

APO-Latanoprost

Contains the active ingredient latanoprost

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about latanoprost. 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. It contains the active ingredient latanoprost.

It is used to:

- lower raised pressure in the eye
- 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.

Latanoprost is used either alone or in combination with other eye

medicines to lower raised pressure within your eye.

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.

Use in children

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

Before you use this medicine

When you must not use it

Do not use this medicine if:

- **You have had an allergic reaction to latanoprost 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 use 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 have or have had any medical conditions, especially the following:
 - severe asthma
 - any other types of glaucoma
 - any other types of eye conditions
3. You are currently pregnant or you plan to become pregnant. Do not use this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breast-feeding or you plan to breast-feed. Do not use this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. 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.

Taking other medicines

Some medicines may interact with latanoprost. These include:

- eye drops which contain an ingredient called thiomersal. If using such eye drops as well as latanoprost, you should wait at least 5 minutes between using these eye drops and latanoprost.
- some other eye drops that contain a prostaglandin. The use of two or more prostaglandin eye drops at the same time is not recommended.

If you are using 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.

How to use this medicine

Use latanoprost only when prescribed by your 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 use

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

Use latanoprost every day, at about the same time each day, preferably in the evening, unless your doctor tells you otherwise.

How to use it

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

The preservative in latanoprost (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 latanoprost.

If using other eye drops in addition to latanoprost, 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. Unscrew the cap and break off from seal.
3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Tilt your head back and look up.
5. Place the tip of the bottle close to but not touching your eye.
6. 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 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.

When to use it

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 use it for

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

Latanoprost helps control your condition but does not cure it.

If you forget to use it

If it is almost time to put your next dose, skip the missed dose and use your next dose at the usual time. Otherwise put it as soon as you remember and then go back to taking your medicine as you would normally.

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

Do not double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints to help you remember.

If you use too much (overdose)

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

If you think that you or anyone else may have swallowed latanoprost, 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.

While you are using this medicine

Things you must do

To make sure latanoprost 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. Your doctor will decide whether you should continue using latanoprost.

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

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 breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists 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.
- Use your medicine to treat any other condition unless your doctor tells you to.
- Stop using your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

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

Latanoprost 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 with latanoprost 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 do not feel well while you are taking latanoprost or if you have any questions or concerns.

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 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
- irritation or feeling of having something in the eye. This may be worse during the first two or three days of using latanoprost
- eye pain
- redness, burning or watering of the eye/s
- discharge, itching of the eye/s, crusty eyelashes
- darkening, thickening, lengthening or an increase in the number of eye lashes and the fine hair on the eyelids
- misdirected eyelashes sometimes causing eye irritation

- darkening of the skin of the eyelids
- crusting, redness, thickening, itching or burning of the eyelids
- skin rash
- headache
- muscle/joint pain
- painful, urgent or frequent urination.

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.

- wheezing, difficulty in breathing (asthma or worsening of asthma)
- chest pain
- dizziness
- white deposits or plaque in the cornea causing the transparent front part of your eye to look white or cloudy.

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

Allergic reactions

If you think you are having an allergic reaction to latanoprost, do not use 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
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to use it.

If you use your medicine out of its original packaging it may not keep well.

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

After opening latanoprost, 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 latanoprost or any other medicine in the bathroom or near a sink. Do not leave in the car or on window sills. Do not carry the eye drops in pockets of your clothes.

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.

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 4 weeks.

Open a new bottle every 4 weeks.

Eye drops contain a preservative, which helps prevent germs from growing in the solution for the first 4 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, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Latanoprost looks like

Latanoprost eye drop is a clear colourless solution.

The eye drops come in a 5 mL plastic bottle with a dropper and screw cap, tamper proof twist off over seal.

When you first receive your latanoprost 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 contains 50 micrograms of latanoprost as the active ingredient. Each drop contains about 1.5 micrograms of latanoprost.

It also contains the following inactive ingredients:

- sodium chloride
- monobasic sodium phosphate dihydrate
- dibasic sodium phosphate dodecahydrate
- purified water
- benzalkonium chloride (as a preservative).

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Latanoprost
50 micrograms/mL eye drops
(Each 5 mL bottle contains 2.5 mL of solution): AUST R 200060.

Sponsor

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