

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

This medicine is dispensed with a doctor's prescription only

Azel-Avenir

Eye drops

Active ingredient:

Azelastine hydrochloride 0.05%

Each drop contains 0.015 mg azelastine hydrochloride.

The medicine contains benzalkonium chloride, which may cause eye irritation.

For a list of Inactive ingredients and allergens – see 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

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.

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

1. What is this medicine intended for?

Azel-Avenir is intended for symptomatic treatment and prevention of seasonal allergic conjunctivitis.

Therapeutic group: Antihistamines.

Antihistamines prevent the effect of a substance called histamine which is produced by the body as part of an allergic reaction. Azelastine hydrochloride reduces the inflammation of the eye.

Azel-Avenir 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 the treatment with Azel-Avenir, tell your doctor:**

- If you are unsure 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 no symptoms are felt in the nose, you may have an infection rather than an allergy.
- If the symptoms worsen or last longer than 48 hours without significant improvement, despite the treatment with Azel-Avenir.
- If you wear contact lenses.

Children and adolescents

There is no information about the safety of use and effectiveness 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 Azel-Avenir is not known to be affected by other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant, think you are pregnant, are planning to become pregnant or are breastfeeding, consult with your doctor or pharmacist before using Azel-Avenir.

Driving and using machines

The use of this medicine may cause blurred vision for a short period following use. If you experience blurred vision, wait until the irritation goes away before you drive or use machinery. Children should be cautioned against riding a bicycle, playing near a road, and the like.

Important information about some of this medicine's ingredients

Azel-Avenir contains the preservative benzalkonium chloride, which is known to be absorbed by soft contact lenses and to discolor them. Avoid contact with soft contact lenses. Remove the contact lenses prior to using the medicine, and wait at least 15 minutes after applying the medicine to the eye before putting them back.

Benzalkonium chloride may cause eye irritation, especially if you have dry eye or a disorder of the cornea (the clear layer at the front of the eye). Contact your doctor if you feel an abnormal sensation in the eye, stinging or pain in the eye after using the medicine.

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, morning and evening, for adults and children above 4 years of age.
- If you anticipate contact with pollen, the usual dose of Azel-Avenir can be used preventively before going outside.
- Continue using Azel-Avenir until the symptoms have passed, but do not use Azel-Avenir continuously for more than six weeks.
- Azel-Avenir is intended to be used in the eyes only, **not to be swallowed**.
- If the symptoms are severe, your doctor may decide to increase the dosage to one drop in each eye, 4 times daily.

Do not exceed the recommended dose.

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How to use:

In order to use the drops correctly, it is advisable to sit in front of the mirror so that you can practice using the drops the first few times.

1. Wash your hands thoroughly.
2. Gently wipe around your eyes with a tissue in order to dry residual moisture (Diagram 1).
3. Open the bottle and check that the dropper is clean.
4. Using a finger, slightly pull your lower eyelid away from the eye (Diagram 2).
5. Place one drop of Azel-Avenir into the space created (Diagram 3), taking care to avoid contact of the dropper with the eye.
6. Release the lower eyelid and gently press on the inner corner of the eye against the bridge of the nose (Diagram 4). While keeping your finger pressed, blink slowly several times in order to spread the medicine over the eye surface.
7. Blot away any remaining medicine with a tissue.
8. Repeat the steps for the other eye.



Diagram 1



Diagram 2

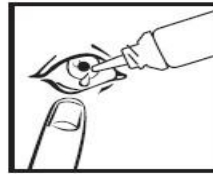


Diagram 3



Diagram 4

If you accidentally put a higher dosage of Azel-Avenir 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 Azel-Avenir before completion of treatment as recommended by your doctor, the 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 Azel-Avenir 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 (effects that occur in 1-10 in 100 users):

- Slight irritation of the eye after applying Azel-Avenir (a burning sensation, itching, tears). This should not last long.

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

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

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

- 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) 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 outside package. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original package.
- Use the medicine within 4 weeks after first opening.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away leftover medicines in order to protect the environment.

6. Additional information:

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

Benzalkonium Chloride, Hypromellose 2910 (Methocel E4M), Disodium Ededate, Sorbitol Liquid (Crystallizing), Sodium hydroxide, Water for Injections.

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

A plastic bottle with a dropper, containing 6 ml of a clear and colorless solution.

Registration holder's name and address: BioAvenir Ltd., 1 David Hamelech Street, Herzliya Pituach 4666101

Manufacturer's name and address: Meiji Pharma, Spain.

This leaflet was revised in October 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 168-19-36043-00.