

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

## **Azelastin-COMOD**

### **Eye drops**

#### **Active ingredient**

azelastine hydrochloride 0.05% (0.5 mg/1 ml)

Each drop contains 0.015 mg azelastine hydrochloride.

Inactive ingredients and allergens in the preparation - see section 6.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

#### **1. What is this medicine intended for?**

Azelastin-COMOD is intended for symptomatic treatment and prevention of seasonal allergic conjunctivitis.

**Therapeutic group:** antihistamines.

Antihistamines prevent the effect of a substance called histamine that the body produces as part of an allergic reaction.

Azelastine hydrochloride reduces the inflammation of the eye.

**Azelastin-COMOD is not intended for treatment of eye infections!**

#### **2. Before using this medicine**

**Do not use this medicine if:**

You are sensitive (allergic) to the active ingredient azelastine hydrochloride or to any of the other ingredients in this medicine (see section 6).

#### **Special warnings about using this medicine**

**Before using Azelastin-COMOD, tell your doctor:**

- If you are not sure whether your eye symptoms are caused by an allergy. In particular, if the symptoms appear only in one eye. If your vision quality is impaired or the eye hurts and you do not have any symptoms in the nose, you may have an infection rather than an allergy.
- If the symptoms worsen or last longer than 48 hours without remarkable improvement despite the treatment with Azelastin-COMOD.
- If you wear contact lenses.

#### **Children and adolescents**

This medicine is not intended for children and infants below 4 years of age.

There is no information about the safety and efficacy of using this medicine in children and infants below 4 years of age.

### **Drug interactions**

**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist,** even though treatment with Azelastin-COMOD is not known to be affected by other medicines.

### **Pregnancy and breast-feeding**

If you are pregnant, think you are pregnant, are planning to become pregnant or if you are breast-feeding, do not use Azelastin-COMOD before you consult your doctor or pharmacist.

### **Driving and using machines**

The use of this medicine may cause blurred vision for a short time after use. If you experience blurred vision, wait until your sight clears before you drive or use machinery. Children should be cautioned against riding a bicycle, playing near a road, and the like.

### **3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:

- One drop in each eye twice daily, in the morning and evening, for adults and children over the age of 4.
- If you anticipate contact with pollen, the usual dose of Azelastin-COMOD may be taken as a preventive measure before going outside.
- Continue using Azelastin-COMOD until the symptoms have passed, but do not use Azelastin-COMOD continuously for more than six weeks.
- Do not swallow! Azelastin-COMOD should only be applied to the eyes.
- If your symptoms are severe, your doctor may decide to increase your dosage to one drop in each eye, up to 4 times a day.

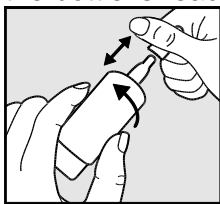
**Do not exceed the recommended dose.**

#### **Instructions for use:**

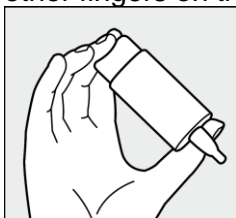
Wash your hands.

Gently wipe around your eyes with a tissue in order to dry residual moisture.

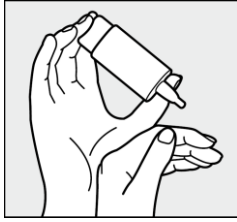
**Step 1:** Remove the cap before use. Before the first application, turn the bottle with its tip down and press onto the bottom of the bottle several times until the first drop appears. Now the bottle is ready for use.



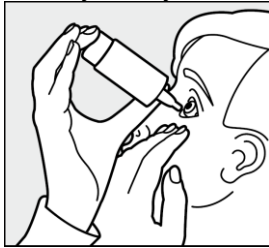
**Step 2:** Hold the bottle upside down with the thumb on the shoulder of the bottle and the other fingers on the bottom of the bottle.



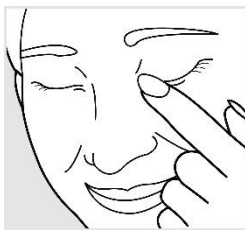
**Step 3:** Support the hand holding the bottle with the other hand.



**Step 4:** Lean your head back slightly, gently pull down your lower eyelid and apply a strong and quick pressure on the middle of bottom of the bottle. This activates the mechanism for the release of one drop. Thanks to the special COMOD valve system, size and speed of each drop are the same independently of how much pressure is applied to the bottle. When applying, avoid any contact between the tip of the bottle and your eye or your skin. Slowly close your eye to allow the fluid to spread evenly on the eyeball.

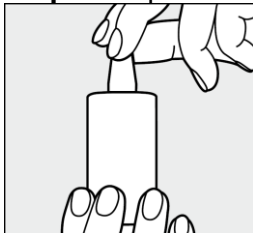


**Step 5:** After instilling, release the lower eyelid and press with your finger on the corner of the eye closest to the nose. While pressing, blink several times to distribute the fluid across the eye surface. Remove surplus eye drops afterwards.



Repeat steps 4-5 for the other eye.

**Step 6:** Replace cap immediately after use. Take care that the dropper tip is dry.



**If you accidentally apply a higher dosage** of Azelastin-COMOD into your eyes, you are unlikely to suffer any symptoms.

**If you have taken an overdose, or if a child has accidentally swallowed some medicine,** immediately go to a hospital emergency room and bring the medicine package with you.

**If you forget to take the medicine at the scheduled time,** do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

**If you stop taking** Azelastin-COMOD before completion of treatment as recommended by your doctor, your symptoms may return.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### **4. Side effects**

Like with all medicines, using Azelastin-COMOD may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Common side effects (affect 1-10 in 100 users):

- Slight irritation in the eye after putting in Azelastin-COMOD (a burning sensation, itching, tears). This should not last long.

Uncommon side effects (affect 1-10 in 1,000 users):

- A bitter taste in your mouth. This disappears quickly, especially after drinking a soft drink.

Very rare side effects (affect less than 1 in 10,000 users):

- An allergic reaction (such as rash and itching).

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

#### **Reporting side effects**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

#### **5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the bottle label and the outer carton. The expiry date refers to the last day of that month.

#### **Storage conditions**

Do not store above 25°C.

- Use the medicine within 12 weeks after first opening.
- Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to throw away this medicine. These measures will help protect the environment.

#### **6. Additional information**

- **In addition to the active ingredient, this medicine also contains:**

Sorbitol, hypromellose, disodium edetate, sodium hydroxide, water for injections.

- **What the medicine looks like and contents of the pack:**

A plastic bottle with the COMOD system (an air-free pump) that contains 10 ml of a clear, colourless solution.

- **Registration holder's name and address:** Kivema Ltd., 33 Hachosh St., Kfar-Shmaryahu 4691000
- **Manufacturer's name and address:**  
Ursapharm Arzneimittel GmbH, Industriestraße 35, 66129 Saarbrücken, Germany
- Revised in May 2023 according to MOH guidelines.
- Registration number of the medicine in the Ministry of Health's National Drug Registry:  
172-13-36275-00