

Vizo-PF Bimatotim 0.3/5

Bimatoprost 300 microgram/m and timolol (as maleate) 5 mg/mL

Eye drops

What is in this leaflet

Please read this leaflet carefully before you start using Vizo-PF Bimatotim 0.3/5 eye drops.

This leaflet answers some common questions about Vizo-PF Bimatotim 0.3/5 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 using Vizo-PF Bimatotim 0.3/5 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 Vizo-PF Bimatotim 0.3/5 are used for

Vizo-PF Bimatotim 0.3/5 eye drops are used to lower raised pressure in the eye and to treat glaucoma for patients who might be sensitive to preservative-containing formulations or for whom the use of a preservative free formulation is otherwise advisable.

Vizo-PF Bimatotim 0.3/5 contains the active ingredients bimatoprost and timolol maleate. Vizo-PF Bimatotim 0.3/5 is a preservative-free antiglaucoma medicine used to alleviate symptoms of a disease in which damage to the optic nerve is caused.

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. Also, some people with glaucoma may have normal eye pressure. Glaucoma is usually caused by a buildup 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.

Although Vizo-PF Bimatotim 0.3/5 help control your glaucoma, it will not cure it.

For more information about glaucoma, contact Glaucoma Australia Inc (telephone 1800 500 880 or Glaucoma New Zealand (on 09 373 8779).

Vizo-PF Bimatotim 0.3/5 contains two active ingredients, bimatoprost and timolol maleate. Their combined effect results in effective treatment of glaucoma.

Bimatoprost belongs to a family of medicines called prostamide analogues which increases the outflow of fluid.

Timolol maleate belongs to a family of medicines called beta-blockers and is suspected to reduce the formation of fluid.

Your doctor may have prescribed Vizo-PF Bimatotim 0.3/5 for another reason.

Ask your doctor if you have any questions about why Vizo-PF Bimatotim 0.3/5 have been prescribed for you.

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

Vizo-PF Bimatotim 0.3/5 are not addictive.

Before you use Vizo-PF Bimatotim 0.3/5

When you must not use it

Do not use Vizo-PF Bimatotim 0.3/5 if:

- the product does not look quite right such as discoloured.
- the packaging shows signs of tampering.
- the expiry date on the bottle has passed.

Always check the ingredients to make sure you can use this medicine.

If you are not sure whether you should start using Vizo-PF Bimatotim 0.3/5, talk to your doctor.

It is not known if Vizo-PF Bimatotim 0.3/5 are safe and useful for children and adolescents under 18 years and therefore its use is not recommended.

Before you start to use it

Tell your doctor if:

- you have any other medical conditions such as:
 - eye problems (inflammation of the eye, trauma, surgery or infection of the eye, swelling of the retina within the eye, separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye, you received surgery to reduce the pressure in the eye)
 - heart problems (such as coronary heart disease, heart failure or low blood pressure), heart rate disturbances (such as slow or irregular heartbeats) or low blood pressure
 - poor blood circulation problems (such as Raynaud's syndrome)
 - lung or breathing problems (such as asthma or chronic obstructive lung disease)
 - diabetes mellitus (blood sugar problems)
 - thyroid disease
 - kidney disease
 - liver disease
 - muscle weakness (a disease called myasthenia gravis)
- take any medicines for any other condition
- have had an allergy to any medicines or any other substances (including silver), such as foods, preservatives or dyes
- are going to have an operation and you are using Vizo-PF Bimatotim 0.3/5, as it may change the effects of some medicines during anaesthesia.

If you have not told your doctor about any of the above, tell them before you start using Vizo-PF Bimatotim 0.3/5.

Pregnancy and breastfeeding:

- Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of using Vizo-PF Bimatotim 0.3/5 during pregnancy and a decision can be made if you should

or should not use it.

- Talk to your doctor if you are breastfeeding or intend to breastfeed. Do not use Vizo-PF Bimatotim 0.3/5 if you are breastfeeding or intend to breastfeed.
- Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

Allergy to silver:

- Vizo-PF Bimatotim 0.3/5 may contain traces of silver. Therefore, if you are allergic to silver, you may be allergic to Vizo-PF Bimatotim 0.3/5. Check with your doctor or pharmacist if you are not sure whether you are allergic to silver.

Beta-blocker eye drops:

- Tell your doctor if you are already using another beta-blocker eye drop. It is not recommended to use two beta-blocker eye drops at the same time.

Contact lens users:

- If you wear soft contact lenses, these should be removed before using Vizo-PF Bimatotim 0.3/5.
- Wait at least 15 minutes after instilling Vizo-PF Bimatotim 0.3/5 before you reinsert the contact lenses.

Growing eyelashes:

- Before you start using Vizo-PF Bimatotim 0.3/5 your doctor should tell you that some changes to your eyes may occur which may be permanent:
 - eyelashes may grow longer and thicker
 - eyelashes, the skin around the eye and the coloured part of the eye may become darker
 - hair may grow where Vizo-PF Bimatotim 0.3/5 eye drops contact the skin
- If only one eye is being treated the cosmetic differences between the eyes may be noticeable
- It is important to use as directed
- None of these changes affect vision. If you have any concerns, ask your doctor or pharmacist.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are using Vizo-PF Bimatotim 0.3/5.

