

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

This medicine is dispensed with a doctor's prescription only

Lataro-Tim, Eye Drops

Active ingredients and its content:

Each 1 ml contains:

latanoprost 0.050 mg

timolol (as maleate) 5 mg

Inactive ingredients and allergens: See section 6 "Additional information" and section 2 "Important information about some of this medicine's ingredients".

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 medical condition is similar to yours.

1. What is this medicine intended for?

To reduce intraocular pressure in patients suffering from open angle glaucoma or increased ocular pressure, who do not respond fully to beta blockers (intended for external use).

Therapeutic group:

Latanoprost - prostaglandin analog. Acts by increasing fluid flow from the eye to the circulation.

Timolol – beta blockers. Acts by slowing fluid production in the eye.

2. Before using this medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients contained in this medicine (listed in section 6).
- You are sensitive (allergic) to beta-blockers.
- You suffer, or have suffered in the past, from respiratory problems such as asthma, severe chronic obstructive bronchitis (a severe lung disease which may be manifested by wheezing, difficulty breathing and/or persistent cough).
- You suffer from serious heart problems or heart rhythm disorders.

Special warnings about using this medicine

- **Before using the medicine, tell your doctor if:**

- you suffer, or have suffered in the past, from coronary heart disease (the symptoms may include chest pain or tightness, shortness of breath or choking), heart failure or low blood pressure.
- you suffer, or have suffered in the past, from heart rate disorders, such as slow heart rate.
- you suffer, or have suffered in the past, from angina pectoris (particularly Prinzmetal angina pectoris).
- you suffer, or have suffered in the past, from respiratory system problems, asthma or chronic obstructive pulmonary disease (COPD).
- you suffer, or have suffered in the past, from a disease impairing normal blood circulation, such as Raynaud's disease or Raynaud's syndrome.
- you suffer, or have suffered in the past, from diabetes, since the medicine may mask symptoms of low blood sugar level.
- you suffer, or have suffered in the past, from hyperthyroidism, since the medicine may mask signs and symptoms of this disease.
- you are due to undergo eye surgery (including cataract surgery) or you have undergone any eye surgery in the past.
- you suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision).
- you suffer from dry eyes.
- you wear contact lenses. You can still use the medicine, but please follow the instructions for using the drops in Section 3 "How to use this medicine?".
- you suffer from severe allergic reactions requiring hospital treatment.
- you suffer, or have suffered in the past, from viral eye infection caused by herpes simplex virus (HSV).

If you are due to undergo any surgery, inform the doctor that you are using Lataro-Tim, as it may cause a change in the effect of some medicines used during anesthesia.

Children and adolescents

There is no information regarding the safety and efficacy of this medicine in children and adolescents below the age of 18.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Lataro-Tim can affect or be affected by concomitant use of additional medicines, including other eye drops for the treatment of glaucoma. In particular, inform your doctor or pharmacist if you are using any of the following medicine types:

- Prostaglandins, prostaglandin analogs or prostaglandin derivatives
- Beta blockers
- Epinephrine

- Medicines for treating hypertension such as oral calcium channel blockers, guanethidine, antiarrhythmics (such as amiodarone), digitalis glycosides (such as digoxin), or parasymphomimetics
- Quinidine (to treat heart diseases and certain types of malaria)
- Antidepressants, such as paroxetine and fluoxetine
- Medicines for treatment of diabetes
- Medicines for treatment of heart disease

Using this medicine and food

Normal diet, food or drink have no effect on when or how you should use the medicine.

Pregnancy and breastfeeding

Pregnancy

Do not use this medicine if you are pregnant, unless your doctor has decided that it is necessary. Tell the doctor immediately if you are pregnant, think you are pregnant, or are planning to become pregnant.

Breastfeeding

Do not use this medicine if you are breastfeeding. This medicine may pass into breast milk. Consult your doctor before taking the medicine during breastfeeding.

Fertility

This medicine has been found to have no effect on male or female fertility in animal studies.

Driving and using machines

While using Lataro-Tim, you may temporarily experience blurred vision. If this happens to you, do not drive, operate dangerous machines or perform any activity requiring alertness until your vision is 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 lead to their discoloration. Therefore, remove contact lenses before using this medicine and place them back 15 minutes later.

Benzalkonium chloride may cause eye irritation, especially if you have dry eyes or problems in the cornea (the transparent layer in the front part of the eye). If you experience an abnormal feeling in the eye, tingling or pain in the eye after using the medicine, consult your doctor.

If you suffer from severe damage to the transparent layer in the front part of the eye (cornea), phosphates may, rarely, cause cloudy areas on the cornea due to calcium accumulation during the 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).

Do not exceed the recommended dose!

Do not use Lataro-Tim more than once a day, since treatment efficacy is reduced if the drops are instilled more than once a day.

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

Complete the course of treatment as recommended by the doctor.

Your doctor may ask you to perform additional tests to check your cardiovascular function during treatment with the medicine.

Wearing contact lenses

If you wear contact lenses, remove them prior to using Lataro-Tim. Wait 15 minutes after using the medicine before placing the lenses back into your eyes.

