

## UNDESIRABLE EFFECTS
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 ), 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. The adverse reactions have been reported during clinical studies and identified from post-marketing surveillance.
Some of these events were similar to the underlying disease being studied.

| System organ class | Adverse reactions |
|---|---|
| Infections and infestations | Rare : rhinitis |
| Immune system disorders | Not known : hypersensitivity |
| Nervous system disorders | Uncommon : headache, dysgeusia<br>Rare : dizziness |
| Eye disorders | Uncommon : punctate keratitis, keratitis, eye pain, dry eye, eyelid oedema, eye pruritus, eye discharge, ocular hyperaemia, eyelid margin crusting, ocular discomfort<br>Rare : photophobia, vision blurred, erythema of eyelid<br>Not known : lacrimation increased |
| Respiratory, thoracic and mediastinal disorders | Uncommon : nasal dryness<br>Not known: cold syndrome and sinusitis |
| Gastrointestinal disorders | Rare : dry mouth<br>Not known : nausea |
| Skin and subcutaneous tissue disorders | Rare : dermatitis contact |
| General disorders and administration site conditions | Uncommon : fatigue<br>Not known: taste perversion |

## OVERDOSE
An ocular overdose of ALERCHEK 0.1% eye drops may be flushed from the eye(s) with lukewarm water.
Due to the characteristics of this preparation, no toxic effects are to be expected with an ocular overdose of this product, nor in the event of accidental ingestion of the contents of one bottle.

## STORAGE AND HANDLING INSTRUCTIONS
Store under normal storage conditions below 30°C. Protect from light.

## SHELF- LIFE
24 Months.
Use the Solution within one month after opening the container.

## PACKAGING INFORMATION
**ALERCHEK 0.1% Eye Drops**: 5 ml LDPE bottle with LDPE Nozzle and HDPE cap.

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Manufactured by:
**INDOCO REMEDIES LTD.**
Plant II, L-32, 33, 34 Verna Industrial Area, Verna, Goa 403 722, INDIA.
Regd. Office: 166, C.S.T. Road, Mumbai 400 098, INDIA.

SIN15527P

**INDOCO REMEDIES LTD.**
**Packaging Development Department**
**Packaging Material Specification**

Item: Leaflet
A/W Code No.: xxxxxxxxxxxx
Open Size: 125 x 200 mm
Folding Pattern: H-Unfolded: 200 mm Folded: 22 mm
W-Unfolded: 125 mm Folded: 125 mm
GSM/Paper: 54 Gsm Maplitho Paper
Colour: Pantone 286 U
**Approved by:**
PDD: _____ HOD: _____
Reason for Preparation: New development for Singapore

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28.02.18 / 11.05.2022