

Package leaflet: Information for the user

Latop-Comp 50 micrograms/ml + 5 mg/ml eye drops, solution Latanoprost/Timolol

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 effect, 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-Comp is and what it is used for
2. What you need to know before you use Latop-Comp
3. How to use Latop-Comp
4. Possible side effects
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1. What Latop-Comp is and what it is used for

Latop-Comp contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Timolol belongs to a group of medicines known as beta-blockers. Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.

Latop-Comp is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe you Latop-Comp when other medicines have not worked adequately.

2. What you need to know before you use Latop-Comp

Latop-Comp can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

Do not use Latop-Comp if you

- are allergic to latanoprost or timolol, to beta-blockers or any of the other ingredients of this medicine (listed in section 6)
- have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- have serious heart problems or heart rhythm disorders
- are pregnant (or trying to become pregnant)
- are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before you use Latop-Comp if you have now or have had in the past any of the following:

- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- dry eyes
- you wear contact lenses. You can still use Latop-Comp but follow the instructions for contact lens wearers in section 3.

- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms
- disturbances of the heart rate such as slow heartbeat
- heart failure
- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking)
- angina (particularly a type known as Prinzmetal angina)
- low blood pressure
- severe allergic reactions that would usually require hospital treatment
- a viral infection of the eye caused by the herpes simplex virus (HSV).

Tell your doctor before you have an operation that you are using Latop-Comp as this medicine may change effects of some medicines used during anaesthesia.

Other medicines and Latop-Comp

Latop-Comp can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are using or intend to use any of the following medicines:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives
- Medicines to lower blood pressure or to treat heart diseases (e.g. beta-blockers, oral calcium channel blockers, guanethidine, antiarrhythmics, digitalis glycosides or parasympathomimetics)
- Medicines to treat diabetes
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine
- Medicines to prevent allergic anaphylactic shock (adrenalin/epinephrine).

Latop-Comp with food and drink

Normal meals, food or drink have no effect on when or how you should use Latop-Comp.

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 before taking this medicine.

Latanoprost and timolol have been found to have no effect on male or female fertility in animal studies.

Driving and using machines

When you use Latop-Comp your vision may become blurred 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-Comp contains benzalkonium chloride

This preservative may cause eye irritation or disruption to the surface of the eye. It can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses. See the instructions for contact lens wearers in Section 3.

3. How to use Latop-Comp

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

If this is the first time that you have used this bottle, write the date in the space provided on the carton so that you will know when they should no longer be used because they are out of date.

The recommended dose for adults (including the elderly) is **one drop** once a day in the affected eye(s).

Do not use Latop-Comp more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use Latop-Comp as instructed by your doctor until your doctor tells you to stop.

Your doctor may want you to have extra checks on your heart and circulation if you use Latop-Comp.

Contact lens wearers

If you wear contact lenses, you should remove them before using Latop-Comp. After using Latop-Comp you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

Please follow these instructions carefully when using Latop-Comp eye drops solution. It is recommended that you wash your hands before putting in your eye drops.

Do not allow the tip of the container to touch your eye or areas around your eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from contact with any surface. Wash your hands and sit or stand comfortably.

1. You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.
2. To open the bottle, unscrew the cap by turning it until the tamper-proof seal breaks.
3. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye (Fig. 1).



Fig. 1

4. Invert the bottle, and press gently as shown (Fig. 2 and 3) until a single drop as instructed by your doctor is dispensed into your eye. **DO NOT TOUCH YOUR EYE OR EYELID WITH THE TIP OF THE CONTAINER.**

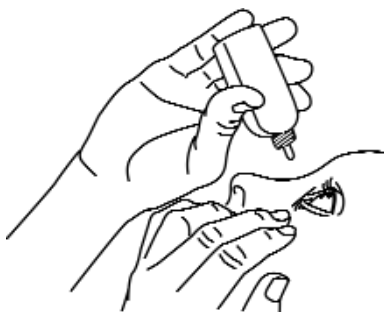


Fig. 2



Fig. 3

5. Repeat steps 3 and 4 with the other eye if instructed to do so by your doctor.
6. After using Latop-Comp, press a finger into the corner of your eye, by the nose (Fig.4) for 2 minutes. This helps to stop the medicine getting into the rest of the body.



Fig. 4

7. Reclose the bottle by turning the cap firmly immediately after use and return the bottle to the original outer carton.
8. The dispenser tip is designed to provide a pre-measured drop; therefore, do not enlarge the hole of the dispenser tip.

If you use Latop-Comp with other eye drops

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

If you use more Latop-Comp than you should

If you put too many drops in 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.

If you swallow Latop-Comp

If you swallow Latop-Comp accidentally you should contact your doctor for advice. If you swallow a lot of Latop-Comp you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

If you forget to use Latop-Comp

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 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.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Latop-Comp without speaking to your doctor.

Listed below are the known side effects of using Latop-Comp. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that Latop-Comp might cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function you should speak to a doctor and tell them you have been using Latop-Comp.

