

## **Package leaflet: Information for the user**

### **Olopatadine Misom 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 Misom 1 mg/ml Eye drops, solution is and what it is used for
2. What you need to know before you use Olopatadine Misom 1 mg/ml Eye drops, solution
3. How to use Olopatadine Misom 1 mg/ml Eye drops, solution
4. Possible side effects
5. How to store Olopatadine Misom 1 mg/ml Eye drops, solution
6. Contents of the pack and other information

#### **1. What Olopatadine Misom 1 mg/ml Eye drops, solution is and what it is used for**

Olopatadine Misom 1 mg/ml Eye drops, solution 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.

Olopatadine Misom 1 mg/ml Eye drops, solution 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 Olopatadine Misom 1 mg/ml Eye drops, solution**

##### **Do not use Olopatadine Misom 1 mg/ml Eye drops, solution:**

- If you are allergic (hypersensitive) to olopatadine or any of the other ingredients of this medicine (listed in section 6).
- You should not use Olopatadine Misom 1 mg/ml Eye drops, solution if you are breast-feeding.

##### **Warning and precautions**

Talk to your doctor, pharmacist before using Olopatadine Misom 1 mg/ml Eye drops, solution.

You should remove contact lenses that are in your eyes before using Olopatadine Misom 1 mg/ml Eye drops, solution.

### **Children**

- Do not use Olopatadine Misom 1 mg/ml Eye drops, solution 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 Olopatadine Misom 1 mg/ml Eye drops, solution**

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 Olopatadine Misom 1 mg/ml Eye drops, solution 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 Olopatadine Misom 1 mg/ml Eye drops, solution. Do not drive or use machines until this has worn off.

### **Olopatadine Misom 1 mg/ml Eye drops, solution contains benzalkonium chloride**

This medicine contains 0.1 mg benzalkonium chloride in each ml of solution.

One drop of solution (approximately 0.03 mL) contains 0.003 mg of benzalkonium chloride

The preservative of Olopatadine Misom 1 mg/ml Eye drops, solution, 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

### **Olopatadine Misom 1 mg/ml Eye drops, solution contains phosphate buffer**

This medicine contains 3.34 mg phosphates in each ml of solution.

One drop of solution (approximately 0.03 mL) contains 0.1mg of phosphates.

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 Olopatadine Misom 1 mg/ml Eye drops, solution

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.

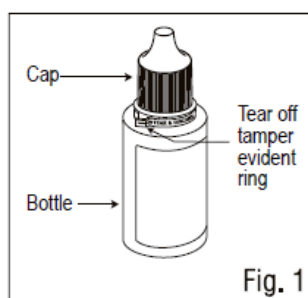
Use this much unless your doctor tells you to do differently. Only use Olopatadine Misom 1 mg/ml Eye drops, solution in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

Olopatadine Misom 1 mg/ml Eye drops, solution should only be used as an eye drop.

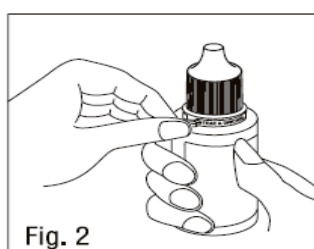
#### **Instructions for use**

##### **Opening the bottle for the first time**

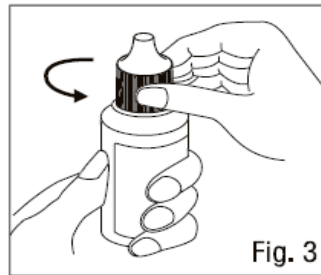
1. Before using the eye drops for the first time, be sure the tamper evident ring between the bottle and the cap is unbroken (Fig 1).



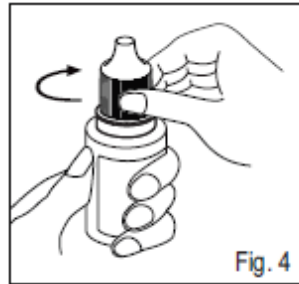
2. Before opening the bottle for the first time, tear off the tamper evident ring to break the seal (Fig 2).



