

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrCOSOPT® and PrCOSOPT® preservative-free

Dorzolamide and timolol ophthalmic solution

Read this carefully before you start taking **COSOPT or COSOPT preservative-free** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **COSOPT or COSOPT preservative-free**.

What is COSOPT and COSOPT preservative-free used for?

COSOPT and COSOPT preservative-free is used to treat high pressure in the eye in patients with the following conditions:

- Ocular hypertension
- Open-angle glaucoma

It is used along with other medicines. COSOPT preservative-free does not contain a preservative. It is used in patients who may be sensitive to a preservative.

How does COSOPT and COSOPT preservative-free work?

COSOPT and COSOPT preservative-free contain a combination of two medicines. One is called a carbonic anhydrase inhibiting medicine. The other is called a beta-blocking medicine. Each one works in a different way to lower the pressure in the eye.

What are the ingredients in COSOPT and COSOPT preservative-free?

Medicinal ingredients: Dorzolamide (as dorzolamide hydrochloride) and timolol (as timolol maleate)

Non-medicinal ingredients: Hydroxyethyl cellulose, mannitol, sodium citrate, sodium hydroxide, and water for injection.

Benzalkonium chloride is only added as a preservative to COSOPT. COSOPT preservative-free does not contain benzalkonium chloride.

COSOPT and COSOPT preservative-free comes in the following dosage forms:

Solution: 20 mg / mL dorzolamide (as dorzolamide hydrochloride) and 5 mg / mL timolol (as timolol maleate).

Do not use COSOPT or COSOPT preservative-free if you:

- are allergic to COSOPT or any of its ingredient. See “What are the ingredients in COSOPT and COSOPT preservative-free?”
- have serious breathing problems such as asthma
- have chronic obstructive lung disease
- have certain heart conditions such as slow or irregular heartbeats or heart failure
- have severe kidney problems
- are taking medicines called carbonic anhydrase inhibitors by mouth
- are less than 18 years of age

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take COSOPT or COSOPT preservative-free. Talk about any health conditions or problems you may have, including if you:

- have lung or breathing problems such as chronic obstructive lung disease.
- have muscle weakness of the eye.
- have had heart problems such as heart failure in the past.
- have a heart condition called a first degree heart block.
- have an allergy to any medication.
- are pregnant or planning to become pregnant.
- are breast-feeding or planning to breast-feed.
- have or have had kidney problems.
- have or have had liver problems.
- have or have had thyroid problems.
- have or have had blood circulation problems such as Raynaud’s syndrome.
- have or have had diabetes or other blood sugar problems.
- have certain eye problems like corneal defects or have had eye surgery in the past.
- are planning to have major surgery, including eye surgery, as COSOPT may change the effects of some medicines during anesthesia.

Other warnings you should know about:

Contact lenses

If you wear contact lenses, consult your doctor before using COSOPT. COSOPT contains the preservative benzalkonium chloride. It can deposit in soft contact lenses. This means that you must remove your contact lenses before you apply COSOPT. Wait 15 minutes before putting your contact lenses back in your eyes.

Driving and using machines

Wait until you can see clearly before driving or operating machines after applying COSOPT or COSOPT preservative-free.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with COSOPT or COSOPT preservative-free:

- Other drugs (including eye drops) that you are using or plan to use.
- Medicines used to lower blood pressure, called calcium channel blockers or clonidine.
- Medicines used to treat heart problems such as quinidine and medicines called beta-blockers.
- Medicines used to treat diabetes such as insulin or oral hypoglycemic agents.
- Medicines used to treat depression called selective serotonin reuptake inhibitors.
- Acetylsalicylic acid used to reduce fever and pain.
- Medicines called sulfa drugs used to treat bacterial infections.

How to take COSOPT or COSOPT preservative-free:

- Take COSOPT exactly as your healthcare professional has told you to.
- If you are using COSOPT with another eye drop, the drops should be applied at least 10 minutes apart.
- Be careful not to touch your eye, the area around your eye, or any other surface with the tip of the container. It may become contaminated with bacteria. This can cause eye infections. This could lead to serious damage of the eye including loss of vision. Keep the tip of the container away from contact with any surface. Contact your healthcare

professional if you think the bottle might be contaminated or if you think you might have an eye infection.

- If you cannot apply COSOPT to yourself a family member or caregiver may help you.
- If you are using COSOPT preservative-free, the container and any remaining contents must be discarded after each application.

COSOPT

1. Before using COSOPT for the first time, be sure the Safety Strip on the front of the bottle is not broken. A gap between the bottle and the cap is normal for an unopened bottle.

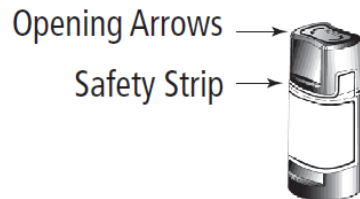


Figure A

2. Tear off the Safety Strip to break the seal.

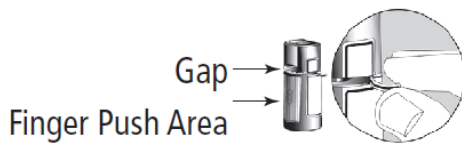
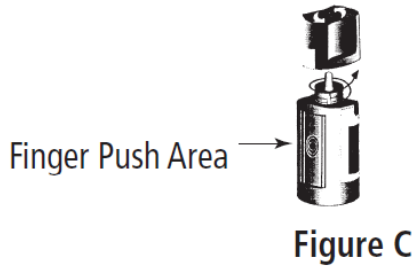


Figure B

3. To open the bottle, unscrew the cap by turning as indicated by the arrows on the top of the cap. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.



4. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.

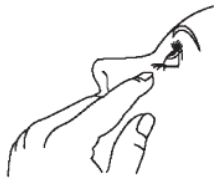


Figure D

5. Invert the bottle and press lightly with the thumb or index finger over the “Finger Push Area” (as shown) until a single drop is dispensed into the eye.



DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP.

6. After application, press a finger into the corner of your eye, by the nose (as shown) for 2 minutes. This helps keep COSOPT in your eye.



Figure F

7. If drop dispensing is difficult after you open the bottle for the first time, replace the cap on the bottle and tighten. Then, remove it by turning the cap in the opposite direction as shown by the arrows on the top of the cap.
8. Repeat steps 4, 5 and 6 with the other eye if instructed to do so by your healthcare professional.
9. Replace the cap by turning until it is firmly touching the bottle. Do not tighten the cap too much. This may damage the bottle and cap.
10. The dispenser tip is designed to provide a single drop into your eye; do not enlarge the hole of the dispenser tip.
11. After you have used all doses, there will be some COSOPT left in the bottle. You should not be concerned since an extra amount of COSOPT has been added to the bottle and you will still get the full amount of COSOPT that your doctor prescribed. Do not attempt to remove excess medicine from the bottle.

COSOPT preservative-free

Use the individual pipette of COSOPT preservative-free immediately after opening. Discard any remaining solution immediately after use.

1. Open the foil pouch which contains 15 individual unit dose pipettes. There are three strips of 5 pipettes each in the pouch.
2. Break off one pipette from the strip and twist open the top of the pipette as shown.

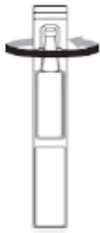


Figure G

3. Tilt your head back and pull your lower eyelid down slightly so that a pocket forms between your eyelid and eye as shown. **Do not allow the pipette to touch your eye or any area around your eye.** Hold the vial so that the fins at the tip of the pipette are aligned with the corners of your eye, as shown in the figure below.
4. Apply one drop in the affected eye(s) as directed by your healthcare professional. Each pipette contains enough solution for both eyes.

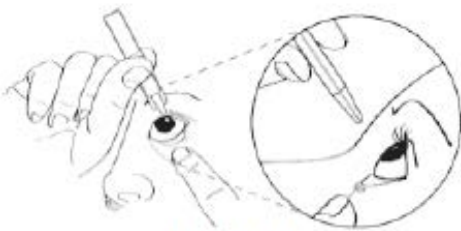


Figure H

5. After application, press a finger into the corner of your eye, by the nose (as shown) for 2 minutes. This helps keep COSOPT preservative-free in your eye.



Figure I

6. After application, throw away the used pipette even if there is solution remaining.
7. Store the remaining pipettes in the foil pouch; the remaining pipettes must be used within 15 days.

Usual dose:

The usual dose is one drop in the affected eye(s) twice a day.

Your healthcare professional will tell you exactly how much COSOPT or COSOPT preservative-free you should apply and for how long you should apply it.

Overdose:

If you feel you have taken too much COSOPT or COSOPT preservative-free and symptoms may include shortness of breath, low heartbeat, dizziness, headache, etc., seek medical help.

If you think you, or a person you are caring for, have taken too much COSOPT or COSOPT preservative-free, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is important to apply COSOPT or COSOPT preservative-free as prescribed by your doctor. If you miss a dose, apply it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not apply a double dose.

What are possible side effects from using COSOPT or COSOPT preservative-free?

These are not all the possible side effects you may have when taking COSOPT or COSOPT preservative-free. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Burning, stinging, itching or redness of the eye.
- Watery eyes.
- Blurred vision.
- Swelling or crusting of the eyelids.
- Altered sense of taste including a bitter taste.
- Muscle pain.
- Abdominal pain.
- Headache.
- Nosebleed.
- Dry mouth.
- Nausea.
- Tiredness.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Slow heartbeat			✓
RARE			
Heart problems: irregular heartbeat, heart block, low blood pressure.			✓
Toxic Epidermal Necrolysis (severe skin reaction): redness, blistering and/or peeling of large areas of the skin.			✓
Allergic Reactions: rash, hives, swelling of the mouth, throat, and lips, difficulty breathing, blue skin, shock, loss of consciousness, low blood pressure.			✓
Stevens-Johnson syndrome (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands.			✓
Urolithiasis (kidney stones): pain when urinating, severe pain in the side and back, below the ribs.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

COSOPT:

Store at room temperature 15°C – 25°C. Protect from light.

COSOPT Preservative-free:

Store at room temperature 15°C – 25°C. Protect from light. COSOPT preservative-free pipettes should be stored in protective foil pouch.

Keep out of reach and sight of children.

If you want more information about COSOPT or COSOPT preservative-free:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.elvium.ca, or by calling 1-833-744-0005.

This leaflet was prepared by Elvium Life Sciences.

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