

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrXALACOM®

Latanoprost and timolol ophthalmic solution

Read this carefully before you start taking **XALACOM** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **XALACOM**.

What is XALACOM used for?

XALACOM is used to reduce eye pressure in patients with conditions called “open angle glaucoma” or “ocular hypertension”. Both these conditions are related to an increase in pressure within the eye. If the high pressure is not reduced, it could damage your eyesight.

How does XALACOM work?

XALACOM contains two drugs, latanoprost and timolol. Both of these drugs lower eye pressure.

Latanoprost works by increasing the natural outflow of fluid from inside the eye. Timolol works by decreasing the fluid production in the eye.

What are the ingredients in XALACOM?

Medicinal ingredients: Each millilitre (mL) contains 50 micrograms of latanoprost and 5 milligrams of timolol as timolol maleate.

Non-medicinal ingredients: Benzalkonium chloride (preservative), disodium hydrogen phosphate anhydrous, hydrochloric acid, sodium chloride, sodium dihydrogen phosphate monohydrate, sodium hydroxide and water for injection.

XALACOM comes in the following dosage forms:

XALACOM is supplied in a 5 mL plastic ophthalmic dispenser bottle with a dropper tip, screw cap and tamper proof overcap.

Do not use XALACOM if:

- you have a reactive airway disease including the following:
 - asthma
 - a history of asthma
 - severe chronic obstructive pulmonary disease (a condition where the lungs are inflamed)
- you have heart problems such as:
 - a sinus bradycardia (a condition where there is a low heart beat)
 - sick sinus syndrome (a heart rhythm disorder)
 - sino-atrial block (a condition in which there is a disorder in the normal rhythm of the heart)

- second or third degree atrioventricular block not controlled with pace-maker
- overt cardiac (heart) failure
- cardiogenic shock (a serious condition in which your heart suddenly cannot pump enough blood)
- you are allergic to latanoprost, timolol, benzalkonium chloride, any other ingredient in the product or any part of the container. (See **What are the ingredients in XALACOM?**)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take XALACOM. Talk about any health conditions or problems you may have, including if you:

- have heart diseases or conditions such as:
 - chest pain or tightness,
 - breathlessness or choking,
 - heart failure,
 - low blood pressure (hypotension).
- have problems with your blood pressure or thyroid.
- have poor blood circulation disease (a condition called Raynaud's disease or Raynaud's syndrome).
- have diabetes or have low blood sugar levels.
- have or have had muscle weakness or have been diagnosed as having myasthenia gravis (a condition where your muscles are weaker).
- are using any other eye drops or taking any other medication.
- are pregnant, think you might be pregnant or you are planning a pregnancy.
- are breast feeding or planning to breastfeed.
- have or have had herpes simplex keratitis (a condition where the cornea is inflamed. This is caused by the herpes simplex virus)
- have eyes that are sensitive to light
- are planning a surgery
- have kidney or liver disease

Other warnings you should know about:

XALACOM is not recommended for use in children.

Driving and Using Machinery:

Your sight may become blurred for a short period of time just after using XALACOM. Do NOT drive or use machines until your sight is clear again.

Surgery:

If you are planning to have surgery, tell your healthcare professional that you are using XALACOM. XALACOM may change the effects of some medicines used during anaesthesia.

Contact Lenses:

XALACOM contains a preservative (benzalkonium chloride) that may be absorbed by contact lenses. The preservative may form a solid with an ingredient (thimerosal) present in many contact lens soaking solutions.

If you wear contact lenses, remove them before using XALACOM. Wait 15 minutes after applying the eye drops before putting your lenses back in.

If you are using more than one type of eye drop medicine, wait at least 5 minutes between each different eye drop

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XALACOM:

Tell your healthcare professional if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes or other medicines including:

- Medicines used to treat blood pressure issues like calcium channel blockers.
- Medicines used to treat heart rhythm conditions like antiarrhythmics such as amiodarone or quinidine.
- Medicines used to treat depression like monoamine oxidase inhibitors, fluoxetine, and paroxetine.
- Medicines used to treat pain like narcotics.
- Medicines used to treat heart conditions like digitalis and beta-adrenergic blocking agents.

XALACOM can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

How to take XALACOM:

Always use XALACOM exactly as your healthcare professional has told you.

Usual adult dose:

1 drop of XALACOM should be dropped into the affected eye(s) once daily.

Do not allow the dropper tip of the bottle to touch the eye or anything else. This could contaminate the tip with common bacteria known to cause eye infections. Serious damage to the eye and loss of vision may result if you use eye drop solutions that have become contaminated.

If you experience any type of eye condition or have surgery, immediately talk to your healthcare professional about continuing to use XALACOM.

Follow these steps to help you use XALACOM properly:

1. Wash your hands and sit or stand comfortably. If you wear contact lenses, remove them before using your eye drops.
2. Twist off the outer protective cap from the bottle.



3. Unscrew the inner cap of the bottle.



4. Once the bottle is opened, hold it in one hand and steady your thumb against your brow or the bridge of your nose.
5. Use your index finger to gently pull down the lower eyelid of the affected eye(s) to create a pocket for the drop.



6. Gently press, or lightly tap, the side of the bottle to allow only a single drop to fall into the pocket. Do not let the tip of the bottle touch your eye.
7. Close your eye for 2 to 3 minutes.
8. If your healthcare professional has told you to use drops in both eyes, repeat the process for the other eye. XALACOM should be used until your doctor tells you to stop.

Overdose:

If you think you, or a person you are caring for, have taken too much XALACOM contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget one dose of XALACOM, continue with the next dose as normal. Do not take two doses to make up for the one that you missed. If you take too many doses, you may irritate your eye.

What are possible side effects from using XALACOM?

These are not all the possible side effects you may have when taking XALACOM. If you experience any side effects not listed here, tell your healthcare professional.

- Change in eye colour
- Longer eye lashes
- Iris cysts
- A feeling that something is in your eye
- Eye redness
- Blurred vision
- Skin rash
- Eye pain
- Eye irritation (for example, burning or stinging eyes)
- Eyelid inflammation
- Infection in nose, sinuses and/or throat
- Headache
- Loss of appetite
- Vomiting
- Nausea
- Muscle pain
- Joint pain
- Chest pain
- Fast-beating or fluttering heart beat
- Asthma
- Low blood sugar in diabetics
- Dry eyes
- Anxiety
- Nervousness
- Dizziness
- Confusion
- Disorientation
- Insomnia
- Hallucinations

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Irregular heartbeat			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations.			✓
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up).			✓
Severe respiratory reactions			✓
Hypersensitivity (allergic reactions): swelling of the mouth, and throat, difficulty breathing, hives, itching, rash.			✓
Muscle weakness: increased muscle weakness in those with myasthenia gravis or a similar condition.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

Before XALACOM is first opened, keep it in a fridge (between 2°C and 8°C).

Once the bottle has been opened, XALACOM can be kept at normal room temperature up to 25°C.

Protect from light.

XALACOM must be used within 10 weeks after opening the bottle. Discard the bottle and/or unused contents after 10 weeks.

XALACOM should not be used after the expiry date on the bottle.

If you want more information about XALACOM:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.viatris.ca, or by calling 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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