3. To open the bottle, remove the cap by turning it in the counterclockwise direction (Fig.3).



4. To close the bottle, replace the cap and tighten the cap in the clockwise direction after every use (Fig 4)

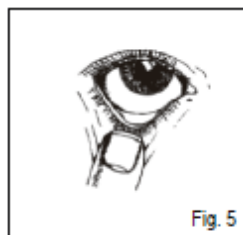


Once the bottle has been opened in this way apply the eye drops as instructed below.

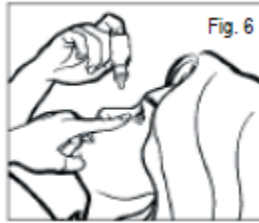
### Using your eye drops

To help you put in your eye drops correctly, you may find it useful to sit in front of a mirror so you can see what you are doing for the first few times.

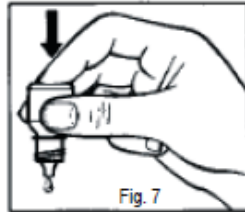
1. Wash your hands.
2. Remove the cap by turning it in the counterclockwise direction (Fig 3)
3. Hold the bottle, pointing down, between your thumb and fingers.
4. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and eye. The drop will go in here (Fig 5).



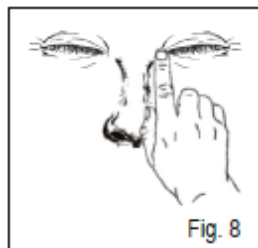
5. Gently press on the base of the bottle to release one drop of Olopatadine Misom 1 mg/ml Eye drops, solution at a time. DO NOT TOUCH YOUR EYE OR EYELID, SURROUNDING AREAS OR OTHER SURFACES WITH THE DROPPER TIP. It could infect the drops left in the bottle (Fig. 6).



6. Don't squeeze the bottle; it is designed so that just a gentle press on the bottom is needed (Fig. 7).



7. After using Olopatadine Misom 1 mg/ml Eye drops, solution, press a finger into the corner of your eye, by the nose, or close your eyelids for 2 minutes. This helps to stop the medicine from getting into the rest of the body (Fig.8).



8. If you use drops in both eyes, repeat steps 3-7 for your other eye.  
9. To close the bottle, replace the cap and tighten the cap in the clockwise direction (Fig 4)

#### **If you use more Olopatadine Misom 1 mg/ml Eye drops, solution than you should**

Rinse it all out with warm water.

Do not put in any more drops until its time for your next regular dose.

#### **If you forget to use Olopatadine Misom 1 mg/ml Eye drops, solution**

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 Olopatadine Misom 1 mg/ml Eye drops, solution**

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

If you have any further questions on the use of this medicine, as 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 Misom 1 mg/ml Eye drops, solution

**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 effect

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 listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Olopatadine Misom 1 mg/ml Eye drops, solution**

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 (or dropper container) 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. Contents of the pack and other information**

### **What Olopatadine Misom 1 mg/ml Eye drops, solution**

The active substance is olopatadine.

One mL of solution contains olopatadine hydrochloride equivalent to 1 mg of olopatadine.

One drop of solution (approximately 0.03 mL) contains 0.03 mg of olopatadine.

The other ingredients are: benzalkonium chloride, sodium chloride, disodium phosphate (E339), water for injections, hydrochloric acid (E507) and/or sodium hydroxide (E524) (for pH adjustment).

### **What Olopatadine Misom 1 mg/ml Eye drops, solution looks like and contents of the pack**

White LDPE container with white LDPE dropper and white HDPE screw cap.

Pack sizes: 1 x 5 ml

3 x 5 ml

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Brown & Burk IR Limited  
22 Northumberland Road,  
Ballsbridge, Dublin 4,  
Ireland

### **Manufacturer**

Eurofins Analytical Services  
Hungary Kft.  
Anonymus u.6.,  
Budapest, 1045,  
Hungary

Misom Labs Limited  
Malta Life Sciences Park,  
LS2.01.06, Industrial Estate,  
San Gwann, SGN 3000, Malta

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