



PACKAGE LEAFLET: INFORMATION FOR THE USER

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

#### 1. What Olopatadine USV is and what it is used for

Olopatadine USV is used for the **treatment of signs and symptoms of seasonal allergic conjunctivitis**.

**Allergic conjunctivitis** is caused by some materials like pollens, house dust or animal fur (known as allergens), which may cause allergic reactions resulting in itching, redness as well as swelling of the surface of your eye.

Olopatadine USV works by reducing the intensity of the allergic reaction.

#### 2. What you need to know before you use Olopatadine USV

##### Do not use Olopatadine USV

- If you are **allergic** to olopatadine or any of the other ingredients of this medicine (listed in section 6).

##### Warnings and precautions

Talk to your doctor or pharmacist before using Olopatadine USV.

You should **remove contact lenses** before using Olopatadine USV (see section 3).

##### Children

Do not use Olopatadine USV in children under the age of 3 years. This is because there is no data to indicate that it is safe and works in children under 3 years.

##### Other medicines and Olopatadine USV

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 taking each medicine. Eye ointments should be administered last.

##### Pregnancy, breast-feeding and fertility

You should not use Olopatadine USV if you are breast-feeding; ask your doctor for advice before using this medicine.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 USV. Do not drive or use machines until this has worn off.

##### Olopatadine USV contains Benzalkonium chloride

- 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 later.
- 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 Olopatadine USV

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.

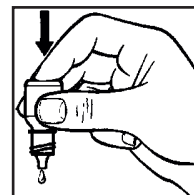
Use this much unless your doctor tells you to do differently. Only use Olopatadine USV in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

Olopatadine USV should only be used as an eye drop.

##### How to use Olopatadine USV



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- Wash your hands and remove any contact lenses.
- Take the bottle and twist off the cap.
- After the cap is removed, remove the tamper-evident plastic collar if it is loose.
- The tamper evident ring should not be broken before first use.
- 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 Olopatadine USV 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 Olopatadine USV than you should**

Rinse out your eye(s) 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 USV**

Use a single drop as soon as you remember, and then take your next dose at the normal time. However, if it is almost time for your next dose, skip the missed dose and carry on as before. Do not use a double dose to make up for the one you missed.

#### **If you stop using Olopatadine USV**

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 Olopatadine USV

##### **Common (may affect up to 1 in 10 people):**

- Eye pain, eye irritation, dry eye, abnormal eye sensation, eye discomfort
- Headache, fatigue, dry nose, bad taste

##### **Uncommon (may affect up to 1 in 100 people)**

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

##### **Not known (frequency cannot be estimated from the available data):**

- Eye swelling, corneal swelling, change in pupil size
- 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 Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://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 USV**

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 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. Content of the pack and other information**

##### **What Olopatadine USV contains**

- The active substance is olopatadine. Each mL of solution contains 1mg of olopatadine (as hydrochloride).
- This medicine contains 0.5 mg benzalkonium chloride in each 5 ml which is equivalent to 0.1 mg/ml.
- The other ingredients are sodium chloride, disodium phosphate dodecahydrate, hydrochloric acid, sodium hydroxide and water for injection.

##### **What Olopatadine USV looks like and contents of the pack**

Olopatadine USV is a clear, colourless 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**

USV UK Limited  
Regus Woburn Place  
16 Upper Woburn Place  
Euston, London  
WC1H 0AF,  
United Kingdom

##### **Manufacturer responsible for batch release and distributor:**

Ennogen Healthcare Ltd  
Unit G2-G4, Riverside Industrial Estate,  
Riverside Way, Dartford,  
DA1 5BS, United Kingdom

**This leaflet was last revised in March 2020**