

XALAPROST

Consumer Medicine Information (CMI) summary

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

1. Why am I using XALAPROST?

XALAPROST contains the active ingredient latanoprost. XALAPROST is used to lower raised pressure in the eye in patients with open-angle glaucoma or ocular hypertension. For more information, see Section [1. Why am I using XALAPROST?](#) in the full CMI.

2. What should I know before I use XALAPROST?

Do not use XALAPROST if you have ever had an allergic reaction to latanoprost or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other health problems, take any other medicines, are pregnant or breastfeeding, or plan to become pregnant or breastfeed.**

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

3. What if I am taking other medicines?

Some medicines may interfere with XALAPROST 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 XALAPROST?

- The usual dose of XALAPROST is one drop into the affected eye, or eyes, once daily. Use it until your doctor tells you to stop.
- If you are wearing soft contact lenses, remove them before putting the drops in your eye.
- While pulling down the lower eyelid and looking upwards with your head tilted back, gently squeeze the bottle to administer one drop. Release the eyelid and close your eye, without blinking or rubbing your eye. 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.

More instructions can be found in Section [4. How do I use XALAPROST?](#) in the full CMI.

5. What should I know while using XALAPROST?

Things you must do

- Tell your doctor, dentist or pharmacist you visit

	<p>that you are using XALAPROST.</p> <ul style="list-style-type: none"> • Get your eyes checked regularly, for monitoring of eye pressure and other changes. • Tell your doctor if you develop an eye infection, receive an injury, or have eye surgery.
Things you must not do	<ul style="list-style-type: none"> • Do not stop using XALAPROST without first talking to your doctor. • Do not use this medicine to treat any other complaints unless your doctor tells you to. • Do not give XALAPROST 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 XALAPROST affects you. XALAPROST generally does not cause any problems,

	but it may cause blurred vision in some people.
Looking after your medicine	<ul style="list-style-type: none">• Before opening: keep the bottle in its box and refrigerate (2°C – 8°C) protected from light.• After opening: keep the bottle in its box, store in a cool, dry place protected from light, below 25°C.• You do not need to keep it refrigerated. Discard four weeks after opening.

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

6. Are there any side effects?

Common side effects of XALAPROST include changes to the eye and the surrounding area (this mainly relates to irritation of the eye and eyelid), headache, muscle/joint pain, and painful/urgent or frequent urination. Serious side effects include breathing difficulties, chest pain, strong/rapid/irregular heartbeats, dizziness, nausea/vomiting, swelling of the face/lips/mouth/tongue/throat, or developing white/cloudy deposits in the front of your eye. 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

XALAPROST

Active ingredient: *latanoprost*

Consumer Medicine Information (CMI)

This leaflet provides important information about using XALAPROST. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using XALAPROST.**

Where to find information in this leaflet:

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

1. Why am I using XALAPROST?

XALAPROST contains the active ingredient latanoprost. XALAPROST belongs to a family of medicines called prostaglandin agonists.

XALAPROST is used to used to lower raised pressure in the eye in patients with open-angle glaucoma or ocular hypertension.

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 buildup 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 a 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.

XALAPROST is used either alone or in combination with other eye medicines to lower raised pressure within your eye.

Although XALAPROST helps control your glaucoma it does not cure it. You must keep using it until your doctor tells you to stop.

Ask your doctor if you have any questions about why XALAPROST has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use XALAPROST?

Warnings

Do not use XALAPROST if:

- you are allergic to latanoprost, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use XALAPROST.
Some of the symptoms of an allergic reaction may include:
 - skin rash, itching or hives;
 - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing;
 - asthma, wheezing or shortness of breath.
 - fainting.
- the bottle or packaging shows signs of tampering.
- the expiry date on the unopened bottle has passed.
- more than four weeks has passed since opening the bottle.

Check with your doctor if you:

- have any other health problems such as severe asthma, any other types of glaucoma or eye conditions such as macular oedema.
- take any medicines for anything else.

- have had any allergy to any other medicines or any other substances, such as food, preservatives, or dyes.

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?](#)

Pregnancy and breastfeeding

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

Your doctor will discuss the possible risks and benefits of using XALAPROST during pregnancy.

XALAPROST may affect your developing baby if you take it during pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the possible risks and benefits of using XALAPROST when breastfeeding.

Use in Children

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

XALAPROST is not addictive.

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 XALAPROST. This may affect how they work and/or cause more side effects. These include:

- eye drops which contain an ingredient called thiomersal.**

If using such eye drops as well as XALAPROST, you should wait at least 5 minutes between using these eye drops and XALAPROST.

