

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using XALACOM Eye Drops.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

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.

SCHEDULING STATUS: **S4**

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

XALACOM® Eye Drops

Latanoprost

Timolol maleate

WHAT XALACOM CONTAINS:

The active ingredients are latanoprost and timolol maleate.

Each millilitre contains 50 µg latanoprost and timolol maleate corresponding to 5 mg timolol.

The other ingredients in XALACOM are benzalkonium chloride (0,02 % m/v), 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 IS USED FOR:

How does XALACOM work:

XALACOM is a combination of two different medicines that both contribute to lowering the pressure in the eye, but in different ways. Timolol is one of a group of medicines known as “beta-blockers” and lowers the pressure in the eye by reducing the inflow of fluid inside the eye. Latanoprost lowers the pressure by increasing the natural outflow of fluid from the inside of the eye.

What is XALACOM used for:

XALACOM is used for lowering increased pressure within the eye (called ocular hypertension) and for the treatment of glaucoma.

BEFORE YOU USE XALACOM:

Do not use XALACOM:

- If you have a respiratory disease such as asthma or a history of asthma, or have severe respiratory problems due to another cause
- If you have heart problems, such as heart failure or heart rhythm disorders
- If you are allergic to latanoprost, timolol maleate, or any of the other ingredients in XALACOM.

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

Take special care with XALACOM:

You should tell your doctor if you have, or have had, asthma or other lung problems, heart problems, circulatory problems, low blood pressure, diabetes or low blood sugar (hypoglycaemia), or allergies to other medicines that you have used.

If you have any heart problems your doctor will want to make sure that the situation is under control before you take your eye drops. Your doctor may want you to have extra checks on your heart and circulation whilst you are using XALACOM.

If you have a coloured part of the eye (iris) that is a mixture of colours i.e. blue/grey-brown, green-brown or yellow-brown, you may find that you slowly and gradually develop an increase in the brown colour of the iris. Changes in purely blue, grey, green or brown eyes are rare. The brown colour change occurs slowly and is noticed only after months to years. If you are being treated with XALACOM in one eye only, this can result in a difference in colour between eyes. The change in colour is harmless but will probably be permanent.

If the coloured parts of your eyes are a mixture of colours or if you observe an increase in the brown colour of the iris, talk to your doctor.

Before surgery and anaesthesia, the doctor/dentist should know that you are being treated with XALACOM, since there is a risk that blood pressure can suddenly fall in association with anaesthesia.

A preservative in XALACOM called benzalkonium chloride may cause eye irritation and can discolour soft contact lenses. If you wear contact lenses it is important that the lenses are taken out before applying XALACOM and not replaced until at least 15 minutes after application.

XALACOM is not recommended for children or adolescents.

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.

If you are pregnant or breastfeeding, ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines:

Possible side effects e.g. blurred vision, can affect the ability to drive and/or operate machines. If you experience any problems, talk to your doctor.

Using other medicines with XALACOM:

XALACOM is often used with other eye drops to treat eye conditions. Tell your doctor if you are using or intend to use other medicines, including other eye drops especially if the eye drops are for the same use as XALACOM (this also applies to medicines obtained without a prescription). There are a few medicines, such as those used to treat high blood pressure, or heart disease, which may interfere with XALACOM. Your doctor will know about these.

You should consult your doctor if you are taking one or more of the following medicines:

- A calcium antagonist (e.g. nifedipine, verapamil or diltiazem) often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud's syndrome
- Digoxin, a medicine used to relieve heart failure or treat abnormal heartbeat
- Anti-dysrhythmic agents such as quinidine, medicines used to treat abnormal heartbeat
- Clonidine, a medicine used to treat high blood pressure
- Other beta-blockers (e.g. other preparations of timolol both oral and/or ocular), which belong to the same group of medicines as XALACOM and could have an additive effect
- Medicine to treat diabetes
- Medicine to enable you to urinate more easily or in order to restore normal bowel movements

- Medicine to reduce swelling of the mucous membranes (for nasal congestion)
- Medicine for asthma that contain adrenaline

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of XALACOM with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO USE XALACOM:

Always take XALACOM exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

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

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

If a dose is missed, you should wait until the next dose. Do not make up for a missed dose by putting an extra drop into the eye.

