428184
TBC
Latanoprost / Timolol
50 micrograms / ml + 5 mg / ml
eye drops, solution
latanoprost / timolol

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Package leaflet: Information for the patient

Latanoprost / Timolol 50 micrograms / 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. 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 of these conditions are linked to an increase in the pressure within your eye, which may eventually affect 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).

Children and adolescents

Latanoprost/Timolol is not recommended for children or adolescents less than 18 years of age.

Do not use Latanoprost / Timolol:
- if you are allergic to 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 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 have a slow heart rate, serious heart problems or heart rhythm disorders (irregular heart beats) and do not have a pacemaker fitted

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, including angina (particularly a type known as Prinzmetal angina), or tightness, breathlessness or choking), heart failure, low blood pressure
- other disturbances of heart rate or heart rhythm such as slow heart beat
- breathing problems or chronic obstructive pulmonary disease
- poor circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes, or episodes of low blood sugar, as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms

Also talk to your pharmacist or doctor:
- if you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- if you suffer from eye problems (such as eye pain, eye irritation, eye inflammation, swelling at the back of the eye, problems with the front of the eyeball (cornea) or the lens of the eye, or blurred vision)
- if you know that you suffer from dry eyes
- if you wear contact lenses. You can still use Latanoprost / Timolol but follow the instructions for contact lens wearers in Section 3
- if you know that you suffer from severe allergic reactions that would usually require hospital treatment as timolol may increase the likelihood or severity of allergic reactions occuring, or reduce the effectiveness of medicines used to treat allergic reactions (such as epinephrine (adrenaline))
- if you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV), especially if this was caused by use of prostagladin analogues.

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 taking or intend to take medicines to lower blood pressure, heart medicines or medicines to treat diabetes. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines (including using eye drops), including those obtained without a prescription.

Tell your doctor or pharmacist if you have recently taken or used, or might take or use any of the following medicines:
- Prostaglandins, prostaglandin analogues or prostaglandin derivatives (taken by mouth, applied into the vagina, or in other eye drops)
- Beta-blockers (taken by mouth or given by injection, or in other eye drops)
- Epinephrine (also known as adrenaline)
- Drugs used to treat high blood pressure such as oral calcium channel blockers, guanethidine, antiarrythmics (like amiodarone), digitalis glycosides (like digoxin) or parasympathomimetics (like bethanechol (used for urinary problems) or nicotine (used to help people stop smoking)
- Quinidine (used to treat heart conditions and some types of malaria)
- Clonidine (used to treat high blood pressure, or to help with flushing)
- Medicines for diabetes
- Antidepressants known as fluoxetine and paroxetine

Pregnancy and breast-feeding

Do not use Latanoprost / Timolol if you are pregnant unless your doctor considers it necessary. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to have a baby.

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.

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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults (including the elderly) is one drop once a day in the affected eye(s). It is normally recommended to use the eye drops in the evening, however, if this is not convenient for you, your doctor or pharmacist may recommended that you use the eye drops in the morning.

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

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.

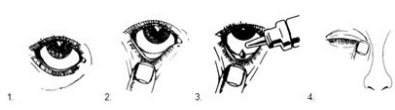
Contact lens wearers

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. Unscrew and remove the outer protective cap from the bottle
3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Place the tip of the bottle close to, but not touching your eye.
5. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
6. After using Latanoprost / Timolol press a finger into the corner of your eye (see figure 4 below), by the nose for 2 minutes.

This helps to stop Latanoprost / Timolol getting into the rest of the body.



7. Repeat in your other eye if your doctor has told you to do this.
8. Close the bottle.

If you use Latanoprost / Timolol with other eye drops

Wait at least 5 minutes between using Latanoprost / Timolol and using 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. You may also notice a slow heart rate, feel faint or dizzy (due to a reduction in blood pressure), have difficulty breathing or wheeziness, or a serious problem with your heart could develop which could lead to heart attack (cardiac arrest).

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 to the dose you have forgotten. If you are unsure about anything talk to your doctor or pharmacist.

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Description	Latanoprost/Timolol Maleate 0.05mg/ml + 5mg/ml 1x2.5ml		
Component Type	Leaflet	Pharma Code	TBC
Affiliate Item Code	428184	SAP No.	NA
Superceded Affiliate Item Code	NA	Vendor Job No.	231209
TrackWise PR No.	428184	Proof No.	4
MA No.	405/70/1	Client Market	Ireland
Packing Site/Printer	Wintac	Keyline/Drawing No.	NA
Supplier Code	TBC	Barcode Info	NA
Sign-offs			

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No. of colours	1	Page Count	1/2
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Non-Print Colours			
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Dimensions	127 x 500 mm		

If you stop using Latanoprost / Timolol
Talk to your doctor or pharmacist before you stop using Latanoprost / Timolol eye drops.

4. Possible side effects

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

You can usually carry on using 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 latanoprost or timolol, the active ingredients (which make the medicine work) in this medicine. The most important side effect is the possibility of a gradual, permanent change in your eye colour.

