

VIZO-PF DORZOLATIM

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. WHY AM I USING VIZO-PF DORZOLATIM?

VIZO-PF DORZOLATIM contains the active ingredients dorzolamide hydrochloride and timolol maleate. VIZO-PF DORZOLATIM is used to lower raised pressure in the eye and to treat glaucoma.

For more information, see Section [1. Why am I using VIZO-PF DORZOLATIM?](#) in the full CMI.

2. What should I know before I use VIZO-PF DORZOLATIM?

Do not use if you have ever had an allergic reaction to VIZO-PF DORZOLATIM or any ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use VIZO-PF DORZOLATIM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VIZO-PF DORZOLATIM and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use VIZO-PF DORZOLATIM?

Use VIZO-PF DORZOLATIM only when prescribed by your doctor. Your doctor will tell you how many drops you need to use each day. The usual dose for adults is one drop of VIZO-PF DORZOLATIM twice a day, in either one or both eyes.

More instructions can be found in Section [4. How do I use VIZO-PF DORZOLATIM?](#) in the full CMI.

5. What should I know while using VIZO-PF DORZOLATIM?

Things you should do	<ul style="list-style-type: none"> Remind any doctor, dentist or pharmacist, eye specialist or optometrist you visit that you are using VIZO-PF DORZOLATIM. Have your eye pressure checked when your eye specialist says, to make sure VIZO-PF DORZOLATIM is working.
Things you should not do	<ul style="list-style-type: none"> Do not stop using VIZO-PF DORZOLATIM without first talking to your doctor. If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.
Driving or using machines	<ul style="list-style-type: none"> VIZO-PF DORZOLATIM may cause blurred vision or dizziness in some people. Make sure you know how you react to VIZO-PF DORZOLATIM or that your vision is clear before driving a car or operating machinery.
Looking after your medicine	<ul style="list-style-type: none"> Store it in a cool dry place below 25 °C and away from moisture, heat or sunlight. Do not freeze. Write the date on the carton when you open the bottle and throw out remaining solution after 4 weeks.

For more information, see Section [5. What should I know while using VIZO-PF DORZOLATIM?](#) in the full CMI.

6. Are there any side effects?

- Serious side effects:** can be related to [heart](#) (fast/irregular heart beats [palpitations], slow/irregular heart beats, dizziness and light-headedness, very slow pulse, chest pain, fainting), [skin](#) (rash, itching, severe and sudden pinkish, itchy skin swellings/hives/nettle rash), [allergy](#) (swelling of the face/lips/mouth/tongue/throat, possibly causing difficulty in breathing/swallowing), [circulation](#) (swollen hands/feet/ankles) or [breathing](#) (wheezing, difficulty in breathing, shortness of breath). **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.**
- Common side effects:** burning/stinging of the eyes, bitter/abnormal taste, irritation/feeling of having something in the eye, conjunctivitis, blurred vision, watering of the eyes/discharge and itching of the eye. **Speak to your doctor if you have any of these less serious side effects and they worry you.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

VIZO-PF DORZOLATIM

Active ingredient(s): *Dorzolamide hydrochloride/Timolol maleate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VIZO-PF DORZOLATIM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VIZO-PF DORZOLATIM.**

Where to find information in this leaflet:

- [1. Why am I using VIZO-PF DORZOLATIM?](#)
- [2. What should I know before I use VIZO-PF DORZOLATIM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VIZO-PF DORZOLATIM?](#)
- [5. What should I know while using VIZO-PF DORZOLATIM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using VIZO-PF DORZOLATIM?

VIZO-PF DORZOLATIM contains the active ingredients **dorzolamide hydrochloride and timolol maleate**. VIZO-PF DORZOLATIM is a preservative-free antiglaucoma medicine used to alleviate symptoms of a disease in which damage to the optic nerve is caused.

VIZO-PF DORZOLATIM is 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. 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 raised eye pressure may not have glaucoma.

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. You may have no symptoms but eventually glaucoma can lead to total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

Although VIZO-PF DORZOLATIM helps control your glaucoma it does not cure it.

