

Xalacom(R) Eye Drops

Latanoprost/Timolol maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Xalacom. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Xalacom against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Xalacom is used for

Xalacom is used to lower raised pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure.

Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this

gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

Xalacom is made up of 2 active ingredients, latanoprost and timolol maleate. Latanoprost works by allowing more fluid to flow out from within your eye(s). Timolol maleate lowers the pressure in the eye by reducing the production of fluid.

Latanoprost belongs to a family of medicines called prostaglandin agonists. Timolol maleate belongs to a family of medicines called beta-blockers.

Although Xalacom helps control your glaucoma it does not cure it. So you must keep using it until your doctor tells you to stop.

Ask your doctor if you have any questions about why Xalacom has been prescribed for you.

Your doctor may have prescribed it for another reason.

Xalacom is not recommended for use in children. The safety and effectiveness of Xalacom in children have not been established.

Before you use Xalacom

When you must not use it

Do not use Xalacom if:

- * **you have an allergy to Xalacom or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include:

- * asthma, wheezing or shortness of breath
- * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- * hives, itching or skin rash
- * fainting
- * **you have asthma, or a history of asthma, chronic obstructive lung disease (emphysema) or other breathing problems**
- * **you have certain heart conditions, such as a very slow heart rate, an irregular heart beat, or heart failure**
- * **the bottle/packaging shows signs of tampering**
- * **the expiry date on the pack has passed.**

If you use this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start using Xalacom, talk to your doctor.

Before you start to use it

Tell your doctor if:

1. you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes

2. you are pregnant or intend to become pregnant

There is no adequate experience with Xalacom in pregnant women, therefore it should not be used during pregnancy.

3. you are breast-feeding or intend to breast-feed

One of the active ingredients in Xalacom has been detected in breast milk. Because of the potential harm to the infant, nursing women should either stop using Xalacom or stop breast-feeding while using it.

4. you have or have had any medical conditions, especially the following:

- * heart disease
- * lung disease
- * any other types of glaucoma or eye conditions
- * diabetes
- * myasthenia gravis
- * hyperthyroidism

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell him or her before you use Xalacom.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Xalacom may interfere with each other. These include:

- * certain medicines used to treat high blood pressure or heart conditions such as beta-blockers, calcium channel blockers or digoxin

- * certain medicines used to treat irregular heart beats such as amiodarone and quinidine
- * some medicines (monoamine oxidase inhibitors, MAOIs) used to treat depression, such as phenelzine, and Parkinson's disease, such as selegiline
- * adrenaline, a hormone used in the treatment of asthma, slow or irregular heart beat, acute allergic disorders and glaucoma
- * some medicines that may have been prescribed to help you pass urine or restore normal bowel movements
- * narcotics such as morphine used to treat moderate to severe pain
- * eye drops which contain an ingredient called thiomersal. If using such eye drops as well as Xalacom, you should wait at least 5 minutes between using these eye drops and Xalacom.
- * medicines used to treat diabetes or high blood sugar
- * some other eye drops that contain a beta-blocker or a prostaglandin. The use of two or more beta-blocker eye drops and/or two or more prostaglandin eye drops at the same time is not recommended.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Xalacom.

How to use Xalacom

Use Xalacom only when prescribed by your doctor.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How much to use

The usual dose of Xalacom is one drop into the affected eye, or eyes, once daily.

Use Xalacom every day, at about the same time each day, unless your doctor tells you otherwise.

Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

How to use it

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

The preservative in Xalacom (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used Xalacom.

If using other eye drops in addition to Xalacom, wait at least 5 minutes before putting any other drops in your eye(s).

Be careful not to touch the dropper tip against your eye, eyelid or anything else.

Touching the dropper tip against something may contaminate the eye drops and give you an eye infection.

You may find it easier to put drops in your eye while you are sitting or lying down.

1. Wash your hands well with soap and water
2. Twist off the protective overcap from the bottle
3. Unscrew the inner cap
4. Use your finger to gently pull down the lower eyelid of your affected eye
5. Tilt your head back and look up.
6. Place the tip of the bottle close to but not touching your eye. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid. Close your eye. Do not blink or rub your eye

7. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique
8. Screw the inner cap back on the bottle
9. Wash your hands again with soap and water to remove any residue

You may feel a slight burning sensation in the eye shortly after using the eye drops.

If this persists, or is very uncomfortable, contact your doctor or pharmacist.

How long to use it

Continue using Xalacom every day for as long as your doctor prescribes.

Xalacom helps control your condition but does not cure it.

If you forget to use it

If you miss a dose, skip the dose you missed and take your next dose when you are meant to.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed Xalacom, immediately telephone your doctor or the Australian Poisons Information Centre (telephone 131 126) or the New Zealand National

Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If Xalacom is accidentally swallowed, or if you use too many drops, you may feel light-headed or dizzy, you may faint, have a very slow pulse rate, or have wheezing or difficulty breathing. Other effects include headache, nausea, abdominal pain, fatigue, hot flushes and sweating.

