

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

This medicine is dispensed with a doctor's prescription only

Latano-Avenir, 50 mcg/ml, Eye Drops

Name and concentration of the active ingredient:

Each 1 ml contains:

Latanoprost 50 mcg

For a list of inactive ingredients and allergens, please see section 2 under '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 for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is intended for treating adults over 18 years old.

1. What is this medicine intended for?

- Reduction of intraocular pressure in patients with open-angle glaucoma and ocular hypertension.

Therapeutic group:

prostaglandin F2 analog. It increases the flow of intraocular fluid into the bloodstream.

2. Before using this medicine:

Do not use this medicine if:

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

Special warnings about using this medicine

- **Before using Latano-Avenir, tell your doctor if:**
 - You have or have ever had eye problems (such as pain, inflammation, irritation, blurred vision).
 - You have or have ever had dry eyes.
 - You have acute asthma or asthma that is not well controlled.
 - You are about to undergo or have recently had eye surgery, including surgery to remove a cataract.
 - You have or have recently had a viral infection of the eye caused by the Herpes simplex virus (HSV).
 - You wear contact lenses; please follow the instructions for using these drops in section 3 'How to use this medicine?'.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly, tell your doctor if you know that you are using prostaglandins, prostaglandin analogs, or prostaglandin derivatives.

Pregnancy and breastfeeding:

Do not use this medicine if you are pregnant or breastfeeding, unless your doctor has decided it is necessary.

If you are pregnant or breastfeeding, think you are pregnant or are planning to have a baby, tell your doctor before you start using this medicine.

Driving and using machines:

While you are using **Latano-Avenir** you may temporarily experience blurred vision. If this happens to you, **do not drive or use dangerous machines** until your vision becomes clear again.

Important information about some of this medicine's ingredients:

This medicine contains benzalkonium chloride (a preservative) and phosphate buffers

Benzalkonium chloride may be absorbed by soft contact lenses and may change their colour. Therefore, you should remove contact lenses before using this medicine and place them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, particularly if you have dry eyes or problems in your cornea (the clear layer in the front of your eye). If you have any unusual feeling in your eye, prickling or pain in your eye after using this medicine, tell your doctor about it.

If you have severe damage in your cornea (the clear layer in the front of your eye), phosphates may very rarely cause cloudy areas on your cornea due to calcium buildup during the course of treatment.

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 once a day in the affected eye(s), in the evening.

Do not exceed the recommended dose!

Do not use **Latano-Avenir** more than once a day, because the effectiveness of the treatment is reduced if you apply the drops more often.

Note: Do not swallow! This medicine is for external use only.

Continue using this medicine according to your doctor's instructions until your doctor tells you to stop.

Complete the course of treatment advised by your doctor.

Wearing contact lenses

If you wear contact lenses, you should remove them before using **Latano-Avenir**. After using **Latano-Avenir**, you should wait 15 minutes before placing the contact lenses back in.

How to use this medicine – general instructions:

- To avoid contamination, do not allow the bottle tip to touch any surface (including your finger and your eye itself). Keep the bottle firmly closed.
- The bottle may not be completely full; this is intended to allow better control of the flow.
- If using in combination with other eye drops, wait at least 5 minutes between treatments.
- If you wear contact lenses – remove your contact lenses before using this medicine and wait at least 15 minutes after applying the medicine in your eye before putting them back in.
- To avoid spreading infection, do not use the same container of medicine for more than one person.

How to use the drops:

- First, wash your hands. Tilt your head back. Use your index finger to pull down the lower eyelid and create a small 'pocket'. Apply the medicine into the 'pocket' you formed. Gently shut your eyes. Do not blink. Keep your eyes closed for 1 to 2 minutes.
- Immediately after applying the drops into your eye, apply pressure to the inner corner of the eye using your middle finger. Continue pressing for 1 to 2 minutes after putting the drops in your eyes. This action helps prevent the medicine from being absorbed into your body, and in this way helps prevent side effects.
- After using this medicine, wash your hands carefully to remove any remaining medicine.

