

Latanoprost 0.005% w/v eye drops solution

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 or for your child only. Do not pass it on to others. It may harm them, even if their symptoms 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 eye drops is and what it is used for
2. What you need to know before you use Latanoprost eye drops
3. How to use Latanoprost eye drops
4. Possible side effects
5. How to store Latanoprost eye drops
6. Contents of the pack and other information

1. What Latanoprost eye drops is and what it is used for

Latanoprost eye drops belongs to a group of medicines known as prostaglandin analogues. It lowers the pressure within your eye by increasing the natural flow of fluid from inside the eye into the blood stream.

Latanoprost eye drops is used to treat adults with open angle glaucoma and ocular hypertension. These conditions are linked with an increase in the pressure within your eye. If they are not treated they may affect your eyesight.

Latanoprost eye drops 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 eye drops

Latanoprost eye drops can be used in adults (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).

Do not use Latanoprost eye drops

- if you are **allergic** (hypersensitive) to latanoprost or any of the other ingredients of Latanoprost eye drops (listed in section 6)
- if you are pregnant or trying to become pregnant
- if you are breast-feeding.

Warning and precautions

Take special care with Latanoprost eye drops:

Talk to your doctor or the doctor treating your child or your pharmacist before you take Latanoprost eye drops or before you give this medicine 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 eye drops, 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 eye drops

Tell your doctor, the doctor treating your child or pharmacist if you or your child are taking or have taken any other medicines (including eye drops).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice. Do not use Latanoprost eye drops when you are pregnant or breast-feeding.

Driving and using machines

As with other eye drops, if your vision is blurred when you first put your drops in, wait until this wears off before you drive or operate machinery.

Latanoprost eye drops contains Benzalkonium chloride

Latanoprost eye drops contains a preservative called benzalkonium chloride. This preservative may cause eye irritation or disruption to the surface of the eye. Benzalkonium chloride can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses.

If you or your child wear contact lenses, you should remove these before using Latanoprost eye drops. See the instructions for contact lens wearers in Section 3.

3. How to use Latanoprost eye drops

Always use Latanoprost eye drops exactly as your doctor or the doctor treating your child has told you until they tell you to stop. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults (including elderly) and the 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 eye drops more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Contact lens wearers

If you or your child wear contact lenses, you should remove these before using Latanoprost eye drops. After using Latanoprost eye drops you should wait 15 minutes before putting the contact lenses back into the eyes.

Using with other eye drops:

If you have to use other eye drops you should **wait for at least five minutes** before using them.

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 protective cap (which 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 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 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 and the eyes may water and turn red. 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 eye drops accidentally.

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 apply a double dose to make up for the missed dose. Instead, just wait until the next time you are supposed to apply it, and then apply your normal dose.

If you stop using Latanoprost eye drops

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

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 develop gradually 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)
- 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 and other hair near the eye.

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).

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, conjunctivitis
- Skin rash.

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

- Inflammation of the iris, the coloured part of your eye (iritis/uveitis); swelling of the retina (macular oedema), 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
- Skin reactions on the eyelids, darkening of the skin of the eyelids
- Asthma, worsening of asthma and shortness of breath (dyspnoea).

Very rare (may affect up to 1 in 10,000 people):

- Chest pain, worsening of angina in patients who also have heart disease, sunken eye appearance (eye sulcus deepening).

Patients have also reported the following side-effects: fluid filled area within the coloured part of the eye (iris cyst), headache, dizziness, awareness of heart rhythm (palpitations), muscle pain, joint pain and developing a viral infection of the eye caused by the herpes simplex virus (HSV).

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. 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 Latanoprost eye drops after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.

Store the unopened bottle in a refrigerator (2°C - 8°C). After opening: do not store above 25°C and use within 4 weeks.

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

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Latanoprost eye drops contains

The active substance is latanoprost 0.005% w/v (50 micrograms in one ml). The other ingredients are: sodium chloride, benzalkonium chloride, sodium dihydrogen phosphate, anhydrous disodium phosphate, water for injections.

What Latanoprost eye drops looks like and contents of the pack

Latanoprost eye drops is a clear colourless solution in a 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 2.5 ml 3 x 2.5ml

Not all packaging sizes may be marketed.

Marketing Authorisation Holder:

Macarthy Laboratories Ltd T/A Martindale Pharma, Bampton Road Harold Hill, Romford, Essex, RM38UG. United Kingdom

Manufacturer:

TUBILUX PHARMA S.p.A. Via Costarica 20/22 00071 Pomezia (RM) - Italy

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

Italy: Iopize 0,005% collirio, soluzione
Spain: Latanoprost cifra 50 microgramos/ml colirio en solución
UK: Latanoprost 0.005% w/v eye drops solution.

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