Some medicines may interfere with Vizo-PF Bimatotim 0.3/5. These include:

- medicines for high blood pressure
- antidiabetic agents
- some medicines prescribed for heart problems/conditions (e.g. digitalis glycosides, anti-arrhythmics and quinidine)
- any medicines used to increase the size of blood vessels (e.g. guanethidine)
- medicines to treat depression.

These medicines may be affected by Vizo-PF Bimatotim 0.3/5, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Vizo-PF Bimatotim 0.3/5.

How to use Vizo-PF Bimatotim 0.3/5

How much to use

- Use Vizo-PF Bimatotim 0.3/5 only when prescribed by your doctor. Your doctor will tell you how many drops you need to use each day. Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.
- The usual dose for adults is one drop of Vizo-PF Bimatotim 0.3/5 in the affected eye(s) once daily, either in the morning or in the evening.
- Follow the instructions provided and use Vizo-PF Bimatotim 0.3/5 until your doctor tells you to stop; they may differ from the information contained in this leaflet.
- Vizo-PF Bimatotim 0.3/5 helps control your condition but does not cure it. Therefore, Vizo-PF Bimatotim 0.3/5 must be used every day. Continue using Vizo-PF Bimatotim 0.3/5 for as long as your doctor prescribes.

Use Vizo-PF Bimatotim 0.3/5 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.

These drops are for topical use only.

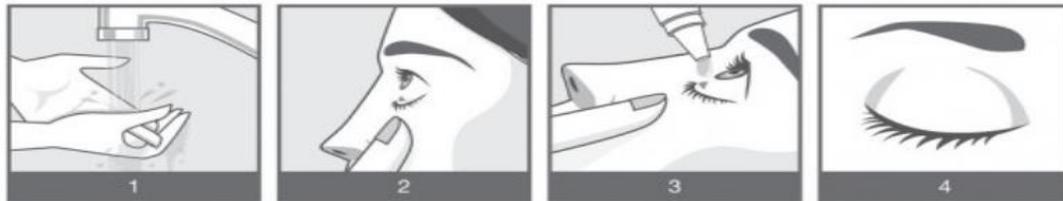
When to use it

- Vizo-PF Bimatotim 0.3/5 should be used 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 – 10 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.



1. Wash your hands well with soap and water.
2. 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.
3. 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.
4. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
5. 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.
6. Replace the lid/cap, sealing it tightly.
7. Wash your hands again with soap and water to remove any residue.

If a drop misses your eye, try again. Wipe off any excess that runs down the cheek.

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.

If you forget to use it

Vizo-PF Bimatotim 0.3/5 should be used regularly at the same time each day. If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

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.

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

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 you missed.

While you are using Vizo-PF Bimatotim 0.3/5

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure Vizo-PF Bimatotim 0.3/5 are working.

Call your doctor straight away if you:

- develop an eye infection, receive an eye injury, or have eye surgery
- become pregnant; your doctor may advise you to stop your treatment with Vizo-PF Bimatotim 0.3/5 if you become pregnant while using Vizo-PF Bimatotim 0.3/5.

If you wear soft contact lenses, remove them before using Vizo-PF Bimatotim 0.3/5. 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 Vizo-PF Bimatotim 0.3/5.

Remind any doctor, dentist or pharmacist, eye specialist or optometrist you visit that you are using Vizo-PF Bimatotim 0.3/5.

Things you must not do

- Do not give Vizo-PF Bimatotim 0.3/5 to anyone else, even if they have the same condition as you.
- Do not stop using Vizo-PF Bimatotim 0.3/5 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

- **Contamination of your eye drops:**
 - Vizo-PF Bimatotim 0.3/5 does not contain any preservatives. Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.
- **Driving or using machines:**
 - Be careful before your drive or use any machines or tools until you know how Vizo-PF Bimatotim 0.3/5 affects you.
 - Vizo-PF Bimatotim 0.3/5 are not expected to cause any problems with your ability to drive a car or operate machinery. However, Vizo-PF Bimatotim 0.3/5 may cause blurred vision, dizziness, drowsiness or tiredness in some people. Make sure you know how you react to Vizo-PF Bimatotim 0.3/5 or that your vision is clear before driving or operating machinery.
- **Alcohol** is not expected to have any effect on the use of Vizo-PF Bimatotim 0.3/5.

