

LATANOPROST / TIMOLOL SANDOZ®

Latanoprost/Timolol maleate Eye Drops

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Latanoprost/Timolol Sandoz Eye drops. 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 Latanoprost/Timolol Sandoz Eye drops 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/Timolol Sandoz Eye drops is used for

This medicine is used to treat 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.

It contains two active ingredients, latanoprost and timolol maleate. Latanoprost belongs to a group of medicines called prostaglandin agonists. Latanoprost works by allowing more fluid to flow out from within your eye(s).

Timolol maleate belongs to a family of medicines called beta blockers. Timolol maleate lowers the pressure in the eye by reducing the production of fluid.

Latanoprost/ Timolol Sandoz Eye Drops will help your glaucoma but will 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 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/Timolol Sandoz Eye drops is not recommended for use in children.

Safety and effectiveness in children has not been established.

Before you use Latanoprost/Timolol Sandoz Eye drops

When you must not use it

Do not use this medicine if you have an allergy to:

- Latanoprost or timolol maleate, the active ingredients, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines.

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 this medicine if you have or have had any of the following medical conditions:

- you have asthma, or a history of asthma, chronic obstructive lung disease (emphysema) or other breathing problems
- you have certain heart conditions, such as a very slow

heart rate, an irregular heartbeat, or heart failure.

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:

- heart disease
- lung disease
- any other types of glaucoma or eye conditions
- diabetes
- myasthenia gravis - a muscle disease in which the muscles become weak and tire easily
- hyperthyroidism - an underactive thyroid gland, causing a decrease in metabolism
- circulation problems.

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

There is no adequate experience with Latanoprost/ Timolol Eye drops in pregnant women, therefore it should not be used during pregnancy. Your doctor can discuss with you the risks and benefits involved

Tell your doctor if you are breast-feeding or intend to breast feed.

One of the active ingredients in Latanoprost/ Timolol Eye drops has been detected in breast milk. Because of the potential harm to the infant, nursing women should either stop using it or stop breast-feeding while using it.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell him/her before you start using Latanoprost/Timolol Sandoz Eye drops.

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 Latanoprost/Timolol Sandoz Eye drops may interfere with each other. These include:

- certain medicines used to treat high blood pressure or heart conditions such as beta-blockers, calcium channel blockers, clonidine or digoxin
- certain medicines used to treat irregular heartbeats such as amiodarone and quinidine
- some medicines used to treat depression, such as monoamine oxidase inhibitors (MAOIs), phenelzine, fluoxetine or paroxetine
- some medicines used to treat Parkinson's disease, such as selegiline
- adrenaline, a hormone used in the treatment of asthma, slow or irregular heartbeat, acute allergic disorders and glaucoma
- some medicines that may have been prescribed to help you pass urine or restore normal bowel movements
- narcotics such as morphine used to treat moderate to severe pain
- eye drops which contain an ingredient called thiomersal. If using such eye drops as well as Latanoprost/Timolol Sandoz Eye drops, you should wait at least 5 minutes between using these eye drops and Latanoprost/Timolol Sandoz 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.

These medicines may be affected by Latanoprost/Timolol Sandoz Eye drops 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 using this medicine.

How to use Latanoprost/Timolol Sandoz Eye drops

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/Timolol Sandoz Eye drops is one drop into the affected eye, or eyes, once daily.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to use.

Follow the instructions they give you.

If you use the wrong dose, Latanoprost/Timolol Sandoz Eye

drops may not work as well and your problem may not improve.

How to use it

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

The preservative in Latanoprost/Timolol Sandoz 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 Latanoprost/Timolol Sandoz Eye drops.

If using other eye drops in addition to Latanoprost/Timolol Sandoz Eye drops, 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.

When to use

Latanoprost/Timolol Sandoz Eye drops

Use your medicine at about the same time each day, 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 long to use

Latanoprost/Timolol Sandoz Eye drops

Continue using your medicine for as long as your doctor tells you.

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

If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

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 use a double dose to make up for the dose that you missed.

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

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(s), immediately rinse your eye(s) in warm water.

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to the Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much

Latanoprost/Timolol Sandoz Eye drops. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

The accidental swallowing of Latanoprost/Timolol Sandoz Eye drops or the use of too many drops may cause lightheadness or dizziness, you may faint, have a very slow pulse rate or may induce wheezing or difficult breathing. You also feel headache, nausea, abdominal pain, fatigue, hot flushes and sweating.

While you are using Latanoprost/Timolol Sandoz Eye drops

Things you must do

To make sure Latanoprost/Timolol Sandoz Eye drops 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 Sandoz Eye drops. Your doctor will decide whether you should continue using Latanoprost/Timolol Sandoz Eye drops.

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/Timolol Sandoz Eye drops because of possible contamination of the old one, or may advise you to stop your treatment with Latanoprost/Timolol Sandoz Eye drops.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Latanoprost/Timolol Sandoz Eye drops.

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.

Things you must not do

Do not use Latanoprost/Timolol Sandoz Eye drops 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/Timolol Sandoz Eye drops affects you.

Latanoprost/Timolol Sandoz Eye drops 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/Timolol Sandoz Eye drops 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 Latanoprost/Timolol Sandoz Eye drops.

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 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
- allergic reactions including redness, swelling and/or itching of the eye
- burning or 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, crusty eyelashes or watering of the eye/s
- drooping of eyelid/s
- darkening, thickening, lengthening or an increase in the number of eye 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 of the eyelids
- 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
- hallucinations, confusion, disorientation or memory loss
- feeling sick (nausea) or vomiting, upset or painful stomach, diarrhoea
- anorexia
- dry mouth
- change to your sense of taste
- cold hands or feet
- numbness, tingling and colour change (white, blue then red) in fingers when exposed to the 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/joint pain
- skin rash.

These are mild side effects of the medicine and are short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- fast or irregular heartbeat, also called palpitations
- dizziness and light-headedness, which may be due to low blood pressure
- skin rash, itching
- swelling of hands, feet, ankles or legs.

The above list includes serious side effects that may require urgent medical attention. Serious side effects are rare.

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
- very slow pulse, chest pain
- fainting
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettlerash
- 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 else that is making you feel unwell.

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

After using Latanoprost/Timolol Sandoz Eye drops

Storage

Keep your medicine in the original container.

Before opening

Latanoprost/Timolol Sandoz Eye drops, keep your medicine in its box in a refrigerator (2°C - 8°C) protected from light.

After opening Latanoprost/Timolol Sandoz Eye drops, 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/Timolol Sandoz Eye drops 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.

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 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 using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Latanoprost/Timolol Sandoz 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/Timolol Sandoz Eye drops 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:

- Each 1mL of Latanoprost/Timolol Sandoz Eye drops contains 50

micrograms of latanoprost and 5 mg of timolol (equivalent to 6.83mg timolol maleate)

- Each drop contains about 1.5 micrograms of latanoprost and 150 micrograms of timolol.

Inactive ingredients:

- sodium chloride
- dibasic anhydrous sodium phosphate
- monobasic dihydrate sodium phosphate
- water for injections
- benzalkonium chloride (as a preservative).

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

Supplier

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