

## 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.

### 1. Why am I using COSOPT?

COSOPT contains TWO active ingredients: dorzolamide hydrochloride and timolol maleate . COSOPT is used to lower raised pressure in the eye and to treat glaucoma.

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

### 2. What should I know before I use COSOPT?

Do not use if you have ever had an allergic reaction to COSOPT or any of the 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 COSOPT?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with COSOPT 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 COSOPT?

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

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

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

### 5. What should I know while using COSOPT?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, or pharmacist that you visit that you are using COSOPT</li><li>• If you are wearing soft contact lenses, remove them before putting the drops in your eye</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly without first talking to your doctor</li><li>• If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur</li><li>• Do not touch the inside of the cap or let the tip of the bottle touch your eye</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• COSOPT may cause blurred vision or dizziness in some people. Make sure you know how you react to COSOPT and that your vision is clear before driving a car or operating machinery.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your COSOPT eye drops in a cool place where the temperature stays below 30°C.</li><li>• Keep the eye drops away from light, moisture or heat.</li><li>• Do not freeze.</li><li>• Write the date you open the bottle on the carton, and throw out any remaining solution after 4 weeks</li></ul>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

### 6. Are there any side effects?

**Common side effects:** dry, itchy, burning, or stinging eyes, feeling like there is something in the eye, blurred vision, watery eyes, discharge from the eyes, conjunctivitis. **Speak to your doctor if you have any of these less serious side effects and they worry you**

**Serious side effects:** fast/slow/irregular heartbeat, lightheadedness/dizziness, slow pulse, chest pain, skin rash, pinkish itchy rash, swelling on face/lips/throat/tongue which may cause difficulty breathing, wheezing, shortness of breath. Swelling of hands/feet/ankles. **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**

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.

# COSOPT\*

Active ingredient(s): *dorzolamide hydrochloride/timolol maleate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using COSOPT. It does not take the place of talking to your doctor or pharmacist. **You should speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COSOPT.**

Where to find information in this leaflet:

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

## 1. Why am I using COSOPT?

COSOPT is used to lower raised pressure in the eye and to treat glaucoma. Although COSOPT helps control your glaucoma, it does not cure it.

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, and causes pressure to rise. The 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.

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. Untreated glaucoma is one of the most common causes of blindness.

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

COSOPT contains 2 active ingredients: dorzolamide hydrochloride and timolol maleate. Dorzolamide hydrochloride belongs to a family of medicines called carbonic anhydrase inhibitors. Timolol maleate belongs to a family of medicines called beta-blockers. Both of these active ingredients lower pressure in the eye by reducing the production of fluid, but they do this in different ways.

COSOPT is not addictive.

## 2. What should I know before I use COSOPT?

### Warnings

Do not use COSOPT 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
- 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.
- 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
- you have severe kidney disease or problems, or a prior history of kidney stones**

Check with your doctor before using COSOPT if you:

- take any medicines for any other condition
- you have excess acidity of the blood** caused by a build up of chloride in the blood (hyperchloraemic acidosis)
- have poor **blood circulation problems** (such as Raynaud's syndrome)
- have **muscle weakness** or been diagnosed as having myasthenia gravis
- have **diabetes or other blood sugar problems**
- have **liver or kidney disease**
- have a history of **allergic problems** including eczma, hives or hay-fever
- have had an allergy to any other medicines or other substances such as foods, preservatives or dyes
- are going to have an operation, that you are using COSOPT, 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 use COSOPT.

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

- **Tell your doctor if 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.
- **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

## 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.

## Use with other 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.
- **.After using COSOPT, wait at least 10 minutes before putting any other eye drops in your eye(s).**

## Use with contact lenses

- **Remove contact lenses before putting the COSOPT drops in your eye(s).** The preservative in COSOPT (benzalkonium chloride) may be deposited in soft contact lenses. **Wait at least 15 minutes after using COSOPT** before replacing your 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 and COSOPT may interfere with each other. These include:

- medicines for high blood pressure or heart conditions, including a group of medicines called betablockers
- 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
- medicines such as morphine used to treat severe cancer pain

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COSOPT.**

## 4. How do I use COSOPT?

### How much to use

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

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

**Use COSOPT only when prescribed by your doctor.**

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

COSOPT helps control your condition but does not cure it. Therefore COSOPT must be used every day. Use COSOPT until your doctor tells you to stop.

### When to use COSOPT

COSOPT 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.

### How to insert COSOPT drops

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

**If you are wearing soft contact lenses, remove them before putting the drops in your eye.**

**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.

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. The 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 our 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 the eye.
10. While your eye is still closed, place your index finger against the inside corner of your eye and press against the nose for about two (2) 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.

