

Latop 50 microgram/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 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.

What is in this leaflet

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

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1 What Latop is and what it is used for

Latop contains the active substance latanoprost. 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.

Latop is 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.

Latop 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 Latop

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

Do not use Latop

- if you are **allergic** 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 Latop 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 no longer have an eye lens, your or your child's posterior eye capsule has broken when putting in an artificial lens, an artificial lens was put in the anterior eye chamber or if you or your child have known risk factors (e.g. damage to the retina or retinal vein thrombosis) for the occurrence of macular oedema (accumulation of liquid at the back of the eye)
- if you or your child are about to have or have had **eye surgery**
- if you or your child have severe **asthma** or the asthma is not well controlled
- if you or your child suffer from **dry eyes**
- if you or your child suffer from **eye problems** such as eye pain, irritation or inflammation, blurred vision
- if you or your child wear **contact lenses** (you can still use Latop, 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 Latop

Please tell your doctor, the doctor treating your child or pharmacist if you or your child are taking or have recently taken or might take any other medicines.

Concomitant use of **two or more prostaglandin analogues** is not recommended since this may lead to an increase of the intraocular pressure.

Pregnancy, breast-feeding and fertility

You should not use Latop when you are pregnant. Tell your doctor immediately if you are pregnant, think you are pregnant, or are planning to become pregnant.

You should not use Latop when you are breast-feeding.

Driving and using machines

When you use Latop 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.

Latop contains benzalkonium chloride

Latop contains the preservative benzalkonium chloride, which may be absorbed by soft contact lenses and may discolour them.

Contact lenses should be removed prior to instillation and may be reinserted 15 minutes following administration. See the instructions for contact lens wearers in section 3. Benzalkonium chloride has been reported to cause eye irritation, dry eyes and may affect the corneal surface. Latop should be used with caution in dry eye patients and in patients where the cornea may be compromised. In addition, monitoring is required with prolonged use in such patients.

3 How to use Latop

Always use this medicine exactly as your doctor or the doctor treating your child or pharmacist has told you. Check with your doctor or the doctor treating your child or pharmacist if you are not sure.

Dosage

The usual dose for adults (including the elderly) and children is:

One drop in the affected eye(s) **once daily**.

The best time to do this is in the evening. Do not use Latop more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

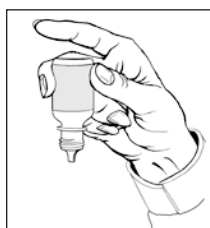
Use Latop as instructed by your doctor or the doctor treating your child until they tell you to stop.

Contact lens wearers

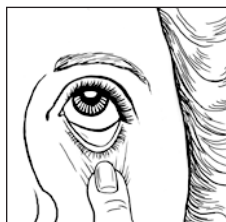
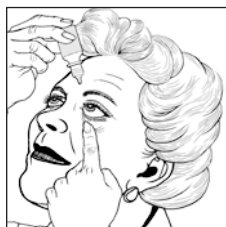
If you or your child wear contact lenses, they should be removed before using Latop. After using Latop you should wait 15 minutes before putting the contact lenses back into the eyes.

Instructions for use

The DROP-TAINER® bottle is designed to assure the delivery of a precise dose of medication. Before using your DROP-TAINER® bottle, read the complete instructions carefully.



1. If you use other topically applied ophthalmic medications, they should be administered at least 10 minutes before or after Latop.
2. Wash hands before each use.
3. Before using the medication for the first time, be sure the Safety Seal on the bottle is unbroken.
4. Tear off the Safety Seal to break the seal.
5. Before each use, shake once and remove the screw cap.
6. Invert the bottle and hold the bottle between your thumb and middle finger, with the tips of the fingers pointing towards your eye.



7. Tilt your head back and position the bottle above the affected eye.
8. With the opposite hand, place a finger under the eye. Gently pull down until a "V" pocket is made between your eye and lower lid. Do not touch the eye with the tip of the dropper.
9. With the hand holding the bottle, place your index finger on the bottom of the bottle. Push the bottom of the bottle to dispense one drop of medication. Do not

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squeeze the sides of the bottle.
Keep your head tilted backward and close your eye to allow absorption of the medication into the eye.

