

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

XALACOM® 50 micrograms/mL + 5 mg/mL, eye drops, solution

Latanoprost, timolol maleate

Read all of this leaflet carefully before you start using XALACOM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- XALACOM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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.

2. What you need to know before you use XALACOM

XALACOM can be used in adult men and women (including the elderly).

Do not use XALACOM:

- If you are hypersensitive (allergic) to 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 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).
- If you have serious heart problems or heart rhythm disorders.
- If you are currently suffering or have suffered from a viral infection of the eye caused by the herpes simplex virus.

If you think any of these points apply to you, do not use XALACOM until you have talked to your doctor.

Warnings and precautions

Take special care with XALACOM:

Before you use this medicine, tell your doctor 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 heartbeat.
- 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 How to use XALACOM.

- You know that you suffer from angina (particularly a type known as Prinzmetal's 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.

Children and adolescents

XALACOM is not recommended for children and adolescents less than 18 years of age.

Other medicines and XALACOM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

XALACOM with food and drink

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

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or planning to become pregnant. XALACOM should not be used during pregnancy.

XALACOM should not be used if you are breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

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. If you experience any problems, talk to your doctor.

It is not always possible to predict to what extent XALACOM may interfere with the daily activities of a

patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which XALACOM affects them.

XALACOM contains benzalkonium chloride

XALACOM contains a preservative called benzalkonium chloride. This preservative may 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.

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. See the instructions for contact lens wearers in section How to use XALACOM.

3. How to use XALACOM

Do not share medicines prescribed for you with any other person.

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

The usual dosage for adults (including the elderly) is one drop into the affected eye(s) once daily.

The safety and effectiveness of XALACOM in children have not been established.

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 will tell you how long your treatment with XALACOM will last. If you have the impression that the effect of XALACOM is too strong or too weak, tell your doctor or pharmacist.

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

If XALACOM is being used together with other eye drops, they should be put in at least 5 minutes apart.

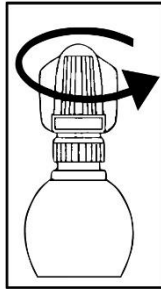
Contact lens wearers

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 XALACOM use

Wash your hands before using eye drops.

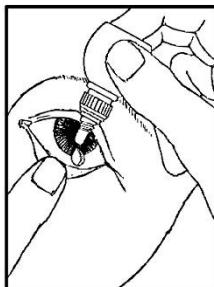
1. Twist off the colourless protective cap with the “wings”.



2. Unscrew the cap.



3. Using your forefinger, gently pull down the lower eyelid of the eye that is to be treated.



4. Place the tip close to the eye and squeeze gently, so that **one drop** falls into the eye.
5. After using XALACOM, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop latanoprost and timolol getting into the rest of the body.



6. Replace the cap after use.

If you use more XALACOM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Be careful when you are squeezing the bottle so that you only put one drop into the affected eye. 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 use a double dose to make up for forgotten individual doses. If you are unsure about anything, talk to your doctor or pharmacist.

4. Possible side effects

XALACOM can have side effects.

Not all side effects reported for XALACOM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using XALACOM, please consult your health care provider for advice.

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.

Tell your doctor if you notice any of the following:

The following are known side effects of using XALACOM:

Frequent side effects

- Infection.
- Sinusitis.
- Upper respiratory tract infection.

- Low blood sugar levels (diabetes mellitus).
- Increased levels of cholesterol in your blood (hypercholesterolaemia).
- Feeling depressed.
- Headache.
- 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 (hyperpigmentation). 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 appear to be no problems associated with the change in eye colour. The eye colour change does not continue after XALACOM treatment is stopped.
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye).
- Changes to the eyelashes and fine hairs around the eye (increased length, thickness, pigmentation and number of eyelashes).
- Blurred vision, inflammation of the eyelids, cloudy lens of the eye (cataract), eye infection (conjunctivitis), hazy or double vision, redness of the eye, eye pain, irritation or disruption of the surface of the eye- (keratitis), sensitivity to light, blind spot in your field of vision.
- High blood pressure.
- Rash or skin disorder.
- Swelling or painful joints.

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:

Frequent side effects

- Eye irritation (burning, grittiness, itching, stinging and foreign body sensation).
- Swelling of the eyelids.
- Red and watery eyes, and sensitivity to light (punctate keratitis).
- Rash.

