

LATANOPROST ACTAVIS

Latanoprost Eye Drops Solution

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about LATANOPROST ACTAVIS.

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 this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT LATANOPROST ACTAVIS IS USED FOR

This medicine 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.

Latanoprost belongs to a group of medicines called prostaglandin agonists.

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

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

LATANOPROST ACTAVIS 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 it for another reason.

This medicine is not addictive.

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

LATANOPROST ACTAVIS is not recommended for use in children.

Safety and effectiveness in children has not been established.

BEFORE YOU USE LATANOPROST ACTAVIS

When you must not use it

Do not use this LATANOPROST ACTAVIS if you have an allergy to latanoprost, the active ingredient, or to any of the other ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

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

Do not use LATANOPROST ACTAVIS if the packaging is torn or shows signs of tampering or the expiry date on the pack has passed. If you use this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. **you have allergies to any other medicines, foods, preservatives or dyes.**
2. **you are pregnant or plan to become pregnant**
Your doctor can discuss with you the risks and benefits involved.
3. **you are breast feeding or plan to breast feed.**
Your doctor can discuss with you the risks and benefits involved.
4. **you have or have had any of the following medical conditions:**
 - severe asthma
 - any other types of glaucoma or eye conditions.

If you have not told your doctor about any of the above, tell him/her before you start using LATANOPROST ACTAVIS.

Taking other medicines

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

Some medicines and LATANOPROST ACTAVIS may interfere with each other. These include:

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

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

HOW TO USE LATANOPROST ACTAVIS

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, 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 LATANOPROST ACTAVIS is one drop into the affected eye, or eyes, once daily.

Use your medicine at about the same time each day preferably in the evening, 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 to use it

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

The preservative in LATANOPROST ACTAVIS (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 ACTAVIS.

If using other eye drops in addition to LATANOPROST ACTAVIS, 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, and 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.

How long to use LATANOPROST ACTAVIS

Continue using LATANOPROST ACTAVIS for as long as your doctor prescribes.

LATANOPROST ACTAVIS 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 take 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 double the amount to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you use too much (overdose)

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

If you think that you or anyone else may have taken too much LATANOPROST ACTAVIS immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE USING LATANOPROST ACTAVIS

Things you must do

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

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

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using LATANOPROST ACTAVIS.

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

Things you must not do

Do not use LATANOPROST ACTAVIS to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine without checking with your doctor.

If you stop using your eye drops, your eye pressures 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 LATANOPROST ACTAVIS affects you.

LATANOPROST ACTAVIS 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 LATANOPROST ACTAVIS 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 have any problems while taking LATANOPROST ACTAVIS, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, LATANOPROST ACTAVIS can have some 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.

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 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 ACTAVIS.
- 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 any of the following happen stop using LATANOPROST ACTAVIS and 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
- dizziness
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

These are rare but serious side effects that may require urgent medical attention.

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

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

AFTER USING LATANOPROST ACTAVIS

Storage

Keep your medicine in the original container.

Keep your eye drops in a safe place away from the sight and reach of children.

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

Before opening LATANOPROST ACTAVIS, keep your medicine in its box in a refrigerator (2°C- 8°C) protected from light.

After opening LATANOPROST ACTAVIS, keep your medicine 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 ACTAVIS 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.

Put the top back on the bottle right away after use to avoid contaminating the eye drops.

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

PRODUCT DESCRIPTION

What it looks like

Your LATANOPROST ACTAVIS eye drops come in a plastic bottle with a dropper and screw cap inside a protective overcap. Remove the overcap before use.

When you first receive your LATANOPROST ACTAVIS bottle, it will appear half full. This corresponds to 2.5mL of eye drop solution, giving a minimum of 80 drops. This volume is enough to last 4 weeks if used in both eyes.

Ingredients

Active ingredients:

- LATANOPROST ACTAVIS "50 micrograms/mL" - "50" micrograms latanoprost

Each drop contains about 1.5 micrograms of latanoprost.

Inactive ingredients:

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

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

LATANOPROST ACTAVIS is supplied in Australia by:

Actavis Pty Ltd
117 Harrington Street
The Rocks, Sydney
NSW 2000
Australia

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50 microgram/mL Eye Drops: AUST R 200059