Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Lataro
Eye Drops

Name and quantity of the active ingredient:
Each 1 ml contains latanoprost 0.05 mg

Inactive ingredients and allergens: 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 of age.

1. What is this medicine intended for?

Reduction of pressure inside the eye in patients who have open angle glaucoma and increased eye pressure (ocular hypertension).

Therapeutic group: prostaglandin F2 analog.
This medicine increases the outflow 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 or to any of the other ingredients in this medicine (listed in section 6).

Special warnings about using this medicine

- **Before using Lataro, tell your doctor if:**
  - You suffer or have suffered from eye problems (such as eye pain, inflammation, irritation, blurred vision).
  - You suffer from dry eyes.
  - You have severe asthma or your asthma is not well controlled.
  - You are about to have or have recently had eye surgery, including cataract surgery.
  - You wear contact lenses; you can still use Lataro. But please follow the instructions for using these drops in section 3 'How to use this medicine?'
  - You are currently suffering or have suffered from a viral infection in the eye caused by the herpes simplex virus (HSV).

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

Pregnancy and breastfeeding
Do not use Lataro if you are pregnant or breastfeeding unless your doctor has decided that it is necessary.
If you are pregnant or breastfeeding or if you think you may be pregnant or are planning to get pregnant tell your doctor before using this medicine.

Driving and using machines
While using Lataro, you may temporarily suffer from blurred vision. If this happens to you, **do not drive** or operate dangerous machines until your vision becomes clear again.

Important information about some of this medicine's ingredients
Lataro contains benzalkonium chloride (a preservative).
Benzalkonium chloride may be absorbed by soft contact lenses and may discolor them. Therefore, remove your contact lenses before using this medicine and put them back in 15 minutes later.
Benzalkonium chloride may also irritate your eye, particularly if you have dry eyes or problems with your cornea (the clear layer in the front of your eye). Tell your doctor if you have any unusual feeling in your eye, stinging or pain in your eye after using this medicine.
Lataro contains phosphate buffers.
Every 1 ml of the medicine contains 6.8 mg phosphates, equivalent to 0.68 %w/v. If you suffer from a severely damaged cornea (the clear layer in the front of your eye), in very rare cases phosphates may cause cloudy patches on your cornea that are the result of calcium build-up during 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 Lataro more than once a day, because the effectiveness of the treatment is reduced if you put drops in your eye more often.

Attention: Do not swallow! This medicine is for external use only.
Use this medicine according to your doctor's instructions, until your doctor instructs you to stop.

Wearing contact lenses
If you wear contact lenses, remove them before using Lataro. After using this medicine, wait 15 minutes before putting your contact lenses back in.

How to use this medicine
- To prevent contamination of the solution, make sure the bottle tip does not touch any surface whatsoever, including your finger or eye, and keep the bottle tightly closed.

- The bottle of eye drops may not be completely full; this is to allow better control of the drip rate.
- In treatment combined with other eye drops, wait at least 5 minutes between treatments.
- To prevent spreading infection, do not use the same bottle of medicine for more than one person.

How to use the drops

- Wash your hands well. Tilt your head backwards or lie down on a bed, and using your finger slightly pull your lower eyelid away from your eye. Squeeze the medicine into the space created. Press a finger against the corner of the eye near your nose for approximately on minute while closing your eye. Do not blink.
- After using this medicine, wash your hands well to remove any remaining medicine.

If you have accidentally taken a higher dose

If you put more than one drop into your eye, you may feel mild irritation in the eye and your eyes may tear and turn red. These effects should pass, but if you are concerned, consult your doctor.

Contact your doctor as soon as possible if you or your child have accidentally swallowed some medicine.

If you forget to take the medicine at the scheduled time, continue the treatment with the next dose at the scheduled time, but under no circumstances should you take a double dose!

If you stop taking this medicine

Consult your doctor if you want to stop your Lataro treatment.
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> 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. <u>Side effects</u>

Like with all medicines, using Lataro 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 1 in 10 users):

- gradual change in eye color by increasing the amount of brown pigment in the colored part of the eye called the iris. If you have mixed-color eyes (blue-brown, gray-brown, yellow-brown or green-brown), you are more likely to see this change than if you have eyes of one color (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 change in color may be permanent and may be more noticeable if you use Lataro in only one eye. No problems appear to be associated with the change in eye color. Change in color does not continue after treatment with Lataro is stopped.
- redness of the eye.
- eye irritation (a feeling of burning, grittiness, stinging, itching, or the sensation of a foreign object in the eye). If you experience eye irritation severe enough to make your eyes water excessively, or make you consider stopping use of this medicine, consult your doctor within a week. Your doctor may reconsider your treatment to ensure that you will continue receiving treatment that is appropriate for your condition.

- gradual changes in your eyelashes and fine hairs around the affected eye. These include darkening (color), increased length, thickness, and number of eyelashes. These changes have primarily been seen in people of Japanese origin.

Common side effects (affect up to 1 in 10 users):
- irritation or disruption of the surface of the eye, eyelid inflammation (blepharitis), eye pain, light sensitivity (photophobia), and conjunctivitis.

Uncommon side effects (affect up to 1 in 100 users):
- blurred vision, eyelid swelling, dry 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.
- angina pectoris, awareness of heart rhythm (palpitations).
- asthma, shortness of breath (dyspnea).
- chest pain.
- headache, dizziness.
- muscle pain, joint pain.
- nausea and vomiting.

Rare side effects (affect up to 1 in 1,000 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 eyelid skin or eyelid skin reactions.
- worsening of existing asthma.
- severe itching of the skin.
- developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Very rare side effects (affect less than 1 in 10,000 users):
- worsening of angina pectoris 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 their 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.

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

- **Storage conditions**
  Before opening: Keep refrigerated at 2°C-8°C, protected from light. Do not freeze.
  After opening: Store at room temperature, below 25°C. Do not use for longer than 4 weeks after first opening the bottle.
- Keep the bottle in the original outer carton, in order to protect it from light.
- If the color of the solution has changed or it has become cloudy, do not use the medicine.
- Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to throw away 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 phosphate dibasic anhydrous, sodium phosphate monobasic monohydrate, sodium chloride, benzalkonium chloride, sodium hydroxide or hydrochloric acid 1N (for pH adjustment), water for injection

What the medicine looks like and contents of the pack:
This medicine is packaged in a 2.5 ml plastic bottle containing a clear solution.

Registration holder's name and address: Taro International Ltd.,14 Hakitor St., Haifa Bay, 2624761

Manufacturer's name and address: Rafarm, S.A., 12 Korinthou St., 154 51 N Psihiko Athens, Greece

Revised in January 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 156-63-34215-00