

Package leaflet: Information for the user

Latanoprost/Timolol 50 microgram/5.0 mg per ml Eye Drops Solution

Latanoprost/timolol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Latanoprost/Timolol is and what it is used for

Latanoprost/Timolol contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Timolol belongs to a group of medicines known as beta-blockers. Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.

Latanoprost/Timolol is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe you Latanoprost/Timolol when other medicines have not worked adequately.

2. What you need to know before you use Latanoprost/Timolol

Latanoprost/Timolol can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

Do not use Latanoprost/Timolol:

- if you are allergic (hypersensitive) to latanoprost, timolol, beta-blockers or any of the other ingredients of this medicine (listed in section 6);
- if you have now or have had in the past respiratory problems such as asthma or severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough);
- if you suffer from certain heart disorders, e.g. slow heartbeat (sinus bradycardia, second or third-degree atrioventricular block), a weak heart (manifest cardiac insufficiency) or in acute or chronic heart failure (cardiogenic shock).

Warnings and precautions

Talk to your doctor or pharmacist before using Latanoprost/Timolol . Tell your doctor or pharmacist if you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- disturbances of heart rate such as slow heart beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms
- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- you suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- you know that you suffer from dry eyes
- you wear contact lenses. You can still use Latanoprost/Timolol but follow the instructions for contact lens wearers in Section 3
- you know that you suffer from angina (particularly a type known as Prinzmetal's angina)
- you know that you suffer from severe allergic reactions that would usually require hospital treatment
- you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Tell your doctor before you have an operation that you are using Latanoprost/Timolol as timolol may change effects of some medicines used during anaesthesia.

Other medicines and Latanoprost/Timolol

Latanoprost/Timolol can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use other medicines to lower blood pressure, heart medicine or medicines to treat diabetes. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, speak to your doctor or pharmacist if you know you are taking any of the following types of medicines:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives
- Beta-blockers
- Epinephrine
- Medicines used to treat high blood pressure such as oral calcium channel blockers, guanethidine,
- Digitalis glycosides (medicines used to relieve heart failure or treat abnormal heartbeat, e.g. digoxin)
- Medicines to enable you to urinate more easily or in order to restore normal bowel movements (parasympathomimetics)
- Clonidine; if you are taking a medicine called clonidine with Latanoprost/Timolol and then you suddenly stop taking clonidine, your blood pressure may rise
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine

Latanoprost/Timolol with food and drink

Normal meals, food or drink have no effect on when or how you should use Latanoprost/Timolol .

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not use Latanoprost/Timolol if you are pregnant unless your doctor considers it necessary.

Breast-feeding

Do not use Latanoprost/Timolol if you are breast-feeding. Latanoprost/Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Fertility

Latanoprost and Timolol have been found to have no effect on male or female fertility in animal studies.

Driving and using machines

When you use Latanoprost/Timolol your vision may become blurred for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

Latanoprost/Timolol eye drops, solution contains benzalkonium chloride and phosphate buffers

This medicinal product contains benzalkonium chloride which may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before putting them back in. Benzalkonium chloride is known to discolour soft contact lenses.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Latanoprost/Timolol

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dosage for adults (including the elderly) is one drop once a day into the affected eye(s).

Do not use Latanoprost/Timolol more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use Latanoprost/Timolol as instructed by your doctor until your doctor tells you to stop.

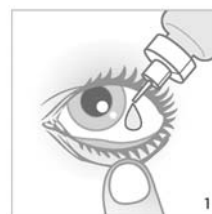
Your doctor may want you to have extra checks on your heart and circulation if you use Latanoprost/Timolol .

Contact lens wearers

If you wear contact lenses, you should remove them before using Latanoprost/Timolol . After using Latanoprost/Timolol you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Twist off the colourless protective cap with the “wings”.
3. Unscrew the cap.



4. Use your finger to gently pull down the lower eyelid of your affected eye (figure 1).
5. Place the tip of the bottle close to, but not touching your eye (figure 1).
6. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid (figure 1).
7. After using Latanoprost/Timolol, press a finger into the corner of your eye, by the nose (figure 2) for 2 minutes. This helps to stop latanoprost/timolol getting into the rest of the body.
8. Repeat in your other eye if your doctor has told you to do this.
9. Put the protective inner cap back on the bottle.



