# **OLOPAT OD** Olopatadine Hydrochloride Ophthalmic Solution USP 0.2% w/v

# **Patient Information Leaflet**

# 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.

## What is in this leaflet?

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

## 1. What Olopat OD Ointment is and what it is used for

Olopat OD 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.

Olopat OD 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 Olopat OD Ointment

## Do not use Olopat OD Ointment

• If you are allergic (hypersensitive) to Olopatadine or any of the other ingredients of this medicine.

• You should not use Olopat OD if you are breastfeeding.

## Warnings and precautions

Talk to your doctor or pharmacist before using Olopat OD. You should remove contact lenses that are in your eyes before using Olopat OD.

## Children

Do not use Olopat OD 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, cosmetics and Olopat OD Ointment

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 and breast-feeding

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

Olopat OD contains Benzalkonium chloride Benzalkonium chloride may cause eye irritation and is known to discolour soft contact lenses, therefore contact with soft contact lenses should be avoided. If you wear contact lens you should remove contact lenses prior to application and wait at least 15 minutes before putting your lenses back in.

# 3. How to use Olopat OD Ointment

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 usual recommended dose of olopatadine 0.2% is 1 drop in each affected eye once daily.

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

Olopat OD should only be used as an eye drop. Before using the eye drops, wash your hands thoroughly. Follow your doctor or pharmacist's instructions on how to use the eye drops. Do not allow the eye dropper to touch any surface. This could contaminate the dropper and lead to an eye infection.

Keep the bottle tightly closed when you are not using it.

Many things can affect the dose of medication that a person needs, such as body weight, other medical conditions, and other medications. If your doctor has recommended a dose different from the ones listed here, do not change the way that you are taking the medication without consulting your doctor.

It is important to use this medication exactly as prescribed by your doctor.

If a drop misses your eye, try again.

# If you use more Olopat OD 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 Olopat OD

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 Olopat OD

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 Olopat OD:

# 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.

## 5. How to store Olopat OD Ointment

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

• Store below 30°C.

• 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.
- Use the solution within one month after opening the vial.

• Do not throw away medicines via waste water 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 Olopat OD contains:

The active substance is: Olopatadine Hydrochloride USP (0.2% w/v)

## List of Excipients:

Benzalkonium Chloride USPNF, Povidone USP, Disodium Hydrogen Phosphate Dodecahydrate BP, Sodium Dihydrogen Phosphate Dihydrate BP, Sodium Hydroxide BP (Pellets), Sodium Chloride BP, Water for Injection BP/USP.

## What Olopat OD looks like and contents of the pack

Clear, Colourless solution free from visible particles 3ml solution filled in 5ml LDPE vial. Carton containing LDPE vial of 5 mL along with patient information leaflet.

Manufacturing Authorization Holder	Manufacturer
Ajanta Pharma Limited Ajanta House,	Ajanta Pharma Limited
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For any information about this medicinal product, please contact Manufacturing Authorization Holder.

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