The following have been seen with Latop-Comp:

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. The colour change may be permanent and may be more noticeable if you use Latop-Comp 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-Comp treatment is stopped.

Common (may affect up to 1 in 10 people)

- eye irritation (including stinging, burning, itching, grittiness or the sensation of a foreign body in the eye)
- eye pain.

Uncommon (may affect up to 1 in 100 people)

- headache
- redness of the eye
- eye infection (conjunctivitis)
- blurred vision
- watering eyes
- inflammation of the eyelids
- irritation or disruption of the surface of the eye
- skin rashes or itching (pruritus).

Other side effects

Although not seen with Latop-Comp, the following additional side effects have been seen with the medicine in latanoprost/timolol and therefore might occur when you use Latop-Comp.

The following side effects have been seen with latanoprost:

Infections and infestations:

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Immune system disorders:

- Symptoms of allergic reaction (swelling and redness of the skin and rash).

Psychiatric disorders:

- Depression, memory loss, decreased sex drive, inability to sleep, nightmares.

Nervous system disorders:

- Dizziness, tingling or numbness in the skin, changes in blood flow to the brain, worsening of symptoms of myasthenia gravis (if you already suffer from this condition), sudden fainting or feeling you may faint (syncope).

Eye disorders:

- Changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), swelling at the back of the eye (macular oedema), inflammation/irritation of the surface of the eye (keratitis), dry eyes, fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus).

Ear disorders:

- Whistling/ringing in the ears (tinnitus).

Heart (cardiac) disorders:

- Worsening of angina, awareness of heart rhythm (palpitations).

Breathing (respiratory) disorders:

- Asthma, worsening of asthma, shortness of breath.

Skin disorders:

- Darkening of the skin around the eyes.

Muscle and skeletal disorders:

- Joint pain, muscle pain.

General disorders:

- Chest pain.

For timolol these are:

Like other medicines applied into eyes, Latop-Comp is absorbed into the blood. The timolol portion of this combination may cause similar side effects as seen with intravenous and/or oral beta-blocking agents. Incidence of side effects after application into the eyes is lower than when medicines are, for example, taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions.

- Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction
- Low blood glucose levels
- Difficulty sleeping (insomnia), depression, nightmares, memory loss
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like pins and needles, and headache
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision
- Slow heart rate, chest pain, palpitations, oedema (fluid buildup), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid buildup), a type of heart rhythm disorder, heart attack, heart failure
- Low blood pressure, Raynaud's phenomenon, cold hands and feet
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash
- Muscle pain not caused by exercise
- Sexual dysfunction, decreased libido
- Muscle weakness/tiredness.

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 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-Comp

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 label and carton. The expiry date refers to the last day of that month.

Before Latop-Comp is first opened, it should be stored at 2-8°C (in a refrigerator).

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

After first opening: use within 28 days; do not store the bottle above 25°C.

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-Comp contains

The active substances are: latanoprost and timolol.

One ml contains 50 micrograms latanoprost and 5 mg timolol (as maleate).

The other ingredients are: benzalkonium chloride (preservative), sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, sodium chloride, sodium hydroxide/hydrochloric acid (for pH-adjustment), water for injection.

What Latop-Comp looks like and contents of the pack

Eye drops, solution

Clear, colourless solution.

This medicinal product is available in transparent plastic bottles with a white screw cap.

Each bottle contains 2.5 ml eye drops.

Pack sizes

1 x 2,5 ml, 2 x 2,5 ml, 3 x 2,5 ml, 4 x 2,5 ml, 5 x 2,5 ml, 6 x 2,5 ml, 7 x 2,5 ml, 8 x 2,5 ml, 9 x 2,5 ml, 10 x 2,5 ml and 12 x 2,5 ml

Not all pack sizes will be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Aeropharm GmbH, François-Mitterrand-Allee 1, 07407 Rudolstadt, Germany.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

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

Bulgaria	OPHTAPROST TIM
Denmark	LATIOTIM
Estonia	Latoxap 0,05mg/5mg/ml
Finland	Latiotim 50 mikrog/ml + 5 mg/ml silmätipat, liuos
Ireland	Latoxap 50 micrograms/ml + 5 mg/ml eye drops, solution
Latvia	Latoxap 0,05 mg/5 mg/ml acu pilieni, šķidums
Norway	Latiotim 50 mikrogram/ml + 5 mg/ml øyedråper, oppløsning
Poland	Polprost Plus
Portugal	Latanoprost + Timolol Sandoz
Romania	Latanoprost/Timolol Sandoz 50 micrograme/5 mg/ml picături oftalmice, soluție
Slovenia	Latanoprost/timolol Sandoz 0,05 mg/5 mg v 1 ml kapljice za oko, raztopina

Spain Latanoprost/Timolol Sandoz 50 microgramos/ml + 5mg/ml colirio en solución

This leaflet was last revised in 01/2017.