



USV Private Limited 	
Market/Country : Malaysia	Co-ordinator Name : Sachin
SAP Code : 3019369	Item type : Packinsert
Date : 11/08/2026	Software : Corel Draw
Product Name : Patasyn	Version : 2025
Actual Size : 190 mm x 240 mm (L x H) (Font & Back)	Artist Name : Ajay
Pharmacode : 369	Font : Swis721 Cn BT
CMYK/Pantone : XXXX Black	Size : 8 pt
Reason : New Development.	
Path : M:\Govandi\Artwork\Venaa - Final Artworks in CDR\Current 08.2010\Formulation\Export\Malaysia	
NOTE TO THE PRINTER: Processor / Printer shall not make any correction / changes / deviation in the approved artwork. If any discrepancy observed in the artwork, Printer / Processor shall return the artwork to USV.	

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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 foetus.

Breastfeeding

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 AUC₀₋₂₄ in lactating rat plasma) following a 1 mg/kg oral administration of ¹⁴C-olopatadine.

Based upon the low level of olopatadine present in human plasma following topical ocular administration (AUC₀₋₆ 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.

SIDE EFFECTS

No serious ophthalmic or systemic adverse reactions related to olopatadine were reported. The most frequent treatment-related adverse reaction was eye pain.

Tabulated list of adverse reactions

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

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eyedrops in some patients with significantly damaged corneas.

SYMPTOMS AND TREATMENT OF OVERDOSE

No data are available in humans regarding overdose by accidental or deliberate ingestion. In the case of overdose, appropriate monitoring and management of the patient should be implemented.

EFFECTS ON ABILITY TO DRIVE OR USE MACHINE

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.

LIST OF EXCIPIENTS

Benzalkonium chloride
Edetate disodium
Povidone K 30
Dibasic sodium phosphate anhydrous
Sodium chloride
Hydrochloric acid
Sodium hydroxide
Water for injection
Nitrogen

STORAGE CONDITION

Store below 30°C. Discard 28 days after opening.

SHELF LIFE

24 months.

PACKAGING AVAILABLE

2.5 mL of solution in white, round LDPE bottle attached with a transparent LDPE nozzle. The bottle is closed with a white HDPE tamper evident screwcap. One bottle per outer box with leaflet.

LEAFLET REVISION DATE

30/08/2023

Product Registration Holder

Synercam (M) Sdn. Bhd.
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Mfd. by:

USV Private Limited



H-13,16,16A,17,18,19,20,21 & E-22, OI DC,
Mahatma Gandhi Udyog Nagar, Dabhel,
Daman - 396 210, India.

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240 mm

190 mm