In case of overdose

If you use too much (overdose)

If you accidentally put several drops of Vizo-PF Bimatotim 0.3/5 in your eye, immediately rinse your eye(s) with warm water.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else:

- may have used too much Vizo-PF Bimatotim 0.3/5, or
- may have swallowed any or all of the contents of Vizo-PF Bimatotim 0.3/5.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your optical practitioner, doctor or pharmacist as soon as possible if you do not feel well while you are using Vizo-PF Bimatotim 0.3/5.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your optical practitioner, 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 eye(s)
- itching/irritation of the eye(s)
- eye dryness
- watery eye(s)
- small lesions/erosions on the eye surface(s)
- feeling of a foreign object in the eye(s)
- excessive sensitivity to bright light
- eye pain
- swelling of the eye(s)
- discomfort in the eye(s)
- red, swollen eyelid(s)
- growth of eyelashes
- darkening of the skin around the eye(s)
- eye allergy
- shortness of breath, wheezing
- slow heartbeat
- high blood pressure
- allergic skin reactions (rash, itching, hives)
- increase in the colouring or pigment in the skin around the eye(s)
- headache.

Additional side effects have been seen in patients using **bimatoprost/timolol** multidose formulation with preservatives and so may possibly be seen with Vizo-PF Bimatotim 0.3/5:

- superficial damage to the front part of the eye(s)
- burning and stinging in the eye(s)
- discharge from the eye(s)
- visual changes
- itchy eyelid(s)
- darkening of the skin around the eye(s)
- eye(s) appear sunken
- swelling of the central retina (light-sensitive layer of the eye)

Speak to your doctor if you have any of these less serious side effects and they worry you.

Additional side effects not listed above have been seen in patients using eye drops containing **timolol** and so may possibly be seen with Vizo-PF Bimatotim 0.3/5.

Serious side effects include:

- severe allergic reactions with swelling and difficulty breathing, which could be life-threatening
- low blood sugar
- anxiety
- confusion
- hallucinations
- difficulty sleeping
- nightmares
- depression
- memory loss
- fainting
- stroke
- decreased blood flow to the brain
- worsening of myasthenia gravis (increased muscle weakness)
- tingling sensation
- heart failure
- irregularity or stopping of the heartbeat
- slowing of heart rate
- too much fluid, mainly water, accumulating in the body
- chest pain.

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Less serious side effects include:

- decreased sensation of the front part of the eye(s)
- double vision
- drooping eyelid(s)
- separation of one of the layers within the eyeball(s) after surgery to reduce the pressure in the eye(s)
- irritation and inflammation of the surface of the eye(s)
- low blood pressure
- swelling or coldness of your hands and feet, caused by constriction of your blood vessels
- pain, discomfort or tiredness in the legs that occurs during walking
- difficulty breathing
- cough
- nasal congestion

- diarrhoea
- stomach pain
- nausea
- vomiting
- feeling and being sick
- changes in your taste sensation
- indigestion
- dry mouth
- red scaly patches on skin
- skin rash
- hair loss
- muscle pain
- reduced sexual urge
- sexual dysfunction
- tiredness
- ringing in the ears.

Speak to your doctor if you have any of these less serious side effects and they worry you.

Additional side effects not listed above have been seen in patients using eye drops containing **bimatoprost** and may possibly be seen with Vizo-PF Bimatotim 0.3/5.

Less serious side effects include:

- allergic reaction in the eye(s)
- inflammation within the eye(s)
- blurred, or decrease in sharpness of vision
- bleeding in the back of the eye(s) (retinal bleeding)
- uncomfortable and tired eye(s)
- inflammation of the coloured part of the eye(s)
- eyelid(s) swelling
- red, itchy eyelid(s)
- twitching eyelid(s)
- eyelid has moved away from the surface of the eye(s)
- redness of the skin around the eye(s)
- darkening of eyelashes
- misdirected upper or lower eyelashes that turn inward towards the eye(s)
- high blood pressure

- feeling weak
- infection from colds
- nausea.

Speak to your doctor if you have any of these less serious side effects and they worry you.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

After using Vizo-PF Bimatotim 0.3/5

Storage

Store it in a cool dry place below 25 °C and away from moisture, heat or sunlight. Do not freeze. Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Disposal

Write the date on the carton when you open the bottle and throw out any remaining solution after 4 weeks from the date of opening.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Do not use this medicine after the expiry date.

Product description

What Vizo-PF Bimatotim 0.3/5 looks like

Clear, colourless, aqueous sterile ophthalmic solution practically free from visible particles.

Vizo-PF Bimatotim 0.3/5 is supplied in a white LDPE multidose bottle with a white nozzle and blue tip and sealed with a white HDPE cap.

Each 5 mL bottle contains approx. 3 mL eye drop solution and is packed into a cardboard carton.

Ingredients

Active ingredient:

- Bimatoprost (300 microgram/mL)
- Timolol maleate (equivalent to timolol 5 mg/mL)

Inactive ingredients:

- Sodium chloride
- Dibasic sodium phosphate heptahydrate
- Citric acid monohydrate
- Sodium hydroxide
- Hydrochloric acid

- Water for injections

Vizo-PF Bimatolim 0.3/5 eye drops are preservative free and contains no antimicrobial agents.

Sponsor Details

Vizo-PF Bimatolim 0.3/5 eye drops are supplied in New Zealand by:

AFT Pharmaceuticals Ltd
Level 1, 129 Hurstmere Road
Takapuna
Auckland 0622
NEW ZEALAND

Email: customer.service@aftpharm.com

Phone: 0800 423 823

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