

APO-Latanoprost/ Timolol Eye Drops

Latanoprost 50 mcg/mL and Timolol (as maleate) 5 mg/mL

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about latanoprost/timolol eye drops. 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 this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Latanoprost/Timolol eye drops are used to lower raised pressure in the eye and to treat glaucoma.

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

Glaucoma is a condition in which the pressure of fluid in the eye may be high, damaging the back of the eye to result in gradual loss of sight. There are usually no symptoms of glaucoma. Untreated glaucoma can lead to serious problems, including total blindness.

How it works

Latanoprost and timolol work together to reduce the amount of fluid in the eye, allowing the eye to return to a normal pressure.

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 this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you use this medicine

When you must not use it

Do not take this medicine if you have an allergy to:

- latanoprost
- timolol maleate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- asthma, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat, which may cause difficulty in swallowing or breathing, or other parts of the body
- rash, itching or hives on the skin
- fainting

Do not take this medicine if you have or have had any of the following medical conditions:

- asthma, or a history of asthma, COPD (emphysema) or other breathing problems.
- certain heart conditions, such as a very slow heart rate, an irregular heartbeat or heart failure.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or you plan to become pregnant.

There is no adequate experience with this medicine in pregnant women.

Tell your doctor if you are breastfeeding.

One of the active ingredients in the medicine has been detected in breast milk. Because of the potential harm to the infant, nursing women should either stop using the eye drops or stop breastfeeding while using it.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease
- lung disease
- circulation problems
- other types of glaucoma or eye conditions
- diabetes
- myasthenia gravis
- hyperthyroidism

Tell your doctor if you are planning to have surgery.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines may interact with latanoprost/timolol eye drops. These include:

- certain medicines used to treat high blood pressure or heart conditions or irregular heartbeats (e.g. beta-blockers, calcium channel blockers, digoxin, amiodarone, quinidine)
- some medicines used to treat depression (e.g. phenelzine, fluoxetine, paroxetine)
- some medicines used to treat Parkinson's disease (e.g. selegiline)
- adrenaline, used to treat asthma, slow or irregular heartbeat, acute allergic disorders and glaucoma
- some medicines used to help you pass urine or restore normal bowel movements
- narcotics used to treat moderate to severe pain (e.g. morphine)
- eye drops which contain an ingredient called thiomersal. If using such eye drops as well as latanoprost/timolol eye drops, you should wait at least 5 minutes between using the eye drops and latanoprost/timolol eye drops.

- 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.

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using latanoprost/timolol eye drops.

Other medicines not listed above may also interact with latanoprost/ timolol eye drops.

How to use this medicine

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ to 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 take

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

How to use it

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

The preservative in the eye drops (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 the eye drops.

If using other eye drops in addition to latanoprost/timolol, 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 or 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

- Screw the inner cap back on the bottle
- 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 feeling persists, or is very uncomfortable, contact your doctor or pharmacist.

When to take it

Use the eye drops every day, at about the same time each day.

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 long to take it for

Continue using the eye drops for as long as your doctor tells you.

Although latanoprost/timolol eye drops help control your glaucoma, it does not cure it. It is important to keep using it until your doctor tells you to stop.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and administer your next dose at the usual time.

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

Do not administer a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you use too much (overdose)

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

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If latanoprost/timolol eye drops are accidentally swallowed or if you use too many drops, you may feel:

- light-headed or dizzy, faintness
- very slow pulse rate
- wheezing or difficulty in breathing
- headache, nausea, abdominal pain, fatigue
- hot flushes and sweating

While you are using this medicine

Things you must do

To make sure your medicine 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 latanoprost/timolol eye drops. Your doctor will decide whether you should continue using the eye drops.

Tell your doctor if you develop an eye infection, receive an eye injury, or have eye surgery.

Your doctor may tell you to use a new container of the eye drops because of possible contamination of the old one or may advise you to stop your treatment with latanoprost/timolol.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using this medicine.

Tell any other doctors and pharmacists who are treating you that you take this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

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

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

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

Things to be careful of

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

These eye drops generally do 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 the eye drops or that your vision is clear before driving a car or operating machinery.

Side effects

Tell your doctor and pharmacist as soon as possible if you do not feel well while using this medicine.

This medicine helps most people with glaucoma, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor if you notice any of the following:

- a slow change in eye colour over a period of time. The iris may become browner 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 eye lid(s)
- darkening, thickening, lengthening or increase in the number of 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 eye lids
- sensitivity to light
- 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
- stomach complaints, including nausea, vomiting, pain, diarrhoea
- loss of appetite
- dry mouth
- change to sense of taste
- cold hands or feet, numbness or tingling in the fingers or toes
- 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 or sexual dysfunction
- muscle or joint pain
- skin rash

Tell your doctor as soon as possible if you notice any of the following:

- fast irregular heartbeat
- dizziness and light headedness, which may be due to low blood pressure
- skin rash, itching
- swelling of hands, feet ankles or legs

The above list includes serious side effects that may need medical attention.

If you experience any of the following, stop using your medicine and contact your doctor immediately or go to Accident and Emergency at your nearest hospital:

- wheezing, difficulty in breathing (asthma or worsening asthma)
- shortness of breath; swelling of the face, lips, tongue, throat, which may cause difficulty in swallowing or breathe, or other parts of the body; rash, itching or hives on the skin (signs of an allergic reaction)
- very slow pulse, chest pain
- fainting
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash
- white deposits or plaque in the cornea causing the transparent front part of your eye to look white or cloudy.

The above list includes very serious side effects and you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

Storage and disposal

Storage

Keep your medicine in its bottle until it is time to take it.

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

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

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

Heat and dampness can destroy some medicines.

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

Keep this medicine where children cannot reach it.

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

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 taking this medicine or the expiry date has passed, ask your pharmacist what to do with the remaining solution.

Product description

What it looks like

Clear and colourless solution in a 5 mL plastic bottle with a dropper and screw cap. AUST R 304898.

When you first receive the eye drop 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

Each 1 mL of the eye drops contains 50 micrograms of latanoprost and 5 mg timolol (equivalent to 6.83 mg timolol maleate).

Each drop contains 1.5 micrograms of latanoprost and 150 micrograms of timolol.

The eye drops also contain the following:

- sodium chloride
- monobasic sodium phosphate dihydrate
- dibasic sodium phosphate dodecahydrate
- benzalkonium chloride (as a preservative)
- hydrochloric acid or sodium hydroxide (for pH adjustment)
- purified water

Sponsor

Arrotex Pharmaceuticals Pty Ltd
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