Package leaflet: Information for the user

Olopatadine 1 mg/ml eye drops, solution

olopatadine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet

1. What Olopatadine is and what it is used for
2. What you need to know before you use Olopatadine
3. How to use Olopatadine
4. Possible side effects
5. How to store Olopatadine
6. Contents of the pack and other information

1. What Olopatadine is and what it is used for

Olopatadine is used for the treatment of signs and symptoms of seasonal allergic conjunctivitis, or hayfever, in adults. Olopatadine works by stopping release of substances in your eyes that can lead to an allergic reaction and cause symptoms such as itchy, watery, red, or inflamed eyes.

2. What you need to know before you use Olopatadine

Do not use Olopatadine
- If you are allergic to olopatadine or any of the other ingredients of this medicine (listed in section 6).
- If you are breast-feeding.
- In children and adolescents under the age of 18 years.

Warnings and precautions
Talk to your doctor or pharmacist before using Olopatadine.

You should consult your doctor before using Olopatadine eye drops if you have dry eyes or conditions where the cornea may be compromised.

You should remove contact lenses that are in your eyes before using Olopatadine.

Stop using Olopatadine if no improvement or if worsening of the symptoms is observed within 48 hours. In such case, refer to your doctor immediately.

Other medicines and Olopatadine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are using other eye drops or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. You should not use Olopatadine if you are breast-feeding, ask your doctor for advice before using this medicine.

Driving and using machines
You may find that your vision is blurred for a time just after you use Olopatadine. Do not drive or use machines until this has worn off.

Olopatadine contains benzalkonium chloride
This medicine contains 0.5 mg benzalkonium chloride in each 5 ml which is equivalent to 0.1 mg/ml.

The preservative in Olopatadine, benzalkonium chloride, may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

Olopatadine contains disodium phosphate dodecahydrate
This medicine contains 16.7 mg phosphates (in 63.05 mg disodium phosphate dodecahydrate) in each bottle of 5 ml, which is equivalent to 3.34 mg/ml.

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Olopatadine

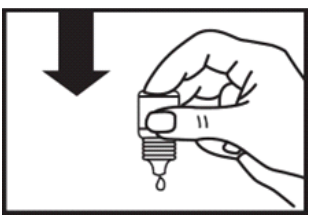
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one drop in the eye or eyes, twice a day, morning and evening.
Do not use more medicine or more often than recommended.
Olopatadine should only be used as an eye drop.

Instructions on using Olopatadine
- Get the Olopatadine bottle and a mirror.
- Wash your hands.
- Take the bottle and twist off the cap.
- After cap is removed, if the tamper evident snap collar is loose, remove before using the product.
- Hold the bottle, pointing down, between your thumb and middle finger.
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here.



- Bring the bottle tip close to the eye. Use the mirror if it helps.
- Don't touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops left in the bottle.
- Gently press on the base of the bottle to release one drop of Olopatadine at a time.
- Don't squeeze the bottle, it is designed so that just a gentle press on the bottom is needed.



- If you use drops in both eyes, repeat the steps for your other eye.
- Put the bottle cap back on firmly immediately after use.
- If a drop misses your eye, try again.

If you use more Olopatadine than you should
Rinse it all out with warm water. Do not put in any more drops until it's time for your next regular dose.

If you forget to use Olopatadine
Use a single drop as soon as you remember, and then go back to your regular dosing routine. However, if it is almost time for your next dose, skip the missed dose before going back to your regular dosing routine. Do not use a double dose to make up for the one missed.

If you stop using Olopatadine
Stop using Olopatadine if no improvement is observed within 48 hours. In such case, refer to your doctor immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Olopatadine and see a doctor straight away, if you notice any of the following serious side effects:
- Hypersensitivity. The signs may include: skin itching or rash, swelling of the face, lips, tongue, body or breathing difficulties.
- Corneal effects (damage to the clear layer at the front of the eye). The signs may include pain, superficial erosions of the cornea, cloudy patches, redness of the eye, blurred vision, sensitivity to light, watery eye.

Additional side effects

Common - may affect up to 1 in 10 people
Effects in the eye
Eye pain, eye irritation, dry eye, abnormal eye sensation, eye discomfort.

General side effects
Headache, fatigue, dry nose, bad taste.

Uncommon - may affect up to 1 in 100 people
Effects in the eye
Blurred, reduced, or abnormal vision, corneal disorder, eye surface inflammation with or without surface damage, inflammation or infection of the conjunctiva, eye discharge, sensitivity to light, increased tear production, itchy eye, redness of the eye, eyelid abnormality, itching, redness, swelling, or crusting of the eyelid.

General side effects
Abnormal or decreased sensation, dizziness, runny nose, dry skin, skin inflammation.

Not known - frequency cannot be estimated from the available data
Effects in the eye
Eye swelling, corneal swelling, change in pupil size.

General side effects
Shortness of breath, increased allergic symptoms, facial swelling, drowsiness, generalized weakness, nausea, vomiting, sinus infection, skin redness and itching.
In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Olopatadine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label (EXP). The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.
You must throw away the bottle four weeks after you first open it, to prevent infections, and use a new bottle. Write down the date you opened it in the space on each bottle label and box.

Do not use this medicine if you notice a change in colour or smell.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Olopatadine contains
- The active substance is olopatadine. Each ml of solution contains 1 mg olopatadine (as hydrochloride).
- The other ingredients are benzalkonium chloride, hydrochloric acid (E507) (for pH adjustment), disodium phosphate dodecahydrate (E339), sodium chloride, sodium hydroxide and water for injections.

What Olopatadine looks like and contents of the pack
Olopatadine 1 mg/ml eye drops, solution is a clear to almost clear colourless solution, practically free from particles.
It is available in a pack size of 1 as a 5 ml opaque low density polyethylene (LDPE) bottle with a LDPE dropper and a high density polyethylene (HDPE) tamper-proof screw-cap.

Marketing Authorisation Holder
Dawa Limited,
5 Sandridge Close,
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HA1 1XD, United Kingdom.

Manufacturer
actrevo GmbH,
Großer Burstah 25,
20457 Hamburg, Germany.

Drugsrus Limited,
5 Sandridge Close,
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This leaflet was last revised in August 2026.

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