

APO-Dorzolamide/Timolol

Contains the active dorzolamide (as hydrochloride) 2.0% and timolol (as maleate) 0.5%

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about dorzolamide/timolol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Dorzolamide/Timolol eye drops. It contains the active ingredients dorzolamide (22.3 mg of dorzolamide hydrochloride) and timolol (6.8 mg of timolol maleate).

It 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. 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 dorzolamide/timolol helps control your glaucoma it does not cure it.

For more information about glaucoma, contact Glaucoma Australia Inc., PO Box 420, Crows Nest 1585, telephone 02 9906 6640.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Dorzolamide/timolol contains two active ingredients, dorzolamide (as hydrochloride) and timolol (as 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 (as hydrochloride) belongs to a family of medicines called carbonic anhydrase inhibitors.

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

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

The safety and effectiveness of dorzolamide in children have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**

- serious breathing problem such as asthma, chronic obstructive lung disease (emphysema), or other breathing problems.
- heart conditions, such as slow heart rate, an irregular heartbeat, or heart failure.
- **You are breastfeeding or intend to breastfeed.**

Your baby may absorb this medicine from breast milk and therefore is a possibility of harm to the baby.

- **You are hypersensitive to, or have had an allergic reaction to, dorzolamide/timolol or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.**

The preservative in dorzolamide/timolol (benzalkonium chloride) may be deposited in soft contact lenses. You can put soft contact lenses back into your eyes at least 15 minutes after you have used dorzolamide/timolol.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - 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
3. You have an allergy to sulfonamide medicines.

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

4. You are already using another beta-blocker eye drop

It is not recommended to use two beta-blocker eye drops at the same time.

5. You have a history of allergic problems, including eczema, hives or hay fever.
6. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
7. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
8. You are planning to have surgery.
9. You are taking or are planning to take any other medicines. This includes vitamins and supplements that

are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with dorzolamide/timolol. These include:

- 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
- medicines to treat diabetes
- tablets used to treat glaucoma
- large amounts of aspirin or salicylates
- medicines used to treat depression

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with dorzolamide/timolol.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how many drops you need to use each day. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The usual dose for adults is one drop of dorzolamide/timolol twice a day, in either one or both eyes.

After using dorzolamide/timolol, wait at least 10 minutes before putting any other eye drops in your eye(s).

How to take it

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

Before opening the bottle for the first time, make sure the safety seal joining the cap to the bottle is not broken. If it is, do not use the bottle and return it to your pharmacist.

You will notice a small space between the cap and the bottle, this is normal.

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. Unscrew the cap and break it off from the seal.

3. Place the cap upside down on a flat surface. Do not touch the inside of the cap. This will help keep the inside of the cap clean and keep germs out of the eye drops.
4. Use your finger to gently pull down the lower eyelid of the affected eye.
5. Tilt your head back and look up.
6. Place the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
7. Squeeze the bottle gently so that only drop goes into your eye, then release the lower eyelid.
8. Close your eye and keep it closed. Do not blink or rub your eye.
9. While your eye is still 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 or pharmacist for more specific instructions on this technique.
10. Screw the cap back on the bottle, sealing it tightly. Do not over tighten the cap.
11. Wash your hands again with soap and water to remove any residue.

Wait at least 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.

Contaminated eye drops may give you an eye infection.

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 it

Use dorzolamide/timolol 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 dorzolamide/timolol, wait at least 10 minutes before putting any other eye drops in your eye(s).

It does not matter if you take it before, with or after food.

How long to take it for

Dorzolamide/timolol helps control your condition but does not cure it.

Therefore dorzolamide/timolol must be used every day. Continue using dorzolamide/timolol for as long as your doctor prescribes.

Make sure you have enough of this medicine to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure dorzolamide/timolol is 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 the eye drops because of possible contamination of the old one, or may advise to stop your treatment with the eye drops.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are going to have surgery or are going into hospital.

Go to your doctor or eye specialist regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

If you stop using your medicine, your eye pressure may rise again and damage to your eye may occur.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Dorzolamide/timolol generally does not cause any problems with your ability to drive a car or operate machinery.

However, it may cause blurred vision or dizziness in some people. Make sure you know how you react to dorzolamide/timolol or that your vision is clear before you drive a car or operate machinery.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking dorzolamide/timolol or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they

are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following:

- **problems with your eye(s) such as:**
 - 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 the eyelids
- **difficulty thinking or working because of:**
 - headache
 - tiredness, weakness
 - ringing or buzzing in the ears
 - difficulty in sleeping, nightmares
 - changes in mood such as depression, memory loss

- mouth or stomach problems:
- feeling sick (nausea), upset stomach, stomach pain
- diarrhoea
- bitter or abnormal taste, dry mouth
- **respiratory problems:**
 - 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 or cheeks and behind your eyes, throbbing ache, also called sinusitis
- **changes in the way your hands and feet feel such as:**
 - 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 the 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.**

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

These may be serious side effects and you may need medical attention:

- fast or irregular heartbeats, also called palpitations
- slow or irregular heart beats
- dizziness and light-headedness, which may be due to low blood pressure
- swelling of the hands or feet
- 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
- skin rash, itchiness.

Serious side effects are rare.

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

Tell your doctor if you notice any other effects

Allergic reactions

If you think you are having an allergic reaction to dorzolamide/timolol, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from light.

Do not store your medicine, 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 this medicine 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 cap off the bottle for any length of time to avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

Dorzolamide/timolol contains 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Dorzolamide/Timolol Eye Drops looks like

Dorzolamide/Timolol eye drop is a clear, colourless to nearly colourless, slightly viscous solution.

The eye drops come in a 5 mL plastic bottle with a dropper and screw cap.

Ingredients

Each eye drop contains 2% w/v of dorzolamide (as hydrochloride) and 0.5% w/v timolol (as maleate) as the active ingredient.

It also contains the following inactive ingredients:

- hyetellose
- mannitol
- sodium citrate dihydrate
- benzalkonium chloride
- sodium hydroxide
- water for injections

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Dorzolamide/Timolol 20/5 eye drops (bottle): AUST R 267121.

Sponsor

Apotex Pty Ltd

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Macquarie Park NSW 2113

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