While you are using Xalacom

Things you must do

To make sure Xalacom is working properly, have your eye pressure checked regularly. Have your eyes checked regularly for any other changes, including a change in eye colour.

A slow change in eye colour, which may be permanent, has been reported to occur in some patients who use Xalacom. Your doctor will decide whether you should continue using Xalacom.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of Xalacom because of possible contamination of the old one, or may advise you to stop your treatment with Xalacom.

If you become pregnant while using Xalacom tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using Xalacom.

Tell all doctors and pharmacists who are treating you that you are using Xalacom.

Things you must not do

Do not give Xalacom to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop using Xalacom without first talking to your doctor.

If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving or operating machinery until you know how Xalacom affects you.

Xalacom generally does not cause any problems with your ability to drive a car or operate machinery. However, it may cause blurred vision in some people. Make sure you know how you react to Xalacom or that your vision is clear before driving a car or operating machinery.

Side effects

Check with your doctor as soon as possible if you have any problems while taking Xalacom, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Xalacom can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- * a slow change in eye colour over a period of time. The iris may become more brown in colour and appear darker. This change may be permanent and more

- noticeable if you are only being treated in one eye
- * blurred vision, double vision or other visual problems
- * allergic reactions including redness, swelling and/or itching of the eye
- * burning, grittiness or stinging of the eyes
- * eye pain
- * redness or watering of the eye/s
- * irritation or feeling of having something in the eye, dry eyes
- * discharge, itching of the eye/s, crusty eyelashes
- * drooping of eyelid/s
- * darkening, thickening, lengthening or an increase in the number of eye lashes and fine hair on the eyelids
- * misdirected eye lashes sometimes causing eye irritation
- * darkening of the skin of the eyelids
- * crusting, redness, thickening, itching or burning of the eyelids
- * headache
- * tiredness, weakness
- * sleepiness
- * ringing or buzzing in the ears
- * difficulty sleeping, nightmares
- * change in mood such as depression, anxiety or nervousness
- * confusion, disorientation or memory loss
- * hallucinations
- * feeling sick (nausea), upset stomach
- * diarrhoea
- * anorexia
- * dry mouth
- * cold hands or feet
- * numbness, tingling and colour change (white, blue then red) in fingers when exposed to the cold (Raynaud's Phenomenon)
- * numbness or tingling in the fingers or toes
- * cough
- * nasal congestion
- * hair loss or thinning

- * less desire for sex
- * impotence
- * muscle/joint pain
- * skin rash

Tell your doctor immediately if you notice any of the following:

- * fast or irregular heart beat, also called palpitations
- * dizziness and light-headedness, which may be due to low blood pressure
- * skin rash, itching
- * swelling of hands, feet, ankles or legs

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop using Xalacom and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- * wheezing, difficulty in breathing (asthma or worsening of asthma)
- * shortness of breath
- * very slow pulse, chest pain
- * fainting
- * swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- * severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash

These are very serious side effects. You may need urgent medical attention. These side effects are rare.

Tell your doctor if you notice any other effects.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Xalacom

Storage

Keep your eye drops in a safe place away from the sight and reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Before opening Xalacom, keep the bottle in its box in a refrigerator (2 degrees C-8 degrees C) protected from light.

After opening Xalacom, keep the bottle in its box in a cool place where the temperature stays below 25 degrees C, but do not refrigerate. Keep the box properly closed and protected from light.

Do not store Xalacom or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Do not carry the eye drops in pockets of your clothes.

Heat and dampness can destroy some medicines.

Put the top back on the bottle right away after use to avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

Open a new bottle every 4 weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

Xalacom eye drops come in a plastic bottle with a dropper and screw cap inside a protective overcap. Remove this overcap before use.

When you first receive your Xalacom bottle, it will appear half full. This corresponds to 2.5 mL of eye drop solution, giving a minimum of 80 drops. This volume is enough to last 4 weeks if used in both eyes.

Ingredients

The active ingredients in Xalacom eye drops are latanoprost and timolol maleate. Each 1 mL of Xalacom contains 50 micrograms of latanoprost and 5mg of timolol (equivalent to 6.83 mg timolol maleate). Each drop contains about 1.5 micrograms of latanoprost and 150 micrograms of timolol.

Xalacom eye drops also contain:

- * sodium chloride
- * monobasic sodium phosphate
- * dibasic anhydrous sodium phosphate
- * water for injections
- * benzalkonium chloride (as a preservative).

Identification

Xalacom can be identified by the Australian Register Number AUST R 80311, which is found on the box.

Supplier

Xalacom is supplied in Australia by:
Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll Free number: 1800 675 229

Xalacom is supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland, New Zealand
Toll Free number: 0800 736 363

For more information about glaucoma, contact Glaucoma Australia Inc. (telephone 1800 500 880), or Glaucoma New Zealand (telephone 09 373 8779).

This leaflet was last revised in March 2006.

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