PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS - 1986

This medicine is dispensed with a physician's prescription only

Optilast, eye drops

Active ingredient:
Azelastine hydrochloride 0.05%

Each drop contains 0.015 mg Azelastine hydrochloride

For a list of inactive and allergenic ingredients in the preparation - see section 6. See also "Important information about some of the medicine's ingredients" in section 2.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult your physician 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.

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

1. What is the medicine used for?

Optilast is used 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 inflammation of the eye.

Optilast is not intended for treatment of eye infections!

2. Before using the medicine

Do not use this medicine if:

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

Special warnings regarding the use of the medicine

Before the treatment with Optilast, tell your physician:

- 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 Optilast.
- If you wear contact lenses.

Children and adolescents

There is no information regarding the safety and efficacy of using the preparation in children and infants below 4 years of age.

Drug interactions

Tell your physician or pharmacist if you are taking or have recently taken other medicines, **including non-prescription medicines and nutritional supplements**, even though Optilast treatment is not known to be affected by other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, ask your physician or pharmacist for advice before using Optilast.

Driving and using machines

Your vision may become blurred for a short time after using this medicine. If you experience blurred vision, wait until the irritation goes away before you drive or use machinery. Children should be cautioned against bicycle riding, playing near roads and the like.

Important information about some of the medicine's ingredients

Optilast contains the preservative benzalkonium chloride, which is known to be absorbed by soft contact lenses and to discolour them. Avoid contact with soft contact lenses. Remove the contact lenses prior to using the preparation and wait at least 15 minutes after applying the medicine drops to the eyes before putting them back.

Benzalkonium chloride may cause eye irritation, especially if you have dry eyes or a disorder of the cornea (the clear layer at the front of the eye).

Consult your physician if you feel an abnormal sensation, stinging or pain in the eye after using the medicine.

3. How should you use the medicine?

Always use according to your physician's instructions. If you are not sure about the dosage or treatment regimen for the preparation, check with your physician or pharmacist.

The dosage and treatment regimen will be determined by your physician only. The usual dosage is generally:

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

Do not exceed the recommended dose.

How to use:

In order to apply the drops correctly, it is advisable to sit in front of a mirror so that you can get used to 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. Slightly pull the lower eyelid away from the eye using your finger (Diagram 2)
5. Place one drop of Optilast 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 this for the other eye


Diagram 1


Diagram 2


Diagram 3


Diagram 4

If you accidentally put too much Optilast into your eyes you are unlikely to suffer any symptoms.

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

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult your physician.

Adhere to the treatment regimen as recommended by the physician.

Even if there is an improvement in your health condition, do not stop treatment with this medicine without consulting with your physician.

If you stop taking Optilast before the completion of treatment as recommended by your physician, the symptoms may return.

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

If you have any further questions regarding use of the medicine, consult your physician or pharmacist.

4. Side effects

As with any medicine, the use of Optilast may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common side effects (effects that occur in 1-10 users out of 100):

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

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

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

Very rare side effects (effects that occur in fewer than one user in 10,000):

- Allergic reaction (such as rash and itching)

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" on the homepage of the Ministry of Health website (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. How should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.
- Do not use this medicine after the expiry date (exp. date) which appears on the bottle label and on the outer package. The expiry date refers to the last day of that month.
- Do not store at a temperature above 25°C.
- Store in the original package.
- Use the medicine within 4 weeks after first opening.
- Do not throw away leftover medicines via wastewater or household waste. As your pharmacist how to throw away leftover medicines in order to protect the environment.

6. Additional information

- In addition to the active ingredients the medicine also contains:
  Sorbitol solution 70%, Methylhydroxypropyl cellulose, Edetate Disodium, Benzalkonium Chloride, Sodium hydroxide, Water for Injections.
- **What does the medicine look like and what does the package contain:**
  A plastic bottle with a dropper, containing 6 ml of a clear and colourless solution.
- **Registration holder and address:**
  MegaPharm Ltd., P.O.B. 519,
  Hod Hasharon 4510501, Israel
- **Manufacturer and address:**
  MEDA Pharma, Bad Homburg, Germany.
- Revised in February 2021 according to MOHs guidelines
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 117-67-29826