

Package leaflet: Information for the patient

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

1. What Loracom is and what it is used for

Loracom 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.

Loracom 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 Loracom when other medicines have not worked adequately.

Loracom 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.

2. What you need to know before you use Loracom

Do not use Loracom

- if you are allergic to latanoprost or timolol, beta-blockers or any of the other ingredients of this medicine (listed in section 6)
- if you have now or have had in 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)
- if you have heart problems, such as heart failure or heart rhythm disorders.

Warnings and precautions

Talk to your doctor or pharmacist before using Loracom if you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- disturbances of heart rate such as slow heart beat
- 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
- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- you suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- you know that you suffer from dry eyes
- you wear contact lenses. You can still use Loracom but follow the instructions for contact lens wearers in section 3
- you know that you suffer from angina (particularly a type known as Prinzmetal angina)
- you know that you suffer from severe allergic reactions that would usually require hospital treatment
- you have suffered or are currently suffering from 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 Loracom as timolol may change effects of some medicines used during anaesthesia.

Other medicines and Loracom

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including using eye drops and medicines obtained without a prescription.

Loracom can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes.

In particular, speak to your doctor or pharmacist if you know that you are taking any of the following types of medicine:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives
- Beta-blockers
- Epinephrine
- Drugs used to treat high blood pressure such as oral calcium channel blockers, guanethidine, antiarrhythmics, digitalis glycosides or parasympathomimetics
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

Do not use Loracom if you are pregnant unless your doctor considers it necessary. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

Breast-feeding

Do not use Loracom if you are breast-feeding. Loracom may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Fertility

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 Loracom 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.

Loracom contains phosphates

This medicine contains 6 mg phosphates in each millilitre.

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 Loracom

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

Dosage

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

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

Use Loracom 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 Loracom.

Contact lens wearers

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

Instructions for proper use

Follow the steps below to help you use Loracom eye drops, solution (hereafter referred to as the eye drops) properly:

1. Wash your hands and sit or stand comfortably.
2. Remove the protective cap (Picture 1.). **To avoid contamination of the solution, the tip of the bottle must not touch anything.**
3. Hold the bottle upside down with the thumb on the shoulder of the bottle and the other fingers on the bottom of the bottle (Picture 2.). **Before the first use, pump the bottle repeatedly, approximately 12 times, until the first drop emerges.**
4. Tilt your head back and gently pull down your lower eyelid to form a pouch between your eye and eyelid.
5. Place the tip of the bottle close to, but not touching your eye.
6. Press down the finger sleeve and the bottom side of the bottle so that only one drop goes into your eye, and then release the lower eyelid (Picture 3.).
7. Press a finger against the corner of the affected eye by the nose (Picture 4.). Hold for 2 minutes whilst keeping the eye closed.
8. Repeat steps 4, 5, 6 and 7 in your other eye if your doctor has told you to do this.
9. After each use the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid from the tip. This is necessary in order to ensure delivery of subsequent drops and to prevent contamination.
10. Put the cap back on the bottle.



Picture 1.



Picture 2.



Picture 3.



Picture 4.

Only use one bottle of medicine at a time. Do not open the cap until you need to use the eye drops. You must throw away the 2.5 ml bottle 30 days and 7.5 ml bottle 90 days after you first opened it, to prevent infections.

Write down the date you opened the bottle in the space on carton box.

If you use Loracom with other eye drops

If you have to use other eye drops, you should wait for at least five minutes after using Loracom. Eye ointments should be administered last.

If you use more Loracom 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 Loracom

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

If you forget to use Loracom

Carry on with the usual dosage at the usual time. Do not use a double dose to make up to the dose you have forgotten.

If you stop using Loracom

You should speak to your doctor if you want to stop using Loracom.

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 using the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Loracom without speaking to your doctor.

Listed below are the known side effects of using Loracom. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that Loracom 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 Loracom.

The following are known side effects of using Loracom:

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 Loracom 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 Loracom treatment is stopped.

Common (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

- Headache.

- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye.
- Skin rashes or itching (pruritus).

Other side effects

Like other medicines used in the eyes, Loracom (latanoprost and timolol) is absorbed into the blood. The incidence of side effects after using eye drops is lower than when medicines are, for example, taken by mouth or injected.

Although not seen with Loracom, the following additional side effects have been seen with the medicines in Loracom (latanoprost and timolol) and therefore might occur when you use Loracom. The listed side effects include reactions seen within the class of beta-blockers (e.g. timolol) when used for treating eye conditions:

- Nausea, vomiting (uncommon).
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).
- 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.
- Dizziness.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucinations.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), unusual sensations like pins and needles, and headache.
- Swelling at the back of the eye (macular oedema), fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus).
- 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.
- Darkening of the skin around the eyes, 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), scarring of the surface of the eye.
- Whistling/ringing in the ears (tinnitus).
- Angina, worsening of angina in patients who already have heart disease.
- Slow heart rate, chest pain, palpitations (awareness of heart rhythm), oedema (fluid build up), 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 build up), a type of heart rhythm disorder, heart attack, heart failure.
- Low blood pressure, poor blood circulation which makes the fingers and toes numb and pale, cold hands and feet.
- Shortness of breath, constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough, asthma, worsening of asthma.
- Taste disturbances, indigestion, diarrhoea, dry mouth, abdominal pain,
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Joint pain, muscle pain not caused by exercise, muscle weakness, tiredness.
- Sexual dysfunction, decreased libido.

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

Website: www.hpra.ie

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

5. How to store Loracom

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 label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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

Do not freeze.

After first opening: do not store above 25°C, keep the bottle in the outer carton in order to protect from light. Do not freeze.

Opened bottle 2.5 ml: use within 30 days.

Opened bottle 7.5 ml: use within 90 days.

Write down the date you opened the bottle in the space on carton box.

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 Loracom contains

- The active substances are latanoprost and timolol.
Each millilitre of solution contains latanoprost 50 micrograms and 5 mg timolol (as maleate).
- The other ingredients are sodium chloride, disodium phosphate, sodium dihydrogen phosphate monohydrate, polysorbate 80, disodium edetate, sodium hydroxide (to adjust pH), hydrochloric acid dilute (to adjust pH), water for injections.

What Loracom looks like and contents of the pack

Loracom is a clear, colourless solution.

The packaging consists of HDPE bottle closed with multidose dropper applicator (PP, HDPE, LDPE) with pump and HDPE cap and PP finger sleeve.

Loracom eye drops, solution (eye drops) is available in the following pack sizes:

1 bottle x 2.5 ml

1 bottle x 7.5 ml

2 bottles x 7.5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Farmaprojects S.A.U.

Calle Provença 392, 6 Planta

08025 Barcelona, Spain

Manufacturer

Lomapharm GmbH
Langes Feld 5, Emmerthal, Niedersachsen, 31860,
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

CZ: Latanoprost/Timolol Polpharma

DE: Lifoduo 50 Mikrogramm/ml + 5 mg/ml Augentropfen, Lösung

ES: Tilator 50 microgramos/ml + 5 mg/ml colirio en solución

FR: Vortia 50 microgrammes/5 mg par mL, collyre en solution

IE: Loracom 0.05 mg/ml + 5 mg/ml eye drops, solution

IT, PT: Lifoduo

This leaflet was last revised in