**After using COSOPT, 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.**

### **If you forget to use COSOPT**

COSOPT should be used regularly at the same time each day. If you miss your dose at the usual time,

**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 your dose or not, talk to your doctor or pharmacist.

**Do not use double the amount to make up for the dose you missed.**

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

### **If you use too much COSOPT**

If you think that you or anyone else has swallowed any or all of the contents of a bottle of COSOPT, or have used too many drops, then you may need urgent medical attention.

**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.**

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 difficulty breathing.

## **5. What should I know while using COSOPT?**

### **Things you should do**

**Have your eye pressure checked when your eye specialist says, to make sure that COSOPT is working.**

**Call your doctor straight away if:**

- **you develop an eye infection, injure your eye or have eye surgery.** 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
- **you become pregnant while using COSOPT**

Tell any doctor and pharmacist you visit that you are using COSOPT.

### **Things you should not do**

- **do not give COSOPT to anyone else, even if they have the same condition as you**
- **do not stop using COSOPT suddenly unless your doctor tells you to stop.** If you stop using your eye drops, your eye pressure may rise again and damage to your eye(s) may occur

### **Driving or using machines**

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

### **Looking after your eye drops**

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

Store the drops where the temperature stays below 30°C. Store them in a cool dry place away from moisture, heat or sunlight. Do NOT store them:

- in the bathroom or near a sink, or
- in the car or on a window sill
- In the pockets of your clothes

**Keep them where young children cannot reach them.**

**Do not leave the cap off the bottle for any length of time to avoid contaminating the eye drops.**

### **When to discard your eye drops**

**Write the date on the bottle when you open the eye drops, and throw out any remaining solution after**

**four weeks.** The preservative in the drops helps prevent germs from growing in the solution for 4 weeks after opening. After this there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

### 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
<p><b>Eye-related:</b></p> <ul style="list-style-type: none"> <li>blurred vision, double vision or other visual problems</li> <li>allergic reactions including redness, swelling and/or itching of the eye</li> <li>burning and stinging of the eyes</li> <li>eye pain</li> <li>watery or discharge from eyes</li> <li>conjunctivitis</li> <li>irritation or feeling of having something in the eye, dry eyes</li> <li>swelling of the eyelids, drooping of the eyelids</li> </ul> <p><b>Difficulty thinking or working because of:</b></p> <ul style="list-style-type: none"> <li>headache</li> <li>tiredness, weakness</li> <li>ringing or buzzing in the ears</li> <li>difficulty sleeping, nightmares</li> <li>changes in mood such as depression, memory loss</li> </ul> <p><b>Mouth or stomach problems:</b></p> <ul style="list-style-type: none"> <li>feeling sick (nausea), upset stomach, stomach pain</li> <li>diarrhoea</li> <li>bitter or abnormal taste, dry mouth</li> </ul> <p><b>Respiratory problems:</b></p> <ul style="list-style-type: none"> <li>cough</li> <li>sore throat or discomfort when swallowing</li> <li>cold or flu-like symptoms such as sneezing, runny nose, cough, red or infected throat</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you</b></p>

<ul style="list-style-type: none"> <li>feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache also called sinusitis</li> </ul> <p><b>Changes to the way your hands and feet feel such as:</b></p> <ul style="list-style-type: none"> <li>cold hands or feet</li> <li>numbness, tingling or colour change (white, blue then red) in fingers when exposed to the cold (Raynaud's Phenomenon)</li> <li>numbness or tingling in the fingers or toes</li> </ul> <p><b>Other effects:</b></p> <ul style="list-style-type: none"> <li>symptoms of a urinary tract infection including an urge to urinate frequently and in small amounts, or painful burning when passing urine</li> <li>back pain</li> <li>nose bleeds</li> <li>hair loss or thinning</li> <li>less desire for sex</li> </ul>	
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### Serious side effects

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

Serious side effects are rare.

## 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](http://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 COSOPT contains

<b>Active ingredient (main ingredient)</b>	<b>Dorzolamide hydrochloride</b> equivalent to dorzolamide 2% w/v <b>Timolol maleate</b> equivalent to timolol 0.5% w/v
<b>Other ingredients (inactive ingredients)</b>	sodium citrate hydroxyethylcellulose sodium hydroxide mannitol water for injections benzalkonium chloride (as preservative)

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

### What COSOPT looks like

COSOPT drops is a clear, colourless to nearly colourless, slightly viscous solution.

COSOPT drops are supplied in a white HDPE bottle.

(Aust R 66103).

### Who distributes COSOPT

COSOPT is supplied in Australia by:

Mundipharma Pty Limited  
10 Carrington Street  
Sydney NSW 2000  
Phone: 1800 188 009

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