Package leaflet: Information for the patient

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** in adults.

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)
- If you are pregnant or trying to become pregnant
- If you are breast-feeding.

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 are about to have or have had **eye surgery** (including cataract surgery)
- If you or your child have severe **asthma** or the asthma is not well controlled
- If you or yor 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
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 or breast-feeding.

Tell your doctor immediately if you are pregnant, think you are pregnant, or are planning to become pregnant.

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.

This medicine contains 0.2 mg benzalkonium chloride in each ml. 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.

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 6.34 mg phosphates in each ml. 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 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.

Dose
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 medicine. Before using your DROP-TAINER® bottle, read the complete instructions carefully.

1. If you use other topically applied ophthalmic medicines, they should be administered at least 5 minutes before or after Latop.
2. Wash hands before each use.
3. Before using the medicine 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 you.

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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 medicine. Do not squeeze the sides of the bottle. Keep your head tilted backward and close your eye to allow absorption of the medicine 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 dose 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.
- Redness of the eye
- Burning sensation, grittiness, itching, stinging or foreign body sensation. 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 eye lashes.

Common side effects (may affect up to 1 in 10 people)
- Light sensitivity (photophobia)
- Conjunctivitis
- 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)
- Inflammation of the coloured part of the eye (uveitis)
- Blurred vision
- Swelling of the retina (macular oedema)
- Skin rash
- Chest pain (angina), awareness of heart rhythm (palpitation)
- Asthma, shortness of breath (dyspnoea)
- Headache, dizziness
- Muscle pain, joint pain.

Rare side effects (may affect up to 1 in 1,000 people)
- Inflammation of the iris, the coloured part of the eye (iritis)
- Symptoms of swelling or scratching/damage to the surface of the eye
- Swelling around the eye (periorbital oedema)
- Growth of lashes in the "wrong" direction which may cause eye irritation
- Growth of an extra row of eyelashes
- Scarring of the surface of the eye
- Fluid filled area within the coloured part of the eye (iris cyst)
- Localized skin reaction on the eyelids
- Darkening of skin of eyelids
- Worsening of asthma symptoms
- Severe itching of the skin
- Developing a viral infection of the eye caused by herpes simplex virus (HSV).

Very rare side effects (may affect up to 1 in 10,000 people)
- Worsening of angina pectoris in patients who also have heart disease
- Sunken eye appearance (eye sulcus deepening).

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.

Storage conditions after first opening:
Do not store above 25°C.

Shelf-life after first opening:
Latop 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 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 Latop contains
The active substance is latanoprost. Each ml of solution contains 50 micrograms of latanoprost (equivalent to 0.005% w/v). Each 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) and water for injection.

What Latop looks like and contents of the pack
Eye drops, solution.
Latop 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 polyvinyl chloride (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 Manufacturer
Marketing Authorization Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer
S.A. ALCON-COUVREUR N.V., Rijksweg14, B-2870 Puurs, Belgium.

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

Germany:	Latanoprost HEXAL 50 Mikrogramm/ml Augentropfen, Lösung
Ireland:	Latop 50 microgram/ml eye drops, solution

This leaflet was last revised in 05/2018.