Manner of use:

How to use the drops:

- Wash your hands. Tilt your head backwards or lie down, and using your finger, gently pull down the lower eyelid of the eye. Place the bottle tip close, but do not let it touch your eye. Instill the medicine into the space created, and release the lower eyelid.
- Press a finger against the corner of the eye close to the nose and hold for about 2 minutes, keeping your eye closed (this helps prevent absorption of the active ingredients into the rest of the body).
- Repeat the procedure in the other eye if your doctor has told you to do so.
- Place the protective cap back on the bottle after each use.
- After using the medicine, wash your hands carefully to remove any remaining medicine.
- If you use Lataro-Tim in combination with other eye drops, wait 5 minutes between the treatments.

If you have accidentally used a higher dose

If you instill more than one drop into the eye, you may feel minor discomfort in the eye, your eye may tear and turn red. These effects should pass, but if you are worried, contact the doctor for advice.

If you or a child has accidentally swallowed some medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, continue the treatment with the next dose as scheduled, but never take a double dose!

Adhere to the treatment as recommended by your doctor.

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

Do not take medicines in the dark! Check the label and dose every time you take a 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 Lataro-Tim may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

A very important possible side effect is a gradual and permanent change in the eye color. In addition, the medicine may affect heart function; therefore, if you notice changes in your heart rate or function, inform the doctor immediately.

Very common side effects (affect more than 1 in 10 users):

Gradual change in the eye color due to increased quantity of the brown pigment in the colored part of the eye called iris. If the color of your eyes is not even (blue-brown, grey-brown, yellow-brown, green-brown), you are more likely to experience this change than if you have even eye color (blue, grey, green or brown eyes). Any change in your eye color may develop over years, although it is usually apparent within 8 months of treatment. The color change may be permanent and may be more noticeable if only one eye is treated with the medicine. Change in eye color does not appear to be associated with any problem. The eye color change does not persist after treatment with Lataro-Tim is stopped.

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

Eye irritation (such as feeling of burning, sand, itching, stinging or sensation of a foreign body in the eye), eye pain.

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

Headache, redness of the eye, conjunctivitis, blurred vision, watery eyes, inflammation of the eyelids, irritation or injury of the eye surface, skin rash or itching.

Additional side effects

Side effects which occur when medicines containing one of the ingredients present in Lataro-Tim are used, and can also occur when this medicine is used:

- Development of a viral eye infection caused by herpes simplex virus (HSV).
- Generalized allergic reactions including swelling under the skin, that can occur in the face and limbs and obstruct the airways, which may cause difficulty breathing or swallowing, hives and itchy rash (widespread or localized), itching, sudden life-threatening allergic reaction.
- Low blood sugar levels.
- Dizziness.
- Insomnia, depression, nightmares, memory loss, hallucinations.
- Fainting, stroke, reduced blood flow to the brain, worsening of symptoms of the muscle weakness disease myasthenia gravis, unusual sensation of pins and needles, headache.
- Swelling in the back part of the eye (macular edema), a cyst filled with fluid in the iris, light sensitivity (photophobia), appearance of a sunken eye (deepening of the eye cleft).
- Signs and symptoms of eye irritation (e.g. burning sensation, stinging, itching, tearing, redness), inflammation of the eyelid and cornea, blurred vision, detachment of the layer containing blood vessels below the retina following a surgical procedure, which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision.
- Darkening of the skin around the eye, changes in the eyelashes and in the thin hair around the eyes (such as increase in the number, length, thickness and darkening of the color), change in the direction of eyelash growth, swelling around the eye, scarring of the eye surface.
- Buzzing/ringing in the ears (tinnitus).
- Angina pectoris, worsening of angina in patients with heart disease.
- Slow heart rate, chest pain, palpitations (awareness of heart rate), edema (fluid buildup), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with characteristics such as shortness of breath, swelling of the legs and feet due to fluid buildup), a type of heart rhythm disorders, heart attack, heart failure.
- Low blood pressure, disorder of blood flow in the body causing numbness in fingers and toes.
- Shortness of breath, constriction of the airways in the lungs (especially in patients with pre-existing disease), difficulty breathing, cough, asthma, exacerbation of asthma.
- Taste disturbance, nausea, indigestion, diarrhea, dry mouth, abdominal pain, vomiting.
- Hair loss, white-silvery (psoriasis-like) skin rash or worsening of psoriasis, skin rash.

- Joint pain, muscle pain not caused by physical exertion, muscle weakness, tiredness.
- Sexual dysfunction, decreased libido.

In very rare cases, during the treatment, in some patients with severe damage to the transparent layer in the front part of the eye (cornea), cloudy areas have developed on the cornea due to calcium accumulation.

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?

- Avoid poisoning! To avoid 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/blister tray/bottle/carton/label. The expiry date refers to the last day of that month.

Storage conditions:

- **Before opening:** Keep refrigerated at the temperature of 2°C-8°C and protected from light. Do not freeze.
- **After opening:** Store at room temperature, below 25°C. Do not use for more than 4 weeks after first opening the bottle.
- Keep the medicine bottle in the original package in order to protect it from light.
- Do not use the medicine if the color of the liquid has changed or it has become cloudy.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to destroy medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients this medicine also contains:

Sodium dihydrogen phosphate monohydrate, sodium chloride, disodium phosphate anhydrous, benzalkonium chloride, NaOH or 1N HCl (for pH adjustment), water for injection

What the medicine looks like and contents of the pack:

The medicine is packed in a plastic bottle containing 2.5 ml of clear liquid.

Registration holder: Taro International, Ltd., 14 Hakitor St., Haifa Bay 2624761

Manufacturer: Rafarm S.A., 12 Korinthou st., 154 51 N Psihiko Athens, Greece

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 156 64 34246 00