If you use Latano-Avenir with other eye drops

Wait at least 5 minutes between using **Latano-Avenir** and instilling other eye drops.

If you have accidentally taken a higher dose

If you apply more than one drop into your eye, you may feel slight discomfort in your eye and the eyes may water and turn red. These effects should pass, but if you are worried consult your doctor.

If you or your child have accidentally swallowed some medicine, contact a doctor as soon as possible.

If you forget to take this medicine at the scheduled time, carry on with the next dose as planned. Never take a double dose!

If you stop taking the medicine

If you wish to stop taking Latano-Avenir, 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 or pharmacist.

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 **Latano-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.

Very common side effects (affect more than one in 10 users):

- gradual change in eye color due to an increase in the amount of brown pigment in the colored part of the eye called the iris. This change is more likely to happen if you have mixed-color eyes (blue-brown, gray-brown, yellow-brown, green-brown) than if you have uniformly colored eyes (blue, gray, green, or brown eyes). Any change in your eye color may take years to develop although it is normally seen within 8 months of treatment. The color change may be permanent and may be more noticeable if you use this medicine in only one eye. The change in eye color does not appear to be associated with any problems. The eye color change does not persist after treatment with **Latano-Avenir** is stopped.
- redness of the eye.
- eye irritation (a feeling of burning, grittiness, stinging, itching, or the sensation of a foreign body in the eye). If you experience eye irritation that is severe enough to make your eyes water excessively or make you consider stopping this treatment, consult your doctor within a week. Your treatment may be reassessed to ensure that you continue to receive treatment that is right for your condition.
- gradual change in the eyelashes and the fine hairs around the treated eye. These changes include darkening (color), and increased length, thickness and number of your eye lashes. These changes were observed mainly in the Japanese population.

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

irritation or disruption on the surface of the eye, eyelid inflammation (blepharitis), eye pain, light sensitivity (photophobia), and conjunctivitis.

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

- blurred vision, swelling of the eyelid, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), inflammation of the colored part of the eye (uveitis), swelling of the retina.
- skin rash.
- chest tightness (angina); awareness of heart rhythm (palpitations).
- asthma, shortness of breath (dyspnea).
- chest pain.
- headache, dizziness.
- muscle pain, joint pain.
- nausea, vomiting

Rare side effects (affect 1-10 out of 10,000 users):

- inflammation of the iris, symptoms of swelling, scratches/damage to the surface of the eye, swelling around the eye, an extra row of eyelashes, scarring on the surface of the eye, an area full of fluid in the colored part of the eye (iris cyst).
- darkening of the skin of the eyelid or skin reactions on the eyelid.
- worsening of existing asthma.
- severe skin itching.
- development of a viral infection in the eye caused by the Herpes simplex virus (HSV).

Very rare side effects (affect less than one in 10,000 users):
worsening angina in patients who have heart disease, sunken eye appearance (eye sulcus deepening).

In very rare cases, some patients with severe damage to the front part of the eye (cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

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.

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 package. The expiry date refers to the last day of that month.

Storage conditions

- Keep refrigerated (2°C-8°C).
- Store in the original package to protect from light.
- After first opening, do not store above 25°C, and use within four weeks of first opening.
- Do not use this medicine if the solution has changed color or has become cloudy.
- Do not discard the medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

Sodium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous, benzalkonium chloride solution, water for injections.

This medicine contains 0.4 mg benzalkonium chloride in each ml.

This medicine contains 6.3 mg phosphates in each ml, which is equivalent to 0.2 mg in each drop.

What the medicine looks like and contents of the pack:

Each bottle contains 2.5 ml solution. The solution is clear, and is supplied in a polyethylene bottle with a dropper and tamper-proof seal.

Registration holder's name and address:

BioAvenir Ltd., 1 David Hamelech St., Herzelia Pituach 4666101, Israel.

Manufacturer's name and address:

Vianex S.A., Nea Erythrea, Greece.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 154-66-34068-00

Revised in 01/2023 according to MOH guidelines.