Package leaflet: Information for the user
Latanoprost 50 microgram/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 or your child 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 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** in adults. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.
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 (hypersensitive) to latanoprost or any of the other ingredients of this medicine (listed in section 6)
- Pregnant or trying to become pregnant
- Breast feeding

Warnings and precautions

Talk to your doctor or the doctor treating your child or your 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:

- If you or your child are about to have or have had eye surgery (including cataract
- surgery)
- If you or your child suffer from eye problems (such as eye pain, irritation or
- inflammation, blurred vision)
- If you or your child suffers from dry eyes
- If you or your child have severe asthma or the asthma is not well controlled
- If you or your child wear contact lenses. You can still use Latanoprost, but follow the instructions for contact lens wearers in Section 3
- If you or your child have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Other medicines and Latanoprost

Latanoprost may interact with other medicines: Please tell your doctor, the doctor treating your child or pharmacist if you or your child are using or have used any other medicines including those medicines (or eye drops) obtained without a prescription. In particular, speak to your doctor or pharmacist if you know that you are using prostaglandins, prostaglandin analogues or prostaglandin derivatives.

Pregnancy and breast-feeding

You should not use Latanoprost if you are pregnant or breast-feeding unless your doctor considers it necessary. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before using this 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 benzalkonium chloride and phosphate buffers

This medicine contains 0.5 mg benzalkonium chloride in each 2.5ml bottle which is equivalent to 0.2 mg/ml.

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. See the instructions for contact lens wearers in Section 3

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.

This medicine contains 9.3mg/ml phosphates which is equivalent to 0.3 mg per drop

If you suffer from severe damage to the clear layer at the front of the eye (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

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

The recommended dosage 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 by 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. Twist off the cap.
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. Replace cap on the bottle

If you use Latanoprost with other eye drops

Wait at least 5 minutes between using Latanoprost and taking 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 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.

If you stop using Latanoprost

You should speak to your doctor or the doctor treating your child if you want to stop taking 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.

The following are known side effects of using Latanoprost:

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, seen mostly in people of Japanese origin. 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, eyelid inflammation (blepharitis), eye pain and light sensitivity (photophobia), conjunctivitis.

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

- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision
- Inflammation of the coloured part of the eye (uveitis)
- Skin rash
- Headache, dizziness
- Nausea, vomiting
- Chest pain (angina); awareness of heart rhythm (palpitations)
- Asthma and shortness of breath (dyspnoea)
- Muscle pain, joint pain
- Swelling of the retina (macular oedema)

Rare (may affect up to 1 in 1,000 people):

- Inflammation of the iris, (iritis);
  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, scarring of the surface of the eye, fluid filled area within the coloured part of the eye (iris cyst).
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Worsening of asthma.

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).
- Fluid filled area within the coloured part of the eye (iris cyst).
- Drug reaction inflammation to the membranes around the eye (pseudopemphigoid of ocular conjunctiva)
- Severe itching of the skin

Very rare (may affect up to 1 in 10,000 people):
- Worsening of angina in patients who also have heart disease, 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

Side effects seen more often in children compared to adults are runny itchy nose and fever.

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
Website: www.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 label after EXP. The expiry date refers to the last day of that month.

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

Before opening the bottle:
Store in a refrigerator (2°C – 8°C). This medicinal product should also be kept refrigerated during transport from the manufacturer to the pharmacy. It is not necessary for you to keep it refrigerated during transport e.g. from the pharmacy to your home.

After first opening the bottle:
Do not store above 25°C and use within four weeks.

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. One ml of eye drops, solution, contains 50 microgram latanoprost. One drop contains approximately 1.5 microgram latanoprost.

- The other ingredients are benzalkonium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate, sodium chloride, purified water.

What Latanoprost looks like and contents of the pack

Latanoprost is a clear, colourless eye drop solution in a plastic bottle with a dropper and plastic cap. Each bottle contains 2.5 ml eye drops, solution corresponding to approximately 80 drops of solution.

Latanoprost is available in packs of 1, 3 and 6 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer:
HBM Pharma s.r.o.
03680 Martin
Sklabinskà 30
Slovak Republik

Pharma Stulln
Werkstr. 3
D-92551 Stulln
Germany

Jadran Galenski Laboratorij d.d.
Svilno 20
Rijeka, 51000
Croatia

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

Ireland: Latanoprost 50 microgram/ml Eye Drops Solution
UK: Latanoprost 50microgram Eye Drops Solution

This leaflet was last revised in March 2022