10. Repeat steps 6 to 9 with other eye if instructed to do so.

11. Replace screw cap by turning until firmly touching the bottle.

If you use Latop with other eye drops

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

If you use more Latop 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 Latop accidentally.

If you forget to use Latop

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 Latop

You should speak to your doctor or the doctor treating your child if you want to stop taking Latop. If you have any further questions on the use of this medicine, 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 have been seen with Latop:

Very common side effects (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 Latop 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 Latop treatment is stopped.
- Mild to moderate redness of eyes
- Burning sensation, grittiness, itching, stinging and foreign body sensation
- Changes of eyelash and vellus hair such as increased length, thickness, pigmentation and number (especially applies to patients with Japanese origin).

Common side effects (may affect up to 1 in 10 people)

- Transient punctual alterations of the corneal tissue (usually not causing discomfort)
- Inflammation of the eyelids (blepharitis)
- Irritation or disruption to the surface of the eye
- Eye pain.

Uncommon side effects (may affect up to 1 in 100 people)

- Swelling of the eyelids
- Dry eye
- Inflammation or irritation of the surface of the eye (keratitis)
- Painful watering of the eye
- Blurred vision
- Discharge from the eye with itching, redness and swelling
- Skin rash
- Conjunctivitis.

Rare side effects (may affect up to 1 in 1000 people)

- Uncomfortable sensitivity to light or painful red eye
- Inflammation of the iris, the coloured part of the eye (iritis/uveitis)
- Symptoms of swelling or scratching/damage to the surface of the eye
- Accumulation of liquid at the back of the eye (macular oedema)
- Symptomatic corneal oedema and erosions
- Swelling around the eye
- Growth of lashes in the "wrong" direction which may cause eye irritation
- Growth of an extra row of eyelashes
- Localized skin reaction on the eyelids
- Darkening of skin of eyelids
- Light sensitivity (photophobia)
- Asthma, worsening of asthma symptoms, breathlessness (dyspnoea).

Very rare side effects (may affect up to 1 in 10000 people)

- Worsening of angina pectoris symptoms
- Sunken eye appearance (eye sulcus deepening)
- Chest pain.

Frequency not known (frequency cannot be estimated from the available data)

- Headache
- Dizziness
- Palpitations (rapid or strong heartbeat)
- Muscle pain

- Joint pain
- Fluid filled area within the coloured part of the eye (iris cyst)
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Latop

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 first opening: Do not store above 25°C.

Latom should be used within 4 weeks after the bottle is first opened but not after the expiry date.

Do not throw away any medicines via wastewater or household water. 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 Latop contains

The active substance is latanoprost.

1 ml of solution contains
50 micrograms of latanoprost (equivalent to 0.005% w/v).
1 drop contains approximately
1.5 microgram of latanoprost.

The other ingredients are:
Benzalkonium chloride
Sodium dihydrogen phosphate monohydrate (E339)
Sodium chloride
Anhydrous disodium phosphate (E339)
Water for Injections

What Latop looks like and contents of the pack

Eye drops, solution.
Latom 50 microgram/ml eye drops, solution is a clear, colourless solution.

4 ml natural LDPE DROP-TAINER® bottle with a natural LDPE dropper applicator, a turquoise polypropylene (PP) screw cap and PVC shrink band around the neck and screw cap of the DROP-TAINER®.

Pack sizes
1 x 2,5 ml, 3 x 2,5 ml and 6 x 2,5 ml solution.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturers

Marketing Authorization Holder
Rowex Ltd., Bantry, Co. Cork, Ireland

Manufacturers

S.A. ALCON-COUVREUR N.V.,
Rijksweg 14, B-2870 Puurs,
Belgium.

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

Germany:	Latanoprost HEXAL 0,05 mg/ml Augentropfen
Ireland:	Latom 50 microgram/ml eye drops, solution

This leaflet was last revised in 07/2017.

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