- other eye drops that contain a prostaglandin.**

The use of 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 XALAPROST.

4. How do I use XALAPROST?

How much to use

- The usual dose of XALAPROST is one drop into the affected eye or eyes, once daily.**
- Follow the instructions provided and use XALAPROST until your doctor tells you to stop.**

When to use XALAPROST

- XALAPROST should be used every day, at about the same time each day, preferably in the evening, unless your doctor tells you otherwise.

Using it at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use it.

How to use XALAPROST

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

The preservative in XALAPROST (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 XALAPROST.

If using other eye drops in addition to XALAPROST, 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.

Instructions:

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.

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 long to use XALAPROST

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

XALAPROST helps control your condition but does not cure it.

If you forget to use XALAPROST

XALAPROST should be used regularly at the same time each day.

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

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

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

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

If you use too much XALAPROST

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 XALAPROST, urgent medical attention may be needed.

You must immediately:

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

Do this even if there are no signs of discomfort or poisoning.

5. What should I know while using XALAPROST?

Things you must do

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

Keep all of your doctor's appointments so that your progress can be checked

Call your doctor straight away 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 XALAPROST because of possible contamination of the old one or may advise you to stop your treatment with XALAPROST.

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

- become pregnant while using XALAPROST, tell your doctor immediately.

Tell your doctor, dentist or pharmacist you visit that you are using XALAPROST.

Things you must not do

- Do not stop using XALAPROST suddenly without first talking to your doctor.
If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.
- Do not give XALAPROST to anyone else, even if they have the same condition as you or their symptoms seem similar.
- Do not use this medicine to treat any other complaints 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 XALAPROST affects you.

XALAPROST eye drops, like other eye preparations, may cause transient blurred vision. Make sure you know how you react to XALAPROST or that your vision is clear before driving a car or operating machinery.

Looking after your medicine

Store the unopened bottle in its original container in a refrigerator (2°C to 8°C), protected from light. Do not freeze.

After opening, store the bottle in its box, protected from light and in a cool place where the temperature stays below 25°C. You do not need to keep it refrigerated.

Put the top back on the bottle as soon as you are finished using the drops, to avoid contamination of the eye drops.

Follow the instructions on the carton on how to take care of your medicine.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills, or
- in the pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep it where young children cannot see or reach it.

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

When to dispose of your medicine

- **Discard XALAPROST four weeks after opening.**

Throw out any remaining solution after four 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 eye drops may become contaminated and cause an eye infection.

- If you no longer need to use it
- After the expiry date (if unopened) or four weeks after opening.
- The tamper evident seal has been damaged when you receive it

Getting rid of any unwanted medicine

Take it to any pharmacy for safe disposal.

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• irritation or feeling of having something in the eye. This may be worse during the first two or three days of using XALAPROST.• 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	<p>Speak to your doctor if you have any of these less serious side effects.</p>

Less serious side effects	What to do
<p>of eye lashes and the fine hair on the eyelids</p> <ul style="list-style-type: none"> • misdirected eyelashes sometimes causing eye irritation • darkening of the skin of the eyelids • crusting, redness, thickening, itching or burning of the eyelids • sensitivity to light • skin rash • headache • muscle/joint pain • painful, urgent or frequent urination. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • wheezing, difficulty in breathing (asthma or worsening of asthma) • shortness of breath • chest pain • you notice strong, rapid or irregular heartbeats 	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> ● dizziness ● nausea and vomiting ● swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing ● white deposits or plaque in the cornea causing the transparent front part of your eye to look white or cloudy. 	

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

Some people may have side effects that are not listed here.

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

XALAPROST is only available with a doctor's prescription.

What XALAPROST contains

Active ingredient (main ingredient)	Latanoprost: 50 microgram/mL (Each drop contains about 1.5 micrograms of latanoprost)
Other ingredients (inactive ingredients)	benzalkonium chloride dibasic sodium phosphate hydrochloric acid monobasic sodium phosphate monohydrate sodium chloride sodium hydroxide water for injections
Potential allergens	benzalkonium chloride (as preservative)

Do not use XALAPROST if you are allergic to any of these ingredients.

What XALAPROST looks like

XALAPROST eye drops come in a plastic bottle with a dropper and screw cap inside a protective overcap. The drops are a clear, colourless solution (AUST R 217151).

XALAPROST is available in a 2.5 mL solution in a 5mL bottle

When you first receive your XALAPROST 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 XALAPROST

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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