For more information about glaucoma, contact Glaucoma Australia (PO Box 420, Crows Nest 1585, telephone 1800 500 880).

VIZO-PF DORZOLATIM contains two active ingredients, dorzolamide hydrochloride and timolol maleate. Both of these active ingredients lower pressure in the eye by reducing the production of fluid, but they do this in different ways.

Dorzolamide hydrochloride belongs to a family of medicines called carbonic anhydrase inhibitors.

Timolol maleate belongs to a family of medicines called beta-blockers.

VIZO-PF DORZOLATIM is not addictive.

2. What should I know before I use VIZO-PF DORZOLATIM?

Warnings

Do not use VIZO-PF DORZOLATIM if:

- you are allergic to dorzolamide hydrochloride or timolol maleate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have now or have had in the past certain serious breathing problem such as asthma, chronic obstructive lung disease (emphysema), or other breathing problems.
- you have certain heart conditions, such as a slow heart rate, an irregular heart beat, or heart failure.

Check with your doctor if you:

- have any other medical conditions such as:
 - heart problems (such as coronary heart disease, heart failure or low blood pressure) heart rate disturbances (such as slow or irregular heartbeats)
 - poor blood circulation problems (such as Raynaud's syndrome)
 - lung or breathing problems (such as asthma or chronic obstructive lung disease)
 - diabetes or other blood sugar problems
 - thyroid disease
 - kidney disease
 - liver disease
- take any medicines for any other condition
- have a history of allergic problems, including eczema, hives or hay fever
- have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes

- are going to have an operation and you are using VIZO-PF DORZOLATIM, as it may change the effects of some medicines during anaesthesia.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

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 DORZOLATIM 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 DORZOLATIM 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 sulfonamide medicines

- One of the active ingredients of VIZO-PF DORZOLATIM, dorzolamide hydrochloride, is a sulfonamide-related compound. Therefore, if you are allergic to sulfonamide medicines you may be allergic to VIZO-PF DORZOLATIM. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfonamides.

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

- VIZO-PF DORZOLATIM has not been studied in people wearing contact lenses.

3. What if I am taking other medicines?

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

Some medicines may interfere with VIZO-PF DORZOLATIM and affect how it works.

- medicines for high blood pressure or heart conditions, including a group of medicines called beta-blockers
- quinidine, a medicine used to treat irregular heart beats
- tablets used to treat glaucoma
- large amounts of aspirin or salicylates
- medicine to treat depression

These medicines may be affected by VIZO-PF DORZOLATIM, or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VIZO-PF DORZOLATIM.

4. How do I use VIZO-PF DORZOLATIM?

How much to use

- Use VIZO-PF DORZOLATIM 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. Follow the instructions provided and use VIZO-PF DORZOLATIM until your doctor tells you to stop.
- The usual dose for adults is one drop of VIZO-PF DORZOLATIM twice a day, in either one or both eyes.
- VIZO-PF DORZOLATIM helps control your condition but does not cure it. Therefore VIZO-PF DORZOLATIM must be used every day. Continue using VIZO-PF DORZOLATIM for as long as your doctor prescribes.

When to use VIZO-PF DORZOLATIM

- VIZO-PF DORZOLATIM 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.
- After using VIZO-PF DORZOLATIM, wait at least 10 minutes before putting any other eye drops in your eye(s).

How to instill VIZO-PF DORZOLATIM

- 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 and keep it closed. Do not blink or rub your eye.
- While your eye is still closed, place your index finger against the inside corner of your eye and press against your nose for about five 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.

You may feel a slight burning sensation in the eye after using the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

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 VIZO-PF DORZOLATIM

VIZO-PF DORZOLATIM should be used regularly at the same time each day. If you miss your dose at the usual time, 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.

If you use too much VIZO-PF DORZOLATIM

If you think that you have used too much [VIZO-PF DORZOLATIM, or if VIZO-PF DORZOLATIM is accidentally swallowed, you may need urgent medical attention. You may feel light-headed or dizzy, you may faint, have a very slow pulse rate, or have wheezing or difficulty breathing.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using VIZO-PF DORZOLATIM?