Instructions for XALACOM use:

Wash your hands before using eyedrops.

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



2. Unscrew the cap



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



- Place the tip close to the eye and squeeze gently, so that **one drop** falls into the eye.
- Replace the cap after use.

If you should accidentally use more XALACOM than you should, always contact your doctor or hospital.

If you use more XALACOM than you should:

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 feel some slight irritation in the eye.

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If XALACOM is accidentally swallowed, you should contact your doctor.

If you forget to use XALACOM:

If you forget to use your eye drops at the usual time, wait until it is time for your next dose. Do not put an extra drop into your eye to make up for the one you may have missed.

POSSIBLE SIDE EFFECTS:

XALACOM can have side effects.

Effects on the eye:

XALACOM may cause a change in eye colour and this may become permanent.

Frequent side effects are:

- Change in the coloured part of the eye (iris) which may be permanent
- For more details refer to the earlier section of this leaflet under the heading **Take special care with XALACOM**
- Eye irritation (including stinging, burning and itching)

- Eye pain

Less frequent side effects are:

- Headache
- Pink/redness of the eye
- Blurred vision
- Watery eyes
- Sore eyelids
- Skin rashes/itching

Some side effects have been seen with the two individual medicines (latanoprost and timolol maleate) within XALACOM. The following effects on the eye may occur with XALACOM:

- Darker, thicker, longer and more eyelashes and fine (vellus) hair
- Eyelashes growing in the “wrong” direction sometimes resulting in eye irritation
- Swelling around the eyes
- Small marks on the eye surface (punctate keratitis), eye discomfort
- Inflammation and swelling in and around the eye/eyelid
- Eye becoming sensitive to light
- Dry eyes
- Visual disturbances (such as double vision)
- Drooping eyelid

When the XALACOM is instilled into the eye, a small amount of active medicines (latanoprost and timolol maleate) in XALACOM can be absorbed into the blood and may cause effects elsewhere in the body, not only in the eye.

The following effects have been reported on the body for the individual medicines (latanoprost and timolol maleate) within XALACOM. These side effects may occur with XALACOM:

- Asthma (acute and worsening of existing asthma), laboured breathing, shortness of breath, cough
- Chest pain, fainting, a slowing of your heart rate
- Worsening of angina in patients with pre-existing disease
- Fatigue (tiredness), dizziness, abnormal sensations, light-headedness, ringing in the ears, depression, abnormal skin sensations

- Joint and muscle pain
- Nausea, diarrhoea, indigestion, dry mouth
- Low blood pressure, stroke, swelling or coldness of your hands, feet and extremities, caused by constriction of the blood vessels in response to stimuli, including the cold
- Depression, memory loss, nightmares, decreased sex drive, difficulty in sleeping

Hypersensitivity reactions such as skin rash (localised or generalised), itching, hair loss, darkening of the skin of the eyelid, exacerbation of psoriasis and a worsening of myasthenia gravis (increased muscle weakness). A more severe allergic-type reaction may cause sudden onset of breathing difficulty or wheezing, swollen mouth, face, hands or feet, fainting and rapid pulse.

If you experience any of these side effects and are concerned please tell your doctor as soon as possible.

If you feel unwell in any other way not mentioned in this leaflet whilst taking XALACOM, please inform your doctor or pharmacist.

Not all side effects reported for XALACOM are included in this leaflet. Should your general health worsen while using XALACOM, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF XALACOM:

Keep all medicines out of the reach and sight of children.

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

Once the bottle has been opened, XALACOM can be kept at room temperature (below 25 °C) for up to 4 weeks. XALACOM should not be used after the expiry date on the bottle. XALACOM should not be used 4 weeks after opening the container for the first time.

Keep the container in the outer carton to protect the medicine from light.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF XALACOM:

The drops are available in a 5 ml colourless, transparent bottle, with a dropper applicator, protected with an inner screw cap, and a tamper-evident overcap.

Each bottle contains 2,5 ml of solution.

IDENTIFICATION OF XALACOM:

The solution is a clear, colourless liquid.

REGISTRATION NUMBER:

36/15.4/0043

NAME AND ADDRESS OF REGISTRATION HOLDER:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

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