

Package Leaflet: Information for the user
Xalacom® Eye Drops, Solution
50 micrograms/mL and 5 mg/mL
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 Xalacom is and what it is used for
2. What you need to know before you use Xalacom
3. How to use Xalacom
4. Possible side effects
5. How to store Xalacom
6. Contents of the pack and other information

1. What Xalacom is and what it is used for

Xalacom 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.

Xalacom 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 Xalacom when other medicines have not worked adequately.

2. What you need to know before you use Xalacom

Xalacom 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 Xalacom eye drops solution:

- if you are allergic (hypersensitive) to either of the medicines in Xalacom (latanoprost or timolol), beta-blockers, or any of the other ingredients of Xalacom (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 serious heart problems or heart rhythm disorders
- if you are pregnant (or trying to become pregnant)
- if you are breast feeding

Warnings and precautions

Talk to your doctor or pharmacist before using Xalacom 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 Xalacom 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 Xalacom as timolol may change effects of some medicines used during anaesthesia.

Other medicines and Xalacom

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.

Xalacom 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

Xalacom with food and drink

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

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 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 Xalacom 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.

Xalacom contains benzalkonium chloride

Xalacom contains a preservative called 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 Xalacom

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

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

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

Use Xalacom 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 Xalacom.

Contact lens wearers

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

Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Twist off the outer cap (which can be thrown away).



Figure 1

3. Unscrew the protective inner cap. The protective cap should be retained.

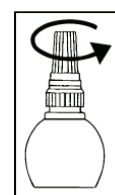


Figure 2

4. Use your finger to gently pull down the lower eyelid of your affected eye.
5. Place the tip of the bottle close to, but not touching your eye.
6. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
7. After using Xalacom, press a finger into the corner of your eye, by the nose (figure 4) for 2 minutes. This helps to stop latanoprost + timolol getting into the rest of the body.
8. Repeat in your other eye if your doctor has told you to do this.
9. Put the protective inner cap back on the bottle.

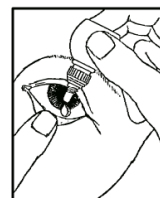


Figure 3



Figure 4

If you use Xalacom with other eye drops

Wait at least 5 minutes between using Xalacom and using the other eye drops.

If you use more Xalacom 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 Xalacom

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

If you forget to use Xalacom

Carry on with the usual dosage at the usual time. Do not take a double dose to make up to the dose you have forgotten. If you are unsure about anything talk to 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 Xalacom without speaking to your doctor.

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

The following are known side effects of using Xalacom:

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 Xalacom 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 Xalacom 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

Although not seen with Xalacom, the following additional side effects have been seen with the medicines in Xalacom (latanoprost and timolol) and therefore might occur when you use Xalacom:

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

Like other medicines applied into eyes, Xalacom 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 topical ophthalmic application 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 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, 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 Xalacom

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated after EXP on the carton and bottle label. The expiry date refers to the last day of that month.

Store the unopened bottle of Xalacom in a refrigerator (between 2°C to 8°C).

After opening the bottle it is not necessary to store it in a refrigerator but do not store it above 25°C. After opening do not use this bottle for more than 4 weeks.

When you are not using Xalacom, keep the bottle in the outer carton, in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. The measures will help protect the environment.

6. Contents of pack and other information

What Xalacom contains

The active substances are latanoprost 50 micrograms/ml and timolol (as timolol maleate) 5 mg/ml.

The other ingredients are:

Sodium chloride

Benzalkonium chloride

Sodium dihydrogen phosphate monohydrate (E399i)

Disodium phosphate anhydrous (E399ii)

Hydrochloric acid solution (for adjustment to pH 6.0)

Sodium hydroxide solution (for adjustment to pH 6.0)

Water for injections

What Xalacom looks like and contents of the pack

This pack contains one bottle containing 2.5 ml of Xalacom Eye Drops, Solution.

Xalacom is a clear, colourless liquid.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

MANUFACTURER

Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

Parallel Product Authorisation number: PPA 465/406/1

Xalacom is a registered trademark of Pfizer Enterprises SARL.

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Xalcom in Denmark, Finland, Iceland, Norway, Romania and Sweden.

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