

APO- Latanoprost/ Timolol Eye Drops

Contains the active ingredients 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
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What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Latanoprost/Timolol eye drops. It contains the active ingredients latanoprost and timolol (as maleate).

It 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.

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.

There is no evidence that this medicine is addictive.

How it works

Latanoprost/timolol eye drops 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 latanoprost/timolol eye drops help control your glaucoma it does not cure it. So you must keep using it until your doctor tells you to stop.

Use in children

This medicine is not recommended for use in children. The safety and effectiveness of latanoprost and timolol in children has not been established.

Before you use this medicine

When you must not use it

Do not take this medicine if:

You have or have had any of the following:

- **Asthma, or a history of asthma, chronic obstructive lung disease (emphysema) or other breathing problems.**
- **Certain heart conditions, such as a very slow heart rate, or heart failure.**
- **You are hypersensitive to, or have had an allergic reaction to, latanoprost, timolol maleate or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to use it

Before you start using this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant as there is no adequate experience with this medicine in pregnant women.

3. You are currently breastfeeding or you plan to breast-feed.

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 medicine or stop breast-feeding while using it.

4. You are planning to have surgery.
5. You have or have had any medical conditions especially the following:
 - heart disease
 - lung disease
 - circulation problems
 - any other types of glaucoma or eye conditions
 - diabetes
 - myasthenia gravis
 - hyperthyroidism
6. You are taking or are planning to take any other medicines.

This includes vitamins and supplements that are available 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 such as beta-blockers, calcium channel blockers or digoxin
- certain medicines used to treat irregular heartbeats such as amiodarone and quinidine
- some medicines used to treat depression, such as phenelzine, fluoxetine or paroxetine
- some medicines used to treat Parkinson's disease, such as selegiline
- adrenaline, a hormone used in the treatment of asthma, slow or

irregular heartbeat, 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 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

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

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

How to use this medicine

Use latanoprost/timolol eye drops only when prescribed by a doctor.

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information 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 of latanoprost/timolol eye drops 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.

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.

When to take it

Use the eye drops 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 long to take it for

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

The eye drops help to control your condition but does not cure it.

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 take 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 take 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.

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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, you may feel faint, have a very slow pulse, or have wheezing or difficulty in breathing. Other effects include 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.

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 the eye drops because of possible contamination of the old one, or may advise you to stop your treatment with latanoprost/timolol.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine

- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- 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 when driving or operating machinery until you know how this medicine affects you.

Latanoprost/timolol 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.

Possible side effects

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

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

Sometimes they are serious but most of the time they are not.

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 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 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
- feeling sick (nausea) or vomiting, upset or painful stomach

- diarrhoea
- anorexia
- dry mouth
- change to sense of taste
- 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 or sexual dysfunction
- muscle/joint pain
- skin rash

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

These may be serious side effects and you may need medical attention:

- fast irregular heartbeat, 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.

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

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- wheezing, difficulty in breathing (asthma or worsening 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 nettlerash.

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

Allergic reactions

If you think you are having an allergic reaction to the eye drops, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging 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 window sill or in the car. Heat and dampness can destroy some medicines. Do not store the eye drops in pockets of your clothes.

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 it has passed its expiry date, ask your pharmacist what to do with the remaining solution.

Product description

What APO-Latanoprost/Timolol Eye Drops looks like

APO- Latanoprost/Timolol Eye Drops come in a 5 mL plastic bottle with a dropper and screw cap. The eye drop solution is clear and colourless.

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

The active ingredients in the eye drops are latanoprost and timolol maleate.

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 inactive ingredients:

- 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

Australian Registration Numbers

APO-Latanoprost/Timolol 0.05/5 eye drops (5 mL bottle): AUST R 304898

Sponsor

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