

Package leaflet: Information for the user

Latanoprost/Timolol 50 microgram/ml + 5 mg/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.

What is in this leaflet

1. What Latanoprost/Timolol is and what it is used for
2. What you need to know before you use Latanoprost/Timolol
3. How to use Latanoprost/Timolol
4. Possible side effects
5. How to store Latanoprost/Timolol
6. Contents of the pack and other information

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

Latanoprost/Timolol contains two active substances: latanoprost and timolol.

Latanoprost belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from the eye into the bloodstream.

Timolol belongs to a group of medicines known as beta-blockers. It 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 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 if you are less than 18 years of age.

Do not use Latanoprost/Timolol:

- if you are allergic to either of the medicines in Latanoprost/Timolol (latanoprost or timolol), beta-blockers or any of the other ingredients of this medicine (listed in section 6).
- if you have now or have had in past respiratory problems such as asthma, 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 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 of low blood sugar
- over activity 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 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 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 anesthesia.

Other medicines and Latanoprost/Timolol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including using eye drops and medicines obtained without a prescription.

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 medicines to lower blood pressure, heart medicine or medicines to treat diabetes.

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

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives (e.g. other medicines for the treatment of glaucoma).
- Beta-blockers (e.g. for high blood pressure).
- Epinephrine (adrenaline).
- Medicines used to treat high blood pressure (e.g. 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

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 using this medicine.

Do not use Latanoprost/Timolol if you are pregnant unless your doctor considers it necessary.
Do not use Latanoprost/Timolol if you are breast-feeding. Timolol may get into your milk.

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 contains benzalkonium chloride

Latanoprost/Timolol contains a preservative called benzalkonium chloride. This preservative may cause eye irritation or disruption to the surface of the eye. It can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses. See the instructions for contact lens wearers in Section 3.

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.

Adults (including the elderly)

The recommended dose for adults is one drop once a day in 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.

After using Latanoprost/Timolol, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop latanoprost or timolol getting into the rest of the body.

Contact lens wearers

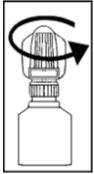
If you wear contact lenses, you should remove them before using Latanoprost/Timolol. After using Latanoprost/Timolol you should wait 15 minutes before putting your contact lenses back in.

Use in children and adolescents

Latanoprost/Timolol is not recommended for children and adolescents.

Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Twist off the outer cap (which can be thrown away).



3. Unscrew the protective inner cap. The protective cap should be retained.



4. Use your finger to gently pull down the lower eyelid of your affected eye.

5. Place the tip of the bottle close to, but not touching your eye.

6. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.



7. Press a finger against the corner of the affected eye by the nose. Hold for 2 minute whilst keeping the eye closed.

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.

If you use Latanoprost/Timolol with other eye drops

After using Latanoprost/Timolol, wait at least 5 minutes before 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 use a double dose to make up for the dose you have forgotten.

If you have any further questions on the use of this medicine, ask 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.

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 effects (may affect more than 1 in 10 people):

- A gradual change in your eye colour due to an increasing 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 effects (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).
- Eye pain.

Uncommon effects (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:

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 following side effects have been seen with latanoprost:

Infections and Infestations:

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Immune System Disorders:

- Symptoms of allergic reaction (swelling and rash).

Psychiatric Disorders:

- Depression, memory loss, decreased sex drive, difficulty sleeping (insomnia), nightmares.

Nervous System Disorder:

Dizziness, tingling or numbness in the skin, reduced blood supply to the brain, worsening of symptoms of myasthenia gravis (muscle disorder)- (if you already suffer from this condition), sudden fainting or feeling you may faint (syncope).

Eye Disorders:

- 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).

Ear Disorders:

- Whistling/ringing in the ears (tinnitus).

Heart (Cardiac) Disorders:

- Worsening of angina, awareness of heart rhythm (palpitations).

Breathing (Respiratory) Disorders:

- Asthma, worsening of asthma, shortness of breath.

Skin Disorders:

- Darkening of the skin around the eyes.

Muscle and Skeletal Disorders:

- Joint pain, muscle pain.

General Disorders:

- Chest pain.

Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with intravenous or oral beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Generalised 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, localised and generalised 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, worsening of symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like pins and needles, 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.
- Slow heart rate, chest pain, palpitations, oedema (fluid buildup), changes in heart rhythm or speed of the heart beat, 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, discolouration/cold fingers and toes (Raynaud's phenomenon) and coldness of the hands and feet.
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing (bronchospasm), cough.
- Taste disturbances, feeling sick (nausea), indigestion, diarrhoea, dyspepsia, dry mouth, abdominal pain, vomiting (being sick).

- Hair loss/baldness (alopecia), skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash, itchy rash or worsening of itchy skin conditions.
- Muscle pain not caused by exercise.
- Sexual dysfunction, decreased libido (decreased sex drive).
- Muscle weakness/fatigue.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRÁ 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 out of the sight and reach of children.

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

Store the unopened bottle of Latanoprost/Timolol in a refrigerator (between 2°C to 8°C). After opening do not store above 25°C and do not use this bottle for more than 28 days. Keep the bottle in the outer carton, in order to protect from light.

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 protect the environment.

6. Contents of the pack and other information

What Latanoprost/Timolol contains

The active substances are latanoprost 50 micrograms/ml and timolol (as timolol maleate) 5 mg/ml. The other ingredients are benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, purified water.

What Latanoprost/Timolol looks like and contents of the pack

Eye drops, solution.

A clear colourless solution.

Pack sizes: 1 bottle x 2.5ml eye drops, 3 bottles x 2.5ml eye drops, 6 bottles x 2.5ml eye drops.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Actavis Group PTC ehf
Reykjavíkurvegi 76-78

220 Hafnarfjordur
Iceland

Manufacturer:
SIFI SpA, Via Ercole Patti 36, 95020 Lavinaio, Aci S. Antonio (CT), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

BE	Latanoprost/Timolol Actavis 0,005%/0,5% oogdruppels, oplossing
DE	Latano-Q comp. 50 comp. Mikrogramm/ml + 5mg/ml Augentropfen
DK	Glauprostol
ES	Latanoprost/Timolol Arrow 0,05 mg/ml / 5 mg/ml colirio en solución
IE	Latanoprost/Timolol 50 micrograms/ml + 5mg/ml Eye Drops, Solution
PL	Timprost
SE	Glauprostol, 50 mikrogram/ml + 5mg/ml ögondroppar, lösning
UK	Latanoprost 50micrograms/ml and Timolol 5mg/ml Eye Drops Solution

This leaflet was last revised in September 2015