

PACKAGE LEAFLET: INFORMATION FOR THE USER

UNILAT

50micrograms/ml Eye Drops Solution

LATANOPROST

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 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 •

What is in this leaflet?

1. What UNILAT is and what it is used for
2. Before you take UNILAT
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1. WHAT UNILAT IS AND WHAT IS IT USED FOR

UNILAT eye drops belong 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 eye drops are used to treat conditions known as **open angle glaucoma** and **ocular hypertension**. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.

UNILAT eye drops are also used to treat increased eye pressure and glaucoma in all ages of children and babies.

2. BEFORE YOU TAKE UNILAT

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

Do not use UNILAT eye drops if you

- are **allergic** to UNILAT or any of the other ingredients of this medicine
- are **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 UNILAT eye drops 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 UNILAT eye drops, 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 UNILAT eye drops

UNILAT eye drops may interact with other medicines: Tell your doctor, the doctor treating your child or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Do not use UNILAT eye drops when you are pregnant. Tell your doctor immediately if you are pregnant, think you are pregnant, or are planning to become pregnant.

Breast-feeding

Do not use UNILAT eye drops when you are breast-feeding.

Driving and using machines

When you use UNILAT 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.

UNILAT eye drops contain benzalkonium chloride

UNILAT eye drops contain 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, they should be removed before using UNILAT eye drops. After using UNILAT eye drops you should wait 15 minutes before putting the contact lenses back in. See the instructions for contact lens wearers in Section 3.

3. HOW TO TAKE 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 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 eye drops more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often. Use UNILAT eye drops as instructed by your doctor or 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 UNILAT eye drops. After using UNILAT eye drops you should wait 15 minutes before putting your 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 UNILAT eye drops with other eye drops

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

If you use more UNILAT eye drops 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 UNILAT eye drops accidentally.

If you forget to use UNILAT eye drops

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 UNILAT eye drops

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

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 UNILAT 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 UNILAT 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 UNILAT 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.

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 and conjunctivitis.
- Skin rash.

Rare (may affect up to 1 in 1000 people):

- 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.
- 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):

- Angina, worsening of angina, 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, 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE UNILAT

Keep 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.