

Package leaflet: Information for the user

Olopatadin Orifarm 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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Olopatadin Orifarm is and what it is used for

Olopatadin Orifarm is used for the treatment of signs and symptoms of seasonal allergic conjunctivitis.

Allergic conjunctivitis. Some materials (allergens) like pollens, house dust or animal fur may cause allergic reactions resulting in itching, redness as well as swelling of the surface of your eye.

Olopatadin Orifarm is a medicine for treatment of allergic conditions of the eye. It works by reducing the intensity of the allergic reaction.

2. What you need to know before you use Olopatadin Orifarm

Do not use Olopatadin Orifarm

- if you are allergic to olopatadine or any of the other ingredients of this medicine (listed in section 6)
- you should not use Olopatadin Orifarm if you are breast-feeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Olopatadin Orifarm.

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

Children

Do not use Olopatadin Orifarm in children under the age of 3 years. Do not give this medicine to children under the ages of 3 years because there is no data to indicate that it is safe and work in children under 3 years.

Other medicines and Olopatadin Orifarm

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 Olopatadin Orifarm 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 Olopatadin Orifarm. Do not drive or use machines until this has worn off.

Olopatadin Orifarm contains Benzalkonium chloride and phosphate buffer

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

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.

This medicine contains 3.3 mg phosphates in each ml which is equivalent to 0.11 mg per drop.

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 Olopatadin Orifarm

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.

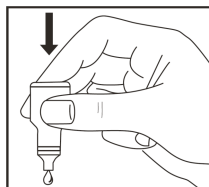
Use this much unless your doctor tells you to do differently. Only use Olopatadin Orifarm in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

Olopatadin Orifarm should only be used as an eye drop.

How to use Olopatadin Orifarm



1



2

- Get the Olopatadin Orifarm 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 (picture 1).
- Bring the bottle tip close to the eye. Use a 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 Olopatadin Orifarm at a time.
- Don't squeeze the bottle, it is designed so that just a gentle press on the bottom is needed (picture 2).
- 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 Olopatadin Orifarm than you should

Rinse it all out with warm water. Do not put in more drops until it's time for your next regular dose.

If you forget to use Olopatadin Orifarm

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 forgotten dose.

If you stop using Olopatadin Orifarm

Do not stop using this medicine without first speaking to your doctor.

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

4. Possible side effects

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

The following side effects have been seen with Olopatadin Orifarm:

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, foreign body sensation in eyes.

General side effects:

Abnormal or decreased sensation, dizziness, runny nose, dry skin, skin inflammation, skin burning sensation.

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.

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Olopatadin Orifarm

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 bottle and the box after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Discard the bottle 4 weeks after opening, even if there is solution remaining to prevent infections. Write down the date you opened it in the space on each bottle label and box.

Do not throw away 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 Olopatadin Orifarm contains

- The active substance is olopatadine. Each ml of solution contains olopatadine hydrochloride corresponding to 1 mg olopatadine.
- The other ingredients are benzalkonium chloride, sodium chloride, disodium phosphate dodecahydrate (E339), hydrochloric acid (E507) (to adjust pH), sodium hydroxide (E524) (to adjust pH), water for injections.

What Olopatadin Orifarm looks like and contents of the pack

Olopatadin Orifarm is a colourless liquid (a solution) supplied in a pack containing either one 5 ml plastic bottle or three 5 ml plastic bottles with screw caps.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark, Sweden: Olopatadin Orifarm

This leaflet was last revised in

2021-12-16

Detailed information on this medicine is available on the web site of {MA/Agency}