It is also possible that this medicine might cause serious changes in the way your heart works or allergic reactions in the body, even though this medicine is used in the eyes. This medicine may also cause some other eye problems.

If you notice any of the following you should speak to a doctor straight away and tell them you have been using Latanoprost / Timolol:

- Changes in your heart rate or heart function.
- A generalised allergic reaction including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway causing difficulty swallowing or breathing, hives or itchy rash.
- Swelling of the coloured part of the eye (iritis/uveitis), sudden eye pain or blurred vision.

The following are other known side effects of this medicine:

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. You may have eye examinations to see if there is any colour change.

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

Although not seen with this medicine, the following additional side effects have been seen with the individual active ingredients in Latanoprost / Timolol (latanoprost and timolol) and therefore might occur when you use Latanoprost / Timolol:

The following side effects have been seen with latanoprost:

- 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), damage to, or erosion of, the front layer of the eyeball (cornea), swelling of the cornea (corneal oedema), changes to the direction of eyelash growth, swelling around the eye, swelling at the back of the eye (macular oedema) in people where the lens of the eye is absent or does not work properly, 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.
- Generalised chest pain.

Like other medicines applied into eyes, this medicine is absorbed into the blood. The timolol portion of this combination may cause similar side effects as seen with 'intraveneous' and/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:

- Low blood glucose levels.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss.
- Fainting, a stroke, or reduced blood supply to the brain (you may collapse, or notice numbness or weakness in the arms or legs, difficulty swallowing, slurred, mixed up or loss of speech), increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like pins and needles.
- Increase in tears, 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, 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 (you may notice sudden chest pain which may spread to the neck/jaw or arm, with shortness of breath and a clammy feeling), heart failure.
- Low blood pressure, restriction of blood flow to fingers and toes causing discolouration and coldness (Raynaud's phenomenon), cold hands and feet.
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), shortness of breath, 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, pharmacist or nurse. 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.

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 unopened bottles of Latanoprost / Timolol in a refrigerator (between 2 °C – 8 °C). After first opening the bottle it is not necessary to store the bottle in a refrigerator but do not store above 25°C. Use within 4 weeks of opening. When you are not using Latanoprost / Timolol, keep the bottle in the outer carton, in order to protect from light.

Do not use this medicine if you notice that the tamper evident seal has been broken or damaged before you first open it.

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 and timolol maleate
Each ml of solution contains 50 micrograms of latanoprost and 6.83 mg of timolol maleate (equivalent to 5 mg of timolol).

The other ingredients are sodium chloride, benzalkonium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous, water for injections, and sodium hydroxide and hydrochloric acid for pH adjustment.

What Latanoprost / Timolol looks like and contents of the pack
Latanoprost / Timolol is a clear colourless, aqueous solution.
Latanoprost / Timolol is packaged in a round translucent plastic dropper bottle with translucent plastic dropper plug and yellow plastic screw cap with tamper evident sealing ring. Each bottle contains 2.5 ml of Latanoprost / Timolol eye drops, solution.

Latanoprost / Timolol is available in the following pack sizes:
1 bottle of 2.5 ml, eyes drops solution,
3 bottles of 2.5 ml, eye drops solution,
6 bottles of 2.5 ml, eye drops solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Generics [UK] Limited,
Station Close,
Potters Bar,
Hertfordshire,
EN6 1TL,
United Kingdom

Manufacturer

Mylan S.A.S (Saint Priest), 117 Allee des Parcs, 69 800 Saint Priest, France.

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

Belgium:	Latanoprost/Timolol Mylan 50 mcg/ml + 5 mg/ml oogdruppels, oplossing
Czech Republic:	Latanoprost/Timolol Mylan 0,05 mg/ml + 5 mg/ml, oční kapky, roztok
France:	LATANOPROST/TIMOLOL MYLAN 50 microgrammes/5 mg par ml, collyre en solution
Germany:	Latanoprost/Timolol Mylan 50 Mikrogramm/ml + 5 mg ml Augentropfen
Ireland:	Latanoprost / Timolol 50 micrograms / ml + 5 mg / ml Eye drops, solution
Italy:	LATANOPROST E TIMOLOLO MYLAN
Luxembourg:	Latanoprost/Timolol Mylan 50 mcg/ml + 5 mg/ml collyre en solution
Netherlands:	Latanoprost / Timolol 50 micrograms / ml + 5 mg / ml Eye drops, solution
Portugal:	Latanoprost + Timolol Anova
Slovakia:	Latanoprost/Timolol Mylan 0,05 mg/ml + 5 mg/ml
Spain:	Latanoprost/Timolol MYLAN Pharmaceuticals 50 microgramos/ml + 5 mg/ml colirio en solución
United Kingdom:	Latanoprost/Timolol Mylan 0,05 + 5 mg/ml, oogdruppels, oplossing

This leaflet was last revised in May 2014.

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Sign-offs			