COSDOR

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using COSDOR, speak to your doctor or pharmacist.

1. Why am I using COSDOR?

COSDOR contains two active ingredients: dorzolamide hydrochloride and timolol maleate. COSDOR is used to lower raised pressure in the eye and to treat ocular hypertension or open-angle glaucoma. For more information, see Section 1. Why am I using COSDOR? in the full CMI.

2. What should I know before I use COSDOR?

Do not use if you have ever had an allergic reaction to COSDOR 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, are pregnant or breastfeeding or plan to become pregnant or breastfeed.** For more information, see Section 2. What should I know before I use COSDOR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COSDOR 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 COSDOR?

Your doctor will tell you how many drops you need to use each day. The usual dose for adults is one drop of COSDOR twice a day, in either one or both eyes.

Remove soft contact lenses before using the eye drops and wait 15 minutes before putting them back in. Tilt your head back, pull down the lower eyelid, look up, and squeeze one drop into the eye. Release the eyelid, close the eye without blinking, and press the inner corner against your nose for about two minutes.

After using COSDOR, 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 COSDOR? in the full CMI.

5. What should I know while using COSDOR?

Things you must do	• Tell your doctor, or pharmacist that you visit that you are using COSDOR. • To make sure COSDOR is working properly, have your eye pressure checked regularly. • Tell your doctor if you develop an eye infection, receive an eye injury, or have eye surgery. • Tell your doctor if you become pregnant while using COSDOR.
Things you must not do	• Do not give COSDOR to anyone else, even if they have the same condition as you or their symptoms seem similar. • Do not stop using your eye drops without first talking to your doctor, your eye pressure may rise again and damage to your eye may occur.
Driving or using machines	• COSDOR may cause blurred vision or dizziness in some people. Make sure you know how you react to COSDOR and that your vision is clear before driving a car or operating machinery.
Looking after your medicine	• Store your COSDOR eye drops in a cool dry place below 25°C and protected from light. • Write the date you open the bottle on the carton and throw out any remaining solution after 4 weeks (28 days).

For more information, see Section 5. What should I know while using COSDOR? 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. **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. 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.

COSDOR

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using COSDOR. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COSDOR.**

Where to find information in this leaflet:

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

1. Why am I using COSDOR?

COSDOR is used to lower raised pressure in the eye and to treat ocular hypertension or open-angle glaucoma. Although COSDOR helps control your glaucoma, it does not cure it.

COSDOR contains two 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.

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, PO Box 420, Crows Nest NSW 1585, telephone 1800 500 880.

COSDOR is not addictive.

2. What should I know before I use COSDOR?

Warnings

Do not use COSDOR 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 COSDOR.
- the seal around the cap is broken.
- the bottle shows signs of tampering.
- the expiry date on the pack has passed. If you use COSDOR 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.**
- **you have excess acidity of the blood caused by a build up of chloride in the blood (hyperchloraemic acidosis).**

Check with your doctor before using COSDOR if you:

- take any medicines for any other condition.
- 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 eczema, 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 COSDOR, as it may change the effects of some medicines during anaesthesia.
- have heart problems (such as coronary heart disease or low blood pressure).
- have any eye conditions including dry eyes. The preservative (benzalkonium chloride) in COSDOR may cause eye irritation, dry eye symptoms, and may affect some structures in the eye.

If you have not told your doctor about any of the above or you are not sure whether you should start using COSDOR, check with your doctor.

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 plan to become pregnant.**

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

- **Do not use COSDOR if you are breastfeeding or plan to breastfeed**.

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

Use in children

There is limited experience with COSDOR in children.

Allergy to sulfonamide medicines

One of the active ingredients of COSDOR, dorzolamide hydrochloride, is a sulfonamide-related compound. Therefore, if you are allergic to sulfonamide medicines you may be allergic to COSDOR. 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 COSDOR, 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 COSDOR drops in your eye(s). The preservative (benzalkonium chloride) in COSDOR may be deposited in soft contact lenses. **Wait at least 15 minutes after using COSDOR** 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 may be affected by COSDOR or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. 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
- medicines to treat pain or severe cancer pain, such as opioids and morphine.

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

4. How do I use COSDOR?

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 COSDOR twice a day, in either one or both eyes.

Use COSDOR 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.

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

When to use COSDOR

COSDOR 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 COSDOR 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.

Instructions:

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
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, placed 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 COSDOR, 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 COSDOR

COSDOR should be used regularly at the same time each day.

If you miss your dose at the usual time and 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 COSDOR

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

You must immediately:

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

Do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using COSDOR?

Things you must do

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

- **become pregnant while using COSDOR.**

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

Things you must not do

- Do not give COSDOR to anyone else, even if they have the same condition as you or their symptoms seem similar.
- Do not stop using COSDOR 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 COSDOR affects you.

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

Looking after your eye drops

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

Store your COSDOR eye drops in a cool dry place below 25°C and protected from light. Do not store it:

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

Keep it where young children cannot reach it.

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

When to dispose of your eye drops

- **Dispose of COSDOR four weeks after opening.**

  Write the date on the bottle when you open the eye drops, and throw out any remaining solution after four weeks (28 days).

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.

- If you no longer need to use it.
- After the expiry date (if unopened) or four weeks after opening.
- The tamper evident seal has been damaged when you receive it.

Getting rid of any unwanted medicine

Take it to any pharmacy for safe disposal.

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
Eye-related: • 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 • watery or discharge from eyes • 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 or discomfort when swallowing	**Speak to your doctor if you have any of these less serious side effects.** **These more common side effects are usually mild and short-lived.**
• 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 to the way your hands and feet feel such as:** • cold hands or feet • numbness, tingling or colour change (white, blue then red) in fingers when exposed to the cold (Raynaud's Phenomenon) • numbness or tingling in the fingers or toes **Other effects:** • 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	

Serious side effects

Serious side effects	What to do
Heart-related: • fast or irregular heartbeats, also called palpitations • slow or irregular heart beats • very slow pulse, chest pain • fainting • dizziness and light-headedness, which may be due to low blood • pressure **Skin or allergy-related:** • 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 **Breathing-related:** • wheezing or shortness of breath, difficulty breathing	**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.** **These side effects are rare.**

Serious side effects	What to do
Circulation-related: • swelling of the hands, feet or ankles	

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

COSDOR is only available with a doctor's prescription.

What COSDOR 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)	sodium citrate dihydrate hyetellose sodium hydroxide mannitol water for injections benzalkonium chloride as preservative
Potential allergens	benzalkonium chloride

Do not use COSDOR if you are allergic to any of these ingredients.

What COSDOR looks like

COSDOR comes as eye drops in a 5 mL bottle with a clear, slightly viscous, colourless liquid (AUST R 217250).

Sponsor

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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