

PATASYN (Olopatadine Hydrochloride) Ophthalmic Solution USP 0.2% w/v

Olopatadine Hydrochloride equivalent to Olopatadine 2mg/mL

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What is PATASYN used for

PATASYN is used for the treatment of eye itching caused by allergy to house dust, pollen, animal fur, or other allergens (allergic conjunctivitis)

How PATASYN works

PATASYN works by reducing the intensity of the allergic reaction.

Before you use PATASYN

-When you must not use it

Do not use PATASYN if you are allergic to olopatadine or any of the other ingredients of PATASYN.

If this applies to you, do not use PATASYN and tell your doctor.

Children and adolescents (below 18 years)

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

Older people (65 years of age or above)

You can use PATASYN if you are aged 65 years or over at the same dose as for other adults.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, you think you may be pregnant or are

planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

-Before you start to use it

PATASYN contains benzalkonium chloride which may cause eye irritation and may possibly discolour soft contact lenses. Contact lenses must be removed before administration of PATASYN and reinserted at least 15 minutes later.

-Taking other medications

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

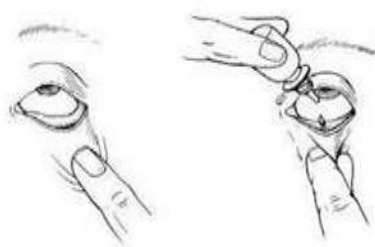
How to use PATASYN

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

-How much to use

The recommended dose is one drop in each affected eye once a day.

For proper application of PATASYN, following steps should be taken:



1. Wash your hands before using.
2. Twist off the cap of the bottle.
3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Place the tip of container close to your eye taking care not to touch your eye.
5. Squeeze the container gently so that one drop goes into your eye, and then release the lower eyelid.
6. Press a finger against the corner of

the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.

7. Repeat it in the other eye if your doctor has told you to do so.

8. Put the cap back.

-When to use it

Use once a day or as directed by your doctor or pharmacist.

-How long to use it

Continue using PATASYN for as long as your doctor recommends.

-If you forget to use it

If you forget to use PATASYN, continue with the next dose as planned. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to make up.

-If you use too much (overdose)

If you use more PATASYN than you should, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

While you are using it

-Things you must do

- Only use PATASYN in your eye(s).
- To avoid contamination, the dropper tip should not touch any surface. The dropper tip should also not come into contact with the eye as this may cause injury to the eye.
- If a drop misses your eye, try again.
- When closing the eyelids for 2 minutes (using nasolacrimal occlusion), the absorption of medicine in other parts of the body (systemic absorption) is reduced. This may result in a decrease in general side effects affecting other parts of the body and an increase in local activity.

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- Keep the bottle tightly closed when not in use.
- If more than one eye medicines are being used, the medicinal products must be administered at least 5 minutes apart. Eye ointments should be administered last.

-Things you must not do

Do not wear a contact lens in case of eye redness.

PATASYN should not be used to treat contact lens related irritation.

-Things to be careful of

Driving and using machines:

As with any eye drop, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at installation, the patient must wait until the vision clears before driving or using machinery.

Side effects

Like all medicines, patients treated with PATASYN may experience side effects, although not everybody gets them.

If you experience any serious side effects, stop using this medicine and tell your doctor immediately.

The following side effects have been seen with PATASYN:

Common:

- Headache, dysgeusia (disturbed sense of taste), eye pain, eye irritation, dry eye, abnormal sensation in eyes, nasal dryness, fatigue (tiredness).

Uncommon:

- Rhinitis (irritation of the nose), dizziness, hypoaesthesia (numbness), disorders related to the cornea, eye discharge,

(photophobia) sensitivity to light, blurred vision, blepharospasm (twitching of the eyelids), eye discomfort, eye itching, disorders of the conjunctiva, increased tear production, eyelid redness, eyelid swelling.

Not known:

- Hypersensitivity, swelling face, somnolence (drowsiness), corneal/ eye swelling, conjunctivitis, visual disturbance, crusting at eyelid margin, mydriasis (eye pupil dilation), difficulty in breathing, sinusitis, dermatitis (skin inflammation), redness, malaise (tiredness), asthenia (abnormal physical weakness/ lack of energy)

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist or healthcare provider.

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of PATASYN

-Storage

Store below 30°C.

Discard 28 days after opening.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

PATASYN is a clear, colourless to pale yellow solution.

-Ingredients

- Active ingredient(s)
2.22 mg of olopatadine hydrochloride in 1 mL solution (0.2% w/w)
- Inactive ingredient(s)
Benzalkonium chloride, Edetate sodium, Povidone K30, Dibasic sodium phosphate anhydrous, Sodium chloride, Hydrochloric acid, Sodium hydroxide, Water for injection

-Packaging available

2.5 mL of solution in a white plastic bottle with white plastic tamper evident screwcap. One bottle per outer box with package insert.

-MAL number

MAL24026039AZ

Manufacturer

USV Private Limited
H-13, 16, 16A, 17, 18, 19, 20, 21, E-22, OI DC Mahatma Gandhi Udyog Nagar, Dabhel Daman, 396210, India

Product Registration Holder

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