Children

There is limited experience with Latanoprost/Timolol in children and adolescents.

If you use Latanoprost/Timolol with other eye drops

Wait at least 5 minutes between using Latanoprost/Timolol and using the other eye drops.

If you use more Latanoprost/Timolol than you should

If you put too many drops in your eye you may experience some minor irritation in your eye and your eyes may water and turn red. This should pass but if you are worried contact your doctor for advice.

If you swallow Latanoprost/Timolol

If you swallow Latanoprost/Timolol accidentally you should contact your doctor for advice. If you swallow a lot of Latanoprost/Timolol you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

If you forget to use Latanoprost/Timolol

Carry on with the usual dosage at the usual time. Do not take a double dose to make up for the dose you have forgotten. If you are unsure about anything talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Latanoprost/Timolol without speaking to your doctor.

Listed below are the known side effects of using Latanoprost/Timolol. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that Latanoprost/Timolol might cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function you should speak to a doctor and tell them you have been using Latanoprost/Timolol.

The following are known side effects of using Latanoprost/Timolol :

Very common (may affect more than 1 in 10 people):

- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop. The colour change may be permanent and may be more noticeable if you use Latanoprost/Timolol in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after Latanoprost/Timolol treatment is stopped.

Common (may affect up to 1 in 10 people):

- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

Uncommon (may affect up to 1 in 100 people):

- Headache
- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye
- Skin rashes or itching (pruritus)

Other side effects

Like other medicines used in the eyes, Latanoprost/Timolol is absorbed into the blood. The incidence of side effects after using eye drops is lower than when medicines are, for example, taken by mouth or injected.

Although not seen with Latanoprost/Timolol, the following additional side effects have been seen with the medicines in Latanoprost/Timolol (latanoprost and timolol) and therefore might occur when you use Latanoprost/Timolol. The listed side effects include reactions seen within the class of beta-blockers (e.g. timolol) when used for treating eye conditions:

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV)
- Dizziness
- Changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), swelling at the back of the eye (macular oedema), inflammation/irritation of the surface of the eye (keratitis), dry eyes, fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus)
- Worsening of angina, awareness of heart rhythm (palpitations)
- Asthma, worsening of asthma, shortness of breath
- Darkening of the skin around the eyes
- Joint pain, muscle pain
- Chest pain
- Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction
- Low blood glucose levels
- Difficulty sleeping (insomnia), depression, nightmares, memory loss
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like pins and needles, and headache
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery 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
- Whistling/ringing in the ears (tinnitus).
- Slow heart rate, chest pain, palpitations (awareness of heart rhythm), oedema (fluid build up), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), a type of heart rhythm disorder, heart attack, heart failure.

- Low blood pressure, Raynaud's phenomenon, cold hands and feet.
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Muscle pain not caused by exercise.
- Sexual dysfunction, decreased libido.
- Muscle weakness/tiredness.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Latanoprost/Timolol

Keep this medicine out of the sight and reach of children.

Before Latanoprost/Timolol is first opened, it should be stored and transported refrigerated (2°C - 8°C).

Once the bottle has been opened, Latanoprost/Timolol can be kept at room temperature (below 25°C) for up to 28 days.

Keep the bottle in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and the dropper after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Latanoprost/Timolol contains

Each millilitre (1 ml) of Latanoprost/Timolol contains:

Active substances:	50 microgram latanoprost and timolol maleate corresponding to 5 mg timolol.
Other ingredients:	sodium dihydrogen phosphate, monohydrate, sodium chloride, disodium phosphate, anhydrous, benzalkonium chloride (preservative) and water for injections.

Each bottle of Latanoprost/Timolol contains 2.5 ml eye drops.

What Latanoprost/Timolol Eye drops, solution looks like and contents of the pack

Latanoprost/Timolol is a clear, colourless liquid. It is supplied in a bottle containing 2.5 ml eye drops solution. The bottles are singly packed.

Latanoprost/Timolol is available in the following pack sizes:

1 bottle x 2.5 ml

3 bottles x 2.5 ml

6 bottles x 2.5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Euro House,
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