PACKAGE LEAFLET

Package leaflet: Information for the patient

Latanoprost 50 micrograms/ml eye drops, solution
latanoprost

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 the doctor treating your child or your pharmacist.
- This medicine has been prescribed for you or for your child 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 the doctor treating your child, or your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Latanoprost is and what it is used for

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

Latanoprost is used to treat conditions known as open angle glaucoma and ocular hypertension. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eyesight.

Latanoprost is also used to treat increased eye pressure and glaucoma in all ages of children and babies.

2. What you need to know before you use Latanoprost

Latanoprost can be used in adult men and women (including the elderly) and in children from birth to 18 years of age. Latanoprost has not been investigated in prematurely born infants (less than 36 weeks gestation).

Do not use Latanoprost:
- if you are allergic to latanoprost or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or the doctor treating your child, or pharmacist before using Latanoprost or before you give this to your child if you think any of the following apply to you or your child:
- are about to have or have had eye surgery (including cataract surgery).
- suffer from eye problems (such as eye pain, irritation or inflammation, blurred vision).
- suffer from dry eyes or have a disease affecting the front of the eye (the cornea).
- have asthma or asthma that is not well controlled.
- have a certain form of glaucoma known as ‘chronic angle-closure’ glaucoma.
- have glaucoma caused by pigments forming within the eye’s angle chamber.
- have glaucoma caused by eye inflammation or new blood vessels forming within the eye.

- have glaucoma at the same time as having no lens or an artificial lens, or if your eye is aphakic (the lens in your eye is missing) or pseudoaphakic with a torn posterior lens capsule or anterior chamber lens.
- have known risk factors for swelling at the back of the eye (macular oedema) or for inflammation of the iris (iritis/uveitis) such as if you have a vascular disorder affecting the eye or abnormalities of the retina as a result of diabetes.
- 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 prostaglandin analogues.
- wear contact lenses. You or your child can still use Latanoprost, but follow the instruction for contact lens wearers in Section 3.
- are pregnant or trying to become pregnant.
- are breast-feeding.

Other medicines and Latanoprost
Latanoprost may interact with other medicines. Tell your doctor, the doctor treating your child or pharmacist if you or your child are taking, have recently taken or might take any other medicines including medicines (or eye drops) obtained without a prescription.

The effect of other prostaglandins or prostaglandin derivatives (used to treat increased eye pressure) can be influenced by Latanoprost. Combining these with Latanoprost is not recommended, as the eye pressure may increase.

Pregnancy and breast-feeding
Do not use Latanoprost when you are pregnant. Tell your doctor immediately if you are pregnant, think you may be pregnant, or are planning to have a baby.

Do not use Latanoprost when you are breast-feeding. Latanoprost may pass into breast milk and therefore the child might be affected.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
When you use Latanoprost you might have blurred vision, 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 contains phosphates and benzalkonium chloride
This medicine contains 6.34 milligrams of phosphate and 0.2 milligrams of benzalkonium chloride in each millilitre.

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.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation or disruption to the surface of the eye, 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.

3. How to use Latanoprost

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

The recommended dose for adults (including the elderly) and children is one drop once a day in the affected eye(s). The best time to do this is in the evening.

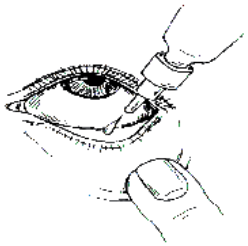
Do not use Latanoprost more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use Latanoprost as instructed by your doctor, or the doctor treating your child until they tell you to stop.

Contact lens wearers
If you or your child wear contact lenses, they should be removed before using Latanoprost. After using Latanoprost you should wait 15 minutes before putting the contact lenses back into the eyes.

Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Unscrew the protective cap. The protective cap should be retained.
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. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.
7. Repeat in your other eye if your doctor has told you to do this.
8. Put the protective cap back on the bottle.

If you use Latanoprost with other eye drops
Wait at least 5 minutes between using Latanoprost and other eye drops.