Other side effects

- Viral infection of the eye (herpetic keratitis).
- Dizziness.
- Changes to the eyelashes and fine hairs around the eye (increased length, thickness, pigmentation and number of eyelashes).
- Blurred vision.
- Swelling of the coloured part of the eye (iritis, uveitis).
- Swelling at the back of the eye (macular oedema).
- Swelling of the cornea.
- Corneal erosion (damage to the front layer of the eyeball).
- Changes to the direction of eyelash growth.
- Fluid filled cyst within the coloured part of the eye (iris cyst).
- Sensitivity to light.
- Eyelid changes resulting in a deepening of your eye socket.
- Skin reaction on eyelids.
- Scarring of the surface of the eye (pseudopemphigoid of ocular conjunctiva).
- Darkening of the skin around the eyes.
- Squeezing, pressure, heaviness or tightness of the chest (angina), awareness of heart rhythm (palpitations).
- Asthma, worsening of asthma, shortness of breath.
- Joint pain, muscle pain.
- Chest pain.

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 medicines. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Generalised 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, localised and generalised rash, itchiness, severe sudden life-threatening allergic

reaction.

- Loss of appetite.
- Low blood glucose levels.
- Confusion.
- Anxiety.
- Altered mental state such as not knowing your location, the time or date.
- Nervousness.
- Memory loss.
- Difficulty sleeping (insomnia).
- Depression.
- Nightmares.
- Seeing or hearing things that are not real.
- Stroke.
- Reduced blood supply to the brain.
- Dizziness.
- Increases in signs and symptoms of myasthenia gravis (muscle disorder).
- Unusual sensations like pins and needles.
- Sleepiness.
- Headache.
- Fainting.
- Blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances.
- Corneal erosion (damage to the front layer of the eyeball).
- Irritation or disruption of the surface of the eye (keratitis).
- Double vision.
- Decreased corneal sensitivity.
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness).
- Dry eyes.

- Visual disturbances.
- Drooping of the upper eyelid (making the eye stay half closed).
- Swelling at the back of the eye (macular oedema).
- Inflammation of the eyelid.
- Ringing in the ears.
- Heart attack.
- Heart failure.
- 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).
- Chest pain.
- A type of heart rhythm disorder.
- Slow heart rate.
- Oedema (fluid build-up).
- Palpitations.
- Worsening of angina (squeezing, pressure, heaviness or tightness of the chest).
- Cold hands and feet.
- Pain in the arms or legs while walking or using the arms.
- Low blood pressure.
- Poor blood circulation disease (Raynaud's phenomenon).
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease).
- Cough.
- Difficulty breathing.
- Stuffy nose.
- Breathing that sounds bubbly, wheezing or gasping.
- Abdominal pain.
- Vomiting.
- Diarrhoea.

- Dry mouth.
- Taste disturbances.
- Indigestion.
- Nausea.
- Pain in the lower abdomen, back, or side.
- Scarring of the surface of the eye (pseudophymoid).
- Skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis.
- Skin rash.
- Hair loss.
- Fever, joint pain, stiffness and swelling, butterfly-shaped rash on face (systemic lupus erythematosus).
- Muscle pain not caused by exercise.
- Sexual dysfunction.
- Decreased libido.
- Scar tissue in the penis, which can cause pain and a bend to the penis (Peyronie's disease).
- 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 (corneal calcification).

If any of the side effects get serious, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of XALACOM.

5. How to store XALACOM

- Store all medicines out of reach of children.
- 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 store it at or below 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 store in a bathroom.
- Do not use XALACOM after the expiry date which is stated after EXP/VERV on the carton and bottle label. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What XALACOM contains

- The active substances are latanoprost and timolol maleate. Each mL contains 50 micrograms latanoprost and timolol maleate corresponding to 5 mg timolol.
- The other ingredients are benzalkonium chloride (0,02 % m/v) as preservative, disodium phosphate anhydrous, sodium chloride, sodium dihydrogen phosphate monohydrate and water for injections. To bring the solution to the correct pH level, very small amounts of hydrochloric acid or sodium hydroxide may be added to the solution during manufacture.

What XALACOM looks like and contents of the pack

A clear and colourless solution, free of visible particles.

The drops are available in a 5 mL multidose, clear, colourless, low-density polyethylene bottle, with a clear, linear, low- or medium-density polyethylene dropper tip (applicator), protected with a yellow inner high-density polyethylene screw cap, and a clear, colourless tamper-evident overcap of low-density polyethylene.

Each bottle contains 2,5 mL of solution.

Holder of Certificate of Registration

Viatriis Healthcare (Pty) Ltd

4 Brewery Street

Isando

Gauteng, 1609

Tel.: +27(011) 451 1300 / +27(071) 281 2503 (24 hours)

Manufacturer: Pfizer Manufacturing Belgium NV, Puurs, Belgium

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