

APO-Dorzolamide Eye Drops

Contains the active dorzolamide (as hydrochloride) 2%

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. 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 eye drops. It contains the active ingredient dorzolamide hydrochloride.

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 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 is used, either alone or in combination with other eye drops or medicines, to lower raised pressure within your eye(s).

Dorzolamide lowers pressure in the eye by reducing the production of fluid.

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

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 are hypersensitive to, or have had an allergic reaction to, dorzolamide 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 (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.

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:
 - kidney disease
 - liver disease.
3. You have an allergy to sulfonamide medicines.

The active ingredient of dorzolamide is a sulfonamide-related compound. Therefore, if you are allergic to sulfonamide medicines you may be allergic to dorzolamide. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfonamides.
4. 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.

5. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
6. 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. These include:

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

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.

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.

When dorzolamide is used alone, the usual dose for adults is one drop three times a day, in either one or both eyes.

If your doctor has recommended that you use dorzolamide with a beta-blocker eye drop, then the usual dose for adults is one drop of dorzolamide twice a day, in either one or both eyes.

After using dorzolamide, 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

If you are using dorzolamide three times a day, use the drops first thing in the morning, in the early afternoon and at bedtime (i.e. approximately 8 hours apart). If you are using dorzolamide twice a day, use the drops in the morning and in the evening (i.e. approximately 12 hours apart).

Use dorzolamide 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.

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

How long to take it for

Dorzolamide helps control your condition but does not cure it.

Therefore dorzolamide must be used every day. Continue using dorzolamide 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 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 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 the eye drops, your pressures may rise again and damage to the eye may occur.

Things to be careful of

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

Dorzolamide generally does not cause any problems with your ability to drive a car or operate machinery. However, it may cause certain side effects in some people, including blurred vision and dizziness. Make sure you know how you react to dorzolamide 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 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 or pharmacist if you notice any of the following:

- eye problems such as burning, stinging, itching, conjunctivitis, watering of the eye(s), redness of the eye(s), swelling or crusting of the eyelid(s), eye pain, blurred vision
- feeling sick

- bitter taste, dry mouth
- nose bleeds
- throat irritation
- headache, dizziness
- tiredness, weakness
- kidney stone
- numbness or tingling in fingers or toes

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

Allergic reactions

If you think you are having an allergic reaction to dorzolamide, 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 30°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 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 Eye Drops looks like

Dorzolamide eye drop is slightly opalescent, 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 1 mL contains 20 mg of dorzolamide (as hydrochloride) 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 20 mg/mL eye drops (bottle):
AUST R 267119

Sponsor

Apotex Pty Ltd
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