

Package leaflet: Information for the user

Opatanol® 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Opatanol is and what it is used for

Opatanol 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.

Opatanol 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 Opatanol

Do not use Opatanol

- **If you are allergic** (hypersensitive) to olopatadine or any of the other ingredients of this medicine (listed in section 6).
- You should not use Opatanol if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Opatanol.

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

Children

Do not use Opatanol 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 Opatanol

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

Opatanol 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 Opatanol, 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.

Opatanol contains Disodium Phosphate Dodecahydrate

This medicine contains 16.72 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 Opatanol

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 Opatanol in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

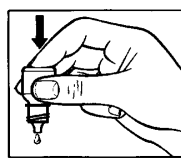
Opatanol should only be used as an eye drop.

TURN THE PAGE FOR MORE ADVICE.

Now turn over.

How to use Opatanol (*continued*)

1



2

How much to use

see side 1

- Get the Opatanol 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 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 Opatanol 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 Opatanol 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 Opatanol

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 Opatanol

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 or pharmacist.

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 Opatanol:

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.

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 national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Opatanol

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 the month.

This medicine does not require any special storage conditions.

You should throw away the bottle four weeks after you first opened 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 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 Content of the pack and other information

What Opatanol contains

- The active substance is olopatadine. Each mL of solution contains 1 mg of olopatadine (as hydrochloride).
- The other ingredients are benzalkonium chloride, sodium chloride, disodium phosphate dodecahydrate (E339), hydrochloric acid (E507) and/or sodium hydroxide (E524) and purified water.

What Opatanol looks like and contents of the pack

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Novartis Pharmaceuticals UK Limited
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White City Place, 195 Wood Lane
London, W12 7FQ
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.emea.europa.eu/>