

Scheduling Status:

S2

**ALLODROP 1 mg/mL
Eye Drops, Solution
Olopatadine 1 mg/ml**

Each millilitre contains benzalkonium chloride 0,01 % m/v as preservative.

Read all of this leaflet carefully because it contains important information for you

ALLODROP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ALLODROP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ALLODROP with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

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

1. What ALLODROP is and what it is used for

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

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

2. What you need to know before you use ALLODROP

Do not use ALLODROP if:

- you are hypersensitive (allergic) to olopatadine hydrochloride, or to any of the other ingredients of ALLODROP (listed in section 6).

Warnings and precautions

Take special care with ALLODROP:

- You should remove contact lenses that are in your eyes before using ALLODROP
- If you notice any allergic reactions or signs of hypersensitivity (see section 4), stop using ALLODROP.
- Prolonged or repeated use of ALLODROP may affect your eye, especially if you have eye conditions, so your doctor may monitor your eyes regularly.

Children and adolescents

Do not use ALLODROP 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 works in children under 3 years.

Other medicines and ALLODROP

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional 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, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before you use ALLODROP.

You should not use ALLODROP if you are pregnant or breastfeeding your baby.

Driving and using machines

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

It is not always possible to predict to what extent ALLODROP may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which ALLODROP affects you.

ALLODROP 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 ALLODROP, 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 10 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.

3. How to use ALLODROP

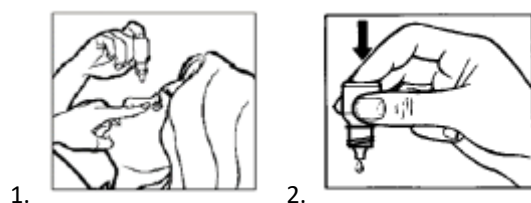
Do not share medicines prescribed for you with any other person.

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

The recommended dose is one drop in the eye or eyes, twice a day, morning and evening.

ALLODROP should only be used as an eye drop.

How to use ALLODROP



- Get the ALLODROP 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 ALLODROP 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 ALLODROP 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 ALLODROP

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

ALLODROP can have side effects.

Not all side effects reported for ALLODROP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ALLODROP, please consult your healthcare provider for advice.

If any of the following happens, stop using ALLODROP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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,
- swelling of the hands, feet, ankles, face, lips and mouth, or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ALLODROP. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- headache, taste disturbance
- eye pain, eye irritation, dry eye, abnormal eye sensation
- nasal dryness
- tiredness

Less frequent side effects

- runny nose
- a decreased sense of touch or sensation
- 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, eye discomfort

- increased tear production, itchy eye, redness of the eye, eyelid abnormality, itching, redness, swelling, or crusting of the eyelid
- itchy, dry skin or a rash on swollen, reddened skin

Side effects with unknown frequency

- sleepiness
- eye swelling, corneal swelling, change in pupil size
- inflammation or infection of the outer membrane of the eyeball and the inner eyelid, eyelids are reddened, crusty and burn
- sinus infection
- nausea, vomiting
- skin redness and itching
- lack of energy, general feeling of discomfort
- dry mouth

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ALLODROP.

5. How to store ALLODROP

Store all medicine out of reach of children.

Store at or below 25 °C.

Once the container is opened the contents must be used within 30 days and may be stored at room temperature up to 25 °C. After opening, the container must be stored in the carton.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What ALLODROP contains

The active ingredient is olopatadine. Each ml of solution contains 1 mg of olopatadine (as hydrochloride).

The other ingredients are benzalkonium chloride, disodium hydrogen phosphate dodecahydrate, sodium chloride, hydrochloric acid and water for injection.

What ALLODROP looks like and contents of the pack

ALLODROP is a sterile, clear colourless solution.

ALLODROP is filled into 5 ml round plastic dropper bottle. The product is stoppered with a Screw Cap and 14166 dropper. The bottle, cap and dropper are ETO sterilised. Packaged in a carton.

Holder of Certificate of Registration:

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Access to the corresponding Professional Information

The Full Professional Information Leaflet is available from iPharma (Pty) Ltd, please email info@ipharma.co.za to request a digital copy.
