

XALAPROST

Latanoprost

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about XALAPROST. 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 taking XALAPROST 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 need to read it again.

What XALAPROST is used for

XALAPROST 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.

XALAPROST belongs to a family of medicines called prostaglandin agonists.

It lowers the pressure in the eye by allowing more fluid to flow out from within your eye.

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

XALAPROST 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 XALAPROST has been prescribed for you.

Your doctor may have prescribed it for another reason.

XALAPROST is not addictive.

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

Before you use XALAPROST

When you must not use it

Do not use XALAPROST if you have an allergy to:

- any medicine containing latanoprost
- any of the ingredients listed at the end of this leaflet
- any other similar medicines

Some of the symptoms of an allergic reaction may include:

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

Do not use this medicine if you are pregnant.

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

Do not use 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 using 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 have or have had any of the following medical conditions:

- severe asthma
- any other types of glaucoma
- any other eye conditions.

Tell your doctor if you are pregnant or breast-feeding or plan to become pregnant or breast-feed.

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

Tell your doctor or 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 and XALAPROST may interfere with each other. 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
- some other eye drops that contain a prostaglandin. The use of two or more prostaglandin eye drops at the same time is not recommended.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use XALAPROST

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

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 XALAPROST 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 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.

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 use it

Use XALAPROST 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 long to use it

Continue using XALAPROST every day for as long as your doctor tells you.

XALAPROST helps to control your condition, but does not cure it.

If you forget to use it

If you miss a dose, skip the dose you missed and administer your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

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

If you use too much (overdose)

If you accidentally put several drops in your eye, immediately rinse your eye 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 the nearest hospital, if you think that you or anyone else may have swallowed XALAPROST. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are 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.

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 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, remind your doctor and pharmacist that you are taking XALAPROST.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

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

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

Things you must not do

Do not use XALAPROST 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.

Do not stop using your medicine or lower the dosage without checking with your doctor.

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

Things to be careful of

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

XALAPROST 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 to XALAPROST or that your vision is clear before driving a car or operating machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using XALAPROST.

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 or pharmacist 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 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 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
- sensitivity to light
- skin rash
- headache
- muscle/joint pain
- painful, urgent or frequent urination.

If any of the following happen, tell your doctor immediately or go to

Accident and Emergency at your nearest hospital:

- wheezing, difficulty in breathing (asthma or worsening of asthma)
- shortness of breath
- chest pain
- you notice strong, rapid or irregular heartbeats
- dizziness
- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

After using XALAPROST

Storage

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

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

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

Do not store XALAPROST or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Do not

carry the eye drops in pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep it 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 dispose of any remaining solution after four weeks.

Open a new bottle every 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 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 any medicine that is left over.

contains approximately 1.5 micrograms of latanoprost.

The eye drops also contain the following inactive ingredients:

- benzalkonium chloride
- dibasic sodium phosphate
- hydrochloric acid
- monobasic sodium phosphate monohydrate
- sodium chloride
- sodium hydroxide
- water for injections.

Sponsor

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Product description

What it 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.

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.

Ingredients

XALAPROST contains 50 micrograms per mL of latanoprost as the active ingredient. Each drop