

LATANOPROST SANDOZ®

Latanoprost Eye Drops Solution

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Latanoprost Sandoz.

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 SANDOZ 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.

How Latanoprost Sandoz works

It contains the active ingredient latanoprost. Latanoprost belongs to a group of medicines called prostaglandin agonists.

It works by lowering the pressure in the eye by allowing more fluid to flow out from 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.

Use in Children

Latanoprost Sandoz is not recommended for use in children.

Safety and effectiveness in children has not been established.

BEFORE YOU USE LATANOPROST SANDOZ

When you must not use it

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

- latanoprost, the active ingredient, 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:

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

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 taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant:

Your doctor can discuss the possible risks and benefits of using Latanoprost Sandoz during pregnancy.

Tell your doctor if you are breastfeeding or intend to breast-feed:

Your doctor can discuss the possible risks and benefits of using Latanoprost Sandoz when breastfeeding.

Tell your doctor if you have or have had any medical conditions such as severe asthma, or 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 Sandoz.

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 Sandoz may interfere with each other. These include:

- eye drops which contain an ingredient called thiomersal. If using such eye drops as well as Latanoprost Sandoz, you should wait at least 5 minutes between using these eye drops and Latanoprost Sandoz.
- 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 Latanoprost Sandoz 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 SANDOZ

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 Sandoz 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.

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

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Latanoprost Sandoz 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.

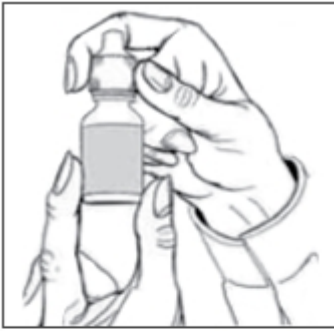
The preservative in Latanoprost Sandoz (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used Latanoprost Sandoz.

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 for use

The DROP-TAINER® bottle is designed to assure the delivery of a precise dose of medication. Before using your DROP-TAINER® bottle, read the complete instructions carefully.



How long to use Latanoprost Sandoz

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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

If you have trouble remembering to take 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 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 Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Latanoprost Sandoz. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE USING LATANOPROST SANDOZ

Things you must do

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

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

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

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

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

1. If you use other topically applied ophthalmic medications, they should be administered at least 10 minutes before or after Latanoprost Sandoz
2. Wash your hands well with soap and water.
3. Before using the medication for the first time. Be sure the safety Seal on the bottle is unbroken.
4. Tear off the Safety Seal to break the seal.
5. Before each use, shake once and remove the screw cap.
6. Invert the bottle and hold the bottle between your thumb and middle finger, with the tips of the fingers pointing towards you.

7. Tilt your head back and position the bottle above the affected eye.
8. With the opposite hand, place a finger under the eye. Gently pull down until a "V" pocket is made between your eye and lower lid. Do not touch the eye with the tip of the dropper.
9. With the hand holding the bottle, place your index finger on the bottom of the bottle. Push the bottom of the bottle to dispense one drop of medication. Do not squeeze the sides of the bottle. Keep your head tilted backward and close your eye to allow absorption of the medication into the eye.
10. Repeat steps 6 to 9 with other eye if instructed to do so.
11. Replace screw cap by turning until firmly touching the bottle.

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 take Latanoprost Sandoz

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.

Things you must not do

Do not use Latanoprost Sandoz 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 Sandoz affects you.

Latanoprost Sandoz 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 Sandoz 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 taking Latanoprost Sandoz.

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
- irritation or feeling of having something in the eye. This may be worse during the first two or three days of using Latanoprost Sandoz.
- eye pain
- dry eye
- 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 serious side effects that may require urgent medical attention. Serious side effects are 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 SANDOZ

Storage

Keep your medicine in the original container.

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

After opening Latanoprost Sandoz, 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 Sandoz 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

Your Latanoprost 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 Sandoz bottle, it will appear half full. This

corresponds to 2.5mL of clear colourless 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 Sandoz 50 micrograms/mL - 50 micrograms latanoprost

Each drop contains about 1.5 micrograms of latanoprost.

Inactive ingredients:

- sodium chloride
- monobasic sodium phosphate monohydrate
- dibasic 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

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Tel: 1800 726 369

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Australian Register Number(s)

50 microgram/mL Eye Drops: AUST R 290733