

Package Leaflet: Information for the user

UNILAT 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What UNILAT is and what it is used for
2. What you need to know before you use UNILAT
3. How to use UNILAT
4. Possible side effects
5. How to store UNILAT
6. Contents of the pack and other information

1. What UNILAT is and what it is used for

UNILAT 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.

UNILAT 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.

UNILAT 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 UNILAT

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

Do not use UNILAT

- if you are allergic to latanoprost or any of the other ingredients of this medicine (listed in 6)
- if you are pregnant or trying to become pregnant
- if you are breast-feeding

Take special care with UNILAT

- If the colour of your eyes is mixed, such as yellow-brown, grey-brown, blue-brown or green-brown. Using UNILAT may cause your eye colour to become browner. Treatment of one single eye may cause a difference in eye colours.

- If you or your child have an eye from which the lens is absent (aphakic) or you have partial or complete opacity of the lens of one or both eyes, which might impair vision or cause blindness (pseudoaphakic).
- 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 eye pain, irritation or inflammation, blurred vision)
- If you or your child know that you suffer from dry eyes
- If you or your child have severe asthma or your asthma is not well controlled
- If you or your child wear contact lenses. You can still use UNILAT, 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).

Talk to your doctor or pharmacist before using UNILAT

Other medicines and UNILAT

UNILAT may interact with other medicines. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you or your child are using other types of eye drops together with UNILAT, these should be put in 5 minutes before or 5 minutes after the application of UNILAT.'

UNILAT with food and drink

Since the medicine is an eye solution, its use has no connection to food and drink.

Pregnancy and breast-feeding

Do not use UNILAT when you are pregnant.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

UNILAT should not be used when breast-feeding. The child might be affected.

Driving and using machines

When you use UNILAT 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.

UNILAT contains benzalkonium chloride

UNILAT 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 wear contact lenses, you should remove them before using UNILAT. After using UNILAT you should wait 15 minutes before putting your contact lenses back in. See the instructions for contact lens wearers in Section 3.

3. How to use UNILAT

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 dose is:

The usual 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 UNILAT more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

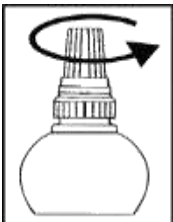
Use UNILAT as instructed by your doctor or by the doctor treating your child until your doctor tells you to stop.

Contact lens wearers

If you or your child wear contact lenses, you should remove them before using UNILAT. After using UNILAT you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Unscrew the bottle cap.



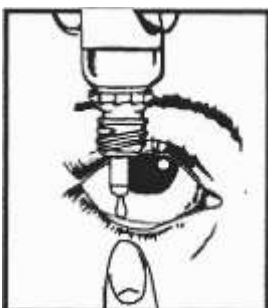
3. Hold the bottle downwards between the thumb and the other fingers.

4. Use your finger to gently pull down the lower eyelid of your affected eye.



5. Place the tip of the dropper close to your eye but so that it does not touch the eye or the adjacent regions of the 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. Immediately after application tightly close the bottle cap.

If you use UNILAT with other eye drops.

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

If you use more UNILAT than you should If you put too many drops into your eye, you may experience some minor irritation in your eye and your eyes may water and turn red, this should pass, but if you are worried contact your doctor for advice.

Contact your doctor as soon as possible if you swallow UNILAT accidentally.

If you forget to use UNILAT

Carry on with the usual dosage at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop using UNILAT

Do not stop taking UNILAT, unless your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or the doctor treating your child or pharmacist.

4. Possible side effects

Like all medicines, UNILAT can cause side effects, although not everybody gets them.

Very common effects (affects more than 1 user in 10):

- 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 UNILAT 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 UNILAT 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.

Common effects (affects 1 to 10 users in 100):

- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis) and eye pain.

Uncommon effects (affects 1 to 10 users in 1,000):

- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision and conjunctivitis.
- Skin rash.

Rare effects (affects 1 to 10 users in 10,000):

- Inflammation of the iris, the coloured part of the 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, light sensitivity (photophobia).
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Asthma, worsening of asthma and shortness of breath (dyspnoea).

Very rare effects (affects less than 1 user in 10,000):

- Worsening of angina in patients who also have heart disease. Chest pain, 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, palpitations, muscle pain joint pain and developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Additional side effects in children

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

If get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store UNILAT

Keep out of the sight and reach of children.

Do not use UNILAT after the expiry date which is stated on the label or carton after mark EXP. The expiry date refers to the last day of that month.

Before first opening: Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original package in order to protect from light.

After first opening: Do not store above 25°C.
Use within 28 days after first opening.

When you are not using UNILAT, keep the bottle in the outer carton, in order to protect from light.

Do not use UNILAT if you observe visible signs of damage to the medicine or if you find that the safety strip at the first open up on the bottle cap is damage. In such case return the medicine to the pharmacy.

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 UNILAT contains

- The active substance is latanoprost 50 micrograms in 1ml of the solution
The other ingredients are:
sodium chloride,
benzalkonium chloride ,
sodium dihydrogen phosphate, monohydrate (E339a),
disodium phosphate, anhydrous (E339b),
hydrochloric acid for pH adjustment,
sodium hydroxide for pH adjustment,
water for injections.

What UNILAT looks like and contents of the pack

UNILAT is clear colourless solution, practically free from particles.

Every bottle of UNILAT contains 2.5 ml of eye drops, solution.

The medicine is available in the following packages: 1 × 2.5 ml, 3 × 2.5 ml (polyethylene bottle with eye dropper).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in {MM/YYYY}.