

APO-LATANOPROST/TIMOLOL 0.05/0.5 Eye Drops

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-LATANOPROST/TIMOLOL?

APO-LATANOPROST/TIMOLOL contains the active ingredient latanoprost and timolol maleate. APO-LATANOPROST/TIMOLOL eye drops are used to lower raised pressure in the eye and to treat glaucoma.

For more information, see Section [1. Why am I using APO-LATANOPROST/TIMOLOL?](#) in the full CMI.

2. What should I know before I use APO-LATANOPROST/TIMOLOL?

Do not use if you have ever had an allergic reaction to latanoprost, timolol maleate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-LATANOPROST/TIMOLOL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-LATANOPROST/TIMOLOL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-LATANOPROST/TIMOLOL?

- The usual dose is one drop into the affected eye or eyes, once daily.
- If you are wearing soft contact lenses, remove them before putting the drops in your eye.
- 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.

More instructions can be found in Section [4. How do I use APO-LATANOPROST/TIMOLOL?](#) in the full CMI.

5. What should I know while using APO-LATANOPROST/TIMOLOL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-LATANOPROST/TIMOLOL• To make sure your medicine is working properly, have your eye pressure checked regularly.• Tell your doctor if you develop an eye infection, receive an eye injury, or have eye surgery.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dosage.• Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how this medicine affects you.
Looking after your medicine	<ul style="list-style-type: none">• 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.

For more information, see Section [5. What should I know while using APO-LATANOPROST/TIMOLOL?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. Tell your doctor or pharmacist as soon as possible if you do not feel well whilst you are taking APO-LATANOPROST/TIMOLOL, even if you do not think it is connected to this medicine.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-LATANOPROST/TIMOLOL

Active ingredient(s): *Latanoprost and Timolol maleate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-LATANOPROST/TIMOLOL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-LATANOPROST/TIMOLOL.**

Where to find information in this leaflet:

- [1. Why am I using APO-LATANOPROST/TIMOLOL?](#)
- [2. What should I know before I use APO-LATANOPROST/TIMOLOL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-LATANOPROST/TIMOLOL?](#)
- [5. What should I know while using APO-LATANOPROST/TIMOLOL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-LATANOPROST/TIMOLOL?

APO-LATANOPROST/TIMOLOL contains the active ingredient **latanoprost and timolol maleate**. APO-LATANOPROST/TIMOLOL 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 APO-LATANOPROST/TIMOLOL helps control your glaucoma it does not cure it. So you must keep using it until your doctor tells you to stop.

2. What should I know before I use APO-LATANOPROST/TIMOLOL?

Warnings

Do not use APO-LATANOPROST/TIMOLOL if:

- You are allergic to latanoprost, timolol, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if you:

- Have any other medical conditions:
 - heart disease
 - lung disease
 - circulation problems
 - other types of glaucoma or eye conditions
 - diabetes
 - myasthenia gravis
 - hyperthyroidism
- Take any medicines for any other condition.
- Tell your doctor if you are planning to have surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

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.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with APO-LATANOPROST/TIMOLOL and affect how it works. 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-LATANOPROST/TIMOLOL.

4. How do I use APO-LATANOPROST/TIMOLOL?

How much to use

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

When to use APO-LATANOPROST/TIMOLOL

- 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 to use APO-LATANOPROST/TIMOLOL

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 feeling persists, or is very uncomfortable, contact your doctor or pharmacist.

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.

If you forget to use APO-LATANOPROST/TIMOLOL

APO-LATANOPROST/TIMOLOL should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much APO-LATANOPROST/TIMOLOL

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using APO-LATANOPROST/TIMOLOL?

Things you should 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.

Call 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.

Remind any doctor, dentist or pharmacist you visit that you are using APO-LATANOPROST/TIMOLOL.

Things you should not do

- Do not stop using this medicine suddenly. If you stop using the eye drops, your eye pressure may rise again and damage to your eyes may occur.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-LATANOPROST/TIMOLOL 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.

Looking after your medicine

- 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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink,
- in the car or on window sills or,
- Do not store the eye drops in pockets of your clothes.

Keep it where young children cannot reach it.

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • 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 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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. 	<p>Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-LATANOPROST/TIMOLOL contains

Active ingredient (main ingredient)	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.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• 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

Do not take this medicine if you are allergic to any of these ingredients.

What APO-LATANOPROST/TIMOLOL looks like

APO-LATANOPROST/TIMOLOL is 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.

Who distributes APO-LATANOPROST/TIMOLOL

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

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