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Package leaflet: Information for the user

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 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
2. What you need to know before you use Latanoprost
3. How to use Latanoprost
4. Possible side effects
5. How to store Latanoprost
6. Contents of the pack and other information

The name of your medicine is Latanoprost 50 micrograms/mL eye drops, solution. In the rest of this leaflet the name of the medicine will be Latanoprost.

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 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 (hypersensitive) 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**:
-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** suffer 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 instruction for contact lens wearers in Section 3
-If you 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. Tell your doctor, **the doctor treating your child** or pharmacist if you **or your child** are using or have recently 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
Do not use Latanoprost when 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 0.525 mg benzalkonium chloride in each vial which is equivalent to
0.21 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.
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 6.3 mg/mL phosphates which is equivalent to 0.2 mg/drop.

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

Always use Latanoprost 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 screw cap. The cap should be retained. 
3. Remove the loose collar before use.
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 1 minute whilst keeping the eye closed. 
8. Repeat in your other eye if your doctor has told you to do this.
9. Put the screw cap back 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, Latanoprost 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, 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), swelling of the retina (macular oedema).
- Skin rash.
- Chest pain (angina), awareness of heart rhythm (palpitations).
- Asthma, shortness of breath (dyspnoea).
- Chest pain.
- Headache, dizziness.
- Muscle pain, joint pain.
- Nausea, Vomiting

Rare (may affect up to 1 in 1000 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.
- Severe itching of the skin.
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

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).

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

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 Yellow Card Scheme,
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
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 after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Keep the bottle in the outer carton in order to protect from light.

After opening the bottle do not store above 25°C and use within 4 weeks. When you are not using Latanoprost, keep the bottle in the outer carton, in order to protect it 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 contains
- The active substance is 50 micrograms/mL latanoprost.
- The other ingredients are: benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate monohydrate and disodium hydrogen phosphate anhydrous dissolved in water for injections.

What Latanoprost looks like and contents of the pack
Latanoprost eye drops solution is a clear, colourless liquid.
Latanoprost is available in pack sizes of 1, 3 and 6 bottles. Not all pack sizes may be marketed.

Low density polyethylene (LDPE) bottle of 5 mL with low density polyethylene (LDPE) dropper insert and high density polyethylene (HDPE) tamper-evident screw cap.

Each bottle contains 2.5mL of Latanoprost eye drops solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Noridem Enterprises Limited, Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.
Manufacturer:
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