

Latanoprost 0.005% w/v eye drops solution

Read all of this leaflet carefully before you (or a child in your care) 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 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In the next sections, the word 'you' means you or a child in your care.

What is in this leaflet

1. What Latanoprost eye drops are and what they are used for
2. What do you need to know before you use Latanoprost eye drops
3. How to use Latanoprost eye drops
4. Possible side effects
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1 WHAT LATANOPROST EYE DROPS ARE AND WHAT THEY ARE USED FOR

Latanoprost belongs to a group of medicines called prostaglandin analogues.

Latanoprost eye drops lower the pressure within your eye by increasing the natural flow of fluid from inside the eye into the blood stream.

Latanoprost eye drops are used to treat **open angle glaucoma** and **ocular hypertension**. These conditions are caused by an increase in the pressure in your eye.

If they are not treated they may affect your eyesight.

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

2 WHAT DO YOU NEED TO KNOW BEFORE YOU USE LATANOPROST EYE DROPS

Do not use Latanoprost eye drops

- if you are **allergic** to the latanoprost or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions

Talk to your doctor or pharmacist before using Latanoprost eye drops, if you or your child have now or have had in the past:

- Eye surgery such as cataract surgery or are about to have eye surgery.
- Eye problems (such as eye pain, irritation or inflammation, blurred vision).
- Dry eyes.
- Severe asthma, or your asthma is not well controlled.
- Viral infection of the eye caused by the herpes simplex virus (HSV).

If you or your child wear contact lenses, you can still use Latanoprost eyes drops, but follow the instruction for contact lenses wearers in section 3.

Other medicines and Latanoprost eye drops

Latanoprost eyes drops 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, breast-feeding and fertility

You should not use Latanoprost eyes drops 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 eye drops 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 eye drops contains benzalkonium chloride and phosphate buffers.

This medicine contains 0.2 mg/ml benzalkonium chloride. 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 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 9.34 mg/ml phosphates. 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 EYE DROPS

Always use Latanoprost eye drops exactly

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

The recommended dose for adults (including elderly) and children is one drop of Latanoprost eye drops dropped into the affected eye(s) once daily. The best time to do this is in the evening.

How to use Latanoprost eye drops

Follow the steps below to help you use Latanoprost eye drops properly.

1. Wash your hands and sit or stand comfortably.
2. Unscrew the outer protective 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 and 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 cap back on the bottle.



If you use Latanoprost eye drops with other eye drops

Wait at least 5 minutes between using Latanoprost eye drops and taking other eye drops.

Contact lens wearers

If you wear contact lenses, they should be removed before using Latanoprost eye drops. After using Latanoprost eye drops you should wait 15 minutes before putting the contact lenses back in.

If you use more Latanoprost eye drops than you should

If you put too many drops in your eye, you may feel some slight irritation in the eye or have some redness around the eye. If this does not stop or Latanoprost eye drops are

accidentally swallowed contact your doctor as soon as possible.
Do not use Latanoprost eye drops more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

If you forget to use Latanoprost eye drops

If you forget to apply your drops at the usual time, just skip that dose. Do not take a double dose to make up for the missed dose. Instead, just wait until the next time you are supposed to take it, and then take your normal dose.

If you stop using Latanoprost eye drops

Latanoprost eye drops should be used until your doctor tells you to stop. If you stop using this medicine the pressure in your eye could increase.

If you have any further questions on the use of this product, 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 eye drops.

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 eye drops 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 eye drops 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 eyelashes.

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).
- Nausea, vomiting
- Chest pain.
- Headache, dizziness.
- Muscle pain, joint pain.

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.
- 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 a runny itchy nose and fever.

Reporting side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: 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 EYE DROPS

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

Do not use Latanoprost eye drops if you notice the bottle is damaged or eye drops don't look right in some other way.

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 eye drops contains

The active substance is latanoprost 50 micrograms in one ml.
The other ingredients are: sodium chloride, benzalkonium chloride, sodium dihydrogen phosphate monohydrate, anhydrous disodium phosphate, water for injections

What Latanoprost eye drops looks like and contents of the pack

Dropper polyethylene container of 5 ml with tamper evident polyethylene screw cap. Each bottle contains 2.5 ml eye drops solution corresponding to approximately 80 drops of solution.
Pack sizes: 1 x 2.5ml, 3 x 2.5ml, 6 x 2.5ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Zentiva Pharma UK Limited,
12 New Fetter Lane,
London, EC4A 1JP,
United Kingdom

Manufacturer:

Zentiva k.s.
U Kabelovny 130
Prague 10, 102 37
Czech Republic

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