

Bimatoprost Sandoz®

bimatoprost 300 microgram/mL Eye Drops Solution Bottle

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Bimatoprost 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 taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT BIMATOPROST SANDOZ 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. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. 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.

Bimatoprost Sandoz eye drops lower the pressure in the eye by helping the flow of fluid out of the eye chamber.

Bimatoprost Sandoz eye drops can be used alone or together with other eyedrops/medicines to lower raised pressure within your eyes.

Although Bimatoprost Sandoz eye drops help control your condition, they will not cure it.

Bimatoprost Sandoz eye drops are only available with a doctor's prescription from pharmacies.

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.

BEFORE YOU USE BIMATOPROST SANDOZ

When you must not use it

Do not take this medicine if you have an allergy to bimatoprost, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description

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

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.

The preservative in Bimatoprost 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 Bimatoprost Sandoz eye drops.

It is not known if Bimatoprost Sandoz eye drops are safe and useful for children and adolescents under 18 years.

These drops are for topical use only.

Do not take 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 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:

- breathing problems
- liver or kidney problems
- low blood pressure or heart rate
- a disease causing swelling of the back of the eye
- an inflammatory eye condition
- a history of viral infections in the eye
- dry eye or damaged cornea

Tell your doctor if you are pregnant or plan to become pregnant and you are breastfeeding or intend to breast-feed.

Like most medicines, Bimatoprost Sandoz eye drops should not be used during pregnancy, unless clearly necessary.

Before you start using Bimatoprost Sandoz eye drops your doctor should tell you that some changes to your eyes may occur which may be permanent.

During treatment, Bimatoprost Sandoz may cause a loss of fat around the eye, which may cause your eyelid crease to deepen, your eye to appear sunken, your upper eyelid to droop, the skin around your eye to tighten and the lower white part of your eye to become more visible. The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking Bimatoprost Sandoz.

Eyelashes may grow longer and thicker, and eyelashes, the skin around the eye and the coloured part of the eye may become darker. If only one eye is being treated the cosmetic differences between the eyes may be noticeable. None of these changes affect vision. If you have any concerns, ask your doctor or pharmacist.

Hair may grow where Bimatoprost Sandoz contacts the skin. It is important to use as directed.

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.

It is not expected that Bimatoprost Sandoz will interact with other medicines, however you should always ask your optical practitioner, doctor or pharmacist if you have any concerns about using Bimatoprost Sandoz eye drops as well as other medications.

There is a potential for the eye pressure effect to be reduced if using other glaucoma eye drops of the same type as Bimatoprost Sandoz.

HOW TO USE BIMATOPROST SANDOZ

How much to use

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.

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

They will tell you exactly how many drops you need to use each day.

The usual dose of Bimatoprost Sandoz eye drops is one drop in the affected eye(s) once daily, given in the evening.

Use Bimatoprost Sandoz eye drops every day, 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.

If you are using more than one eye drop product, wait 5 minutes before using the second product.

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 to use it

You may find it easier to put drops in your eye while you are sitting or lying down.

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

- Wash your hands well with soap and water.
- Remove the lid/cap.
- Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
- Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
- Tilt your head back and look up.
- Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
- Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
- Close your eye. Do not blink or rub 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. 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.

- Replace the lid/cap, sealing it tightly.
- Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.

How long to use it

Continue taking 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 using your medicine every day.

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 take 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 take 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) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of Bimatoprost Sandoz eye drops, 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. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING BIMATOPROST SANDOZ

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure Bimatoprost Sandoz eye drops are working.

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 Bimatoprost Sandoz eye drops because of possible contamination of the old one.

If you become pregnant while using Bimatoprost Sandoz eye drops tell your doctor immediately.

If you wear soft contact lenses, remove them before using Bimatoprost Sandoz eye drops. Leave your lenses out for at least 15 minutes after putting in the eye drops.

Tell your doctor if your condition gets worse or does not get better while using Bimatoprost Sandoz eye drops.

If you are about to start any new medicine tell your doctor and pharmacist that you are using Bimatoprost Sandoz eye drops.

Things you must not do

Do not use Bimatoprost 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 Bimatoprost Sandoz eye drops without first talking to 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

Your vision may blur for a short time after you put in your Bimatoprost Sandoz eye drops. If this happens you should wait until you can see well again before you drive or use machinery.

Bimatoprost Sandoz eye drops are not expected to cause any problems with your ability to drive a car or operate machinery. However, as a general precaution be careful driving or operating machinery until you know how Bimatoprost Sandoz eye drops affect you.

SIDE EFFECTS

Tell your doctor optical practitioner, or pharmacist as soon as possible if you do not feel well while you are taking Bimatoprost Sandoz.

Check with your doctor as soon as possible if you have any problems while taking Bimatoprost Sandoz, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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 if you notice any of the following and they worry you:

- red, congested eyes
- growth of eyelashes
- itching or irritation of eye/s

More often the following effects have been seen:

- loss of fat in the eye region which can lead to deepening of your eyelid crease, sunken eye, drooping eyelid, tightening of the skin around your eye, and the lower white part of your eye to become more visible.

Less often the following effects have been seen:

Other eye-related effects such as discharge from the eye, eye discomfort, eye itchiness, redness in or around the eye, increased tears and inflamed areas around eye/s, small lesions or erosions on the eye surface, allergic effects on eye and surrounding eyelid, deepened eyelids, pain in the eye, feeling of something in the eye, burning of eye and nearby eyelid, dryness, irritation, sensitivity to light, an increase in colouring or pigment of area around eye, blurred vision, visual changes, eyelash darkening, darkening of the coloured part of the eye, swelling of the back of the eye.

Rarely:

Other eye related problems can occur such as spasm of the eye where there is uncontrolled blinking and squeezing of eyelid, swelling of eyelid, inflammation of the coloured part of eye, bleeding in eye chamber, eyelid retraction, deepened eyelid sulcus (sockets sunken), precipitation of calcium salts on corneal surface.

There can also be effects on the body as a whole such as headache, weakness, and very rarely dizziness, hypersensitivity, depression, infection, nausea, high blood pressure, skin pigmentation, asthma, exacerbation of asthma,

shortness of breath and abnormal hair growth.

AFTER USING BIMATOPROST SANDOZ

Storage

Keep your medicine in a cool dry place where the temperature stays below 25 °C.

Do not store Bimatoprost 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.

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.

Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops.

Disposal

Throw out any remaining solution after four weeks from the date of opening.

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. A new bottle should be opened.

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.

PRODUCT DESCRIPTION

What Bimatoprost Sandoz eye drops look like

Clear, colourless, sterile solution.

Ingredients

Active ingredient:

- Bimatoprost 300 µg/ml

Inactive ingredients:

- benzalkonium chloride (Preservative)
- dibasic sodium phosphate heptahydrate
- citric acid monohydrate
- sodium chloride
- purified water
- hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

Supplier

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