

COSOPT®

Dorzolamide hydrochloride/Timolol maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about COSOPT. 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 COSOPT 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 COSOPT is used for

COSOPT 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. 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 COSOPT helps control your glaucoma it does not cure it.

COSOPT 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.

COSOPT is not addictive.

Before you use COSOPT

When you must not use it

Do not use COSOPT if you have an allergy to COSOPT or any of the ingredients listed at the end of this leaflet.

Do not use COSOPT if:

- 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 slow heart rate, an irregular heartbeat, or heart failure.

Do not use COSOPT if you are breast-feeding or intend to breast-feed.

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

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

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

Do not use COSOPT if:

- the seal around the cap is broken
- the bottle shows signs of tampering
- the expiry date on the pack has passed.

If you use this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start using COSOPT, talk to your doctor.

There is limited experience with COSOPT in children.

Before you start to use it

Tell your doctor if:

1. you are pregnant or intend to become pregnant

Your doctor will discuss the possible risks and benefits of using COSOPT during pregnancy and a decision can be made if you should or should not use it.

2. you have 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. if you have an allergy to sulfonamide medicines

One of the active ingredients of COSOPT, dorzolamide hydrochloride, is a sulfonamide-related compound. Therefore, if you are allergic to sulfonamide medicines you may be allergic to COSOPT. 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 have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you use COSOPT.

Tell your doctor before you have an operation that you are using COSOPT, as it may change the effects of some medicines during anaesthesia.

Taking other medicines

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

and COSOPT may interfere with each other. 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 to treat depression

These medicines may be affected by COSOPT, 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 using COSOPT.

How to use COSOPT

How much to use

Your doctor will tell you how many drops you need to use each day.

Use COSOPT only when prescribed by your doctor.

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

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

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

How to use it

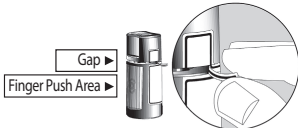
You may find it easier to put drops in your eye while you are sitting or lying down.

Before opening the bottle for the first time, make sure the Safety Strip on the front of 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. To open the bottle for the first time, tear off the Safety Strip to break the seal. Then hold the bottle upright, and turn the cap in the direction of the arrows until you can lift it off.



3. Place the cap upside down (arrows face 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. Hold the bottle upside down in one hand, with your thumb or index finger over the "finger push" area.



5. Using your other hand, gently pull down your lower eyelid to form a pouch.
6. Tilt your head back and look up.



7. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
8. Release one drop into the pouch formed between your eye and eyelid by gently squeezing the bottle.
9. Close your eye and keep it closed. Do not blink or rub your eye.
10. 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 for more specific instructions on this technique.
11. Replace the cap, sealing it tightly. Do not overtighten the cap.
12. 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 after using the eye drops.

If this persists, or is very uncomfortable, contact your doctor or pharmacist.

How long to use it

COSOPT helps control your condition but does not cure it. Therefore COSOPT must be used every day. Continue using COSOPT for as long as your doctor prescribes.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and have 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 you use too much (overdose)

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of COSOPT, or used too many drops, immediately contact your doctor or go to the accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If COSOPT is accidentally swallowed, or if you use too many drops, you may feel light-headed or dizzy, you may faint, have a very slow pulse rate, or have wheezing or difficulty breathing.

While you are using COSOPT

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure COSOPT 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 bottle of COSOPT because of possible contamination of the old one, or may advise you to stop your treatment with COSOPT.

If you become pregnant while using COSOPT, tell your doctor.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using COSOPT.

Things you must not do

Do not give COSOPT to anyone else, even if they have the same condition as you.

Do not stop using COSOPT 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

Be careful driving or operating machinery until you know how COSOPT affects you.

COSOPT generally does not cause any problems with your ability to drive a car or operate machinery. However, COSOPT may cause blurred vision or dizziness in some people. Make sure you know how you react to COSOPT or that your vision is clear before driving a car or operating machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using COSOPT.

COSOPT helps most people with high eye pressure and glaucoma, but it may have unwanted side effects in a few people. 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 side effects.

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:

- **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 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, cheeks and behind your eyes, sometimes with a 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 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

These are usually mild side effects.

Tell your doctor immediately if you notice any of the following:

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

These may be serious side effects. You may need urgent medical attention.

Serious side effects are rare.

If any of the following happen, stop using COSOPT and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- wheezing, difficulty in breathing, shortness of breath
- very slow pulse, chest pain
- fainting
- 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

These are serious side effects. You may need urgent medical attention. These 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.

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

After using COSOPT

Storage

Keep your eye drops in a cool place. Do not store above 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Do not carry the eye drops in pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep the eye drops away from light.

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 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.

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

Product description

How does it come?

COSOPT comes as eye drops in a 5mL bottle.

Ingredients

Active ingredients:

- dorzolamide hydrochloride, equivalent to dorzolamide 2% w/v
- timolol maleate, equivalent to timolol 0.5% w/v

Inactive ingredients:

- sodium citrate
- hydroxyethylcellulose
- sodium hydroxide
- mannitol
- water for injections
- benzalkonium chloride as preservative

Marketing Authorization Holder

Mundipharma Pty Limited, located at 88 Phillip Street, Sydney NSW 2000 Australia

Manufacturer:

Laboratoires Merck Sharp & Dohme-Chibret
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