If you use more Latanoprost than you should
If you put too many drops into the eye, it may lead to some minor irritation in the eye and the eyes may water and turn red. This should pass, but if you are worried contact your doctor or the doctor treating your child for advice.

Contact your doctor as soon as possible if you or your child swallows Latanoprost accidentally.

If you forget to use Latanoprost
Carry on with the usual dose 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.

If you stop using Latanoprost
You should speak to your doctor or the doctor treating your child if you want to stop using Latanoprost.

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.

If you notice any of the following side effects, stop using the medicine and contact your doctor or go to your nearest hospital emergency department as soon as possible:

Uncommon (may affect up to 1 in 100 people)
- Inflammation of the surface or middle layer of the eye which you may notice as eye pain, blurred vision, sensitivity to light, watery eyes, eye redness, possibly with floaters across yor vision.
- Swelling of the back of the eye (macular oedema) or fluid filled cysts at the back of the eye.
- Chest pain, which may spread to the arms, neck or jaw, chest discomfort with a feeling of tightness or pressure, breathlessness or feeling sick (nausea). These may be signs of angina where your heart is not getting enough blood.

Rare (may affect up to 1 in 1,000 people)
- A viral infection of the eye caused by the herpes simplex virus, causing inflammation/irritation of the surface of the eye (keratitis).

The following side effects have also been reported:

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 although it is normally seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use Latanoprost 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 treatment is stopped.
- Redness of the eye.
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye). If you experience eye irritation severe enough to make your eyes water excessively, or make you consider stopping this medicine, talk to your doctor, pharmacist or nurse promptly (within a week). You may need your treatment to be reviewed to ensure you keep receiving appropriate treatment for your condition.
- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.

Common (may affect up to 1 in 10 people)
- Irritation or disruption to the surface of the eye which you may not notice, eyelid inflammation (blepharitis), eye pain or light sensitivity (photophobia).
- Itchy, red, watering of the eyes with a stick coating on the eyelashes (conjunctivitis).

Uncommon (may affect up to 1 in 100 people)
- Headache, dizziness.
- Eyelid swelling, dryness of the eye, blurred vision.
- Skin rash.
- Fast heart beats that feel like thumpping in your chest (palpitations).
- Asthma or shortness of breath (dyspnoea).
- Muscle pain or joint pain.
- Chest pain.

Rare (may affect up to 1 in 1,000 people)
- Symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema) misdirected eyelashes or an extra row of eyelashes.
- Fluid filled area within the coloured part of the eye (iris cyst).
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Itching skin.
- Worsening of asthma

Very rare (may affect up to 1 in 10,000 people)
- Sunken eye appearance (eye sulcus deepening).

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.

Additional side effects in children and adolescents
Side effects seen more often in children compared to adults are a runny, itchy nose, sore throat and fever.

Reporting of side effects
If you get any side effects, talk to your doctor, the doctor treating your child 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

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.

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

Store the unopened bottle 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 it above 25°C. Use within 4 weeks of opening.

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 contains

- The active substance is latanoprost.
- Each ml of solution contains 50 micrograms of latanoprost.
- The other ingredients are benzalkonium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate (see section 2, ‘Latanoprost contains phosphates and benzalkonium chloride’), sodium chloride and water for injections.

What Latanoprost looks like and contents of the pack

Latanoprost is a clear colourless, aqueous solution.
Latanoprost is packaged in a round translucent plastic dropper bottle with translucent plastic dropper plug and plastic screw cap with tamper evident sealing ring.

Each bottle contains 2.5 ml of Latanoprost eye drops, solution.

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

Wessling Hungary Kft., Fóti út 56, H-1047 Budapest, Hungary.

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

Denmark:	Latanoprost Mylan
France:	Latanoprost Mylan 50 microgrammes/ml, collyre en solution
Ireland:	Latanoprost 50 micrograms/ml eye drops, solution
Iceland:	Latanoprost Mylan
Italy:	Latanoprost Mylan
Portugal:	Latanoprost Mylan
Sweden:	Latanoprost Mylan
The Netherlands:	Latanoprost Mylan 0,05 mg/ml, oogdruppels, oplossing

This leaflet was last revised in 06/2018.