Things you should do

Have your eye pressure checked when your eye specialist says, to make sure VIZO-PF DORZOLATIM is working.

Call your doctor straight away if you

- develop an eye infection, receive an eye injury, or have eye surgery; your doctor may advise you to stop your treatment with VIZO-PF DORZOLATIM become pregnant while using VIZO-PF DORZOLATIM

Remind any doctor, dentist or pharmacist, eye specialist or optometrist you visit that you are using VIZO-PF DORZOLATIM.

Things you should not do

- Do not give VIZO-PF DORZOLATIM to anyone else, even if they have the same condition as you.
- Do not stop using VIZO-PF DORZOLATIM without first talking to your doctor.
- If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.

Contamination of your eye drops

- VIZO-PF DORZOLATIM 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 you drive or use any machines or tools until you know how VIZO-PF DORZOLATIM affects you.

VIZO-PF DORZOLATIM may cause blurred vision or dizziness in some people. Make sure you know how you react to VIZO-PF DORZOLATIM or that your vision is clear before driving a car or operating machinery.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Problems with your eye/s such as: <ul style="list-style-type: none"> – blurred vision, double vision or other visual problems – allergic reactions including redness, swelling and/or itching of the eye – burning and stinging of the eyes, eye pain – watering of the eyes or discharge – conjunctivitis – irritation or feeling of having something in the eye, dry eyes – swelling of the eyelids, drooping of eyelids • Difficulty thinking or working because of headache <ul style="list-style-type: none"> – tiredness, weakness – ringing or buzzing in the ears – difficulty sleeping, nightmares – changes in mood such as depression, memory loss • Mouth or stomach problems: <ul style="list-style-type: none"> – feeling sick (nausea), upset stomach, stomach pain – diarrhoea – bitter or abnormal taste, dry mouth • Respiratory problems: <ul style="list-style-type: none"> – cough – sore throat and discomfort when swallowing – cold or flu-like symptoms such as sneezing, runny nose, cough, red or infected throat – feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, also called sinusitis • Changes in the way your hands and feet feel such as: <ul style="list-style-type: none"> – 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 • Symptoms of a urinary tract infection including an urge to urinate frequently and in small amounts, or painful burning when passing urine • Back pain • Nose bleeds • Hair loss or thinning • Less desire for sex 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Heart-related: <ul style="list-style-type: none"> – fast or irregular heart beats, also called palpitations – slow or irregular heart beats – dizziness and light-headedness, which may be due to low blood pressure – very slow pulse, chest pain – fainting • Skin- and allergy-related: <ul style="list-style-type: none"> – skin rash, itching – swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing or swallowing – severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash • Circulation-related: <ul style="list-style-type: none"> – swelling of the hands, feet or ankles • Breathing-related: <ul style="list-style-type: none"> – wheezing, difficulty in breathing, shortness of breath 	<p>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.</p>

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What VIZO-PF DORZOLATIM contains

Active ingredients (main ingredients)	Dorzolamide hydrochloride equivalent to dorzolamide 2% w/v Timolol maleate equivalent to timolol 0.5% w/v
Other ingredients (inactive ingredients)	Mannitol Sodium citrate Hyetellose Sodium hydroxide Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

VIZO-PF DORZOLATIM is preservative free and contains no antimicrobial agents.

What VIZO-PF DORZOLATIM looks like

VIZO-PF DORZOLATIM is a clear, slightly viscous, colourless, aqueous, sterile ophthalmic solution practically free from visible particulates.

VIZO-PF DORZOLATIM is supplied in a white opaque LDPE multidose bottle with a white nozzle and blue tip and sealed with a white HDPE cap.

Each 11 mL bottle contains approx. 5 mL eye drop solution and is packed into a cardboard carton.

AUST R 341770

Who distributes VIZO-PF DORZOLATIM

AFT Pharmaceuticals Pty Ltd
113 Wicks Road
North Ryde
NSW 2113

Email: customer.service@aftpharm.com
Freephone (AU): 1800 AFTPHARM (1800 238 74276)

This leaflet was prepared in September 2021.