

NDA 20-869/S-030

Page 3

Patient Information about
COSOPT^{®1} (dorzolamide hydrochloride–timolol maleate ophthalmic solution)
COSOPT (pronounced “CO-sopt”)

Read this information before you start using COSOPT and each time you refill your prescription. This is in case any information has changed. This leaflet provides a summary of certain information about COSOPT. Your doctor or pharmacist can give you more complete information about COSOPT. This leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss COSOPT when you start using your medicine and at regular checkups. Only your doctor can prescribe COSOPT for you.

What is COSOPT?

COSOPT is an eyedrop. It contains dorzolamide hydrochloride, which is an ophthalmic carbonic anhydrase inhibiting drug. It also contains timolol maleate, which is a beta-blocking drug. Both drugs work to lower pressure in the eye, but in different ways.

COSOPT is a medicine for lowering pressure in the eye in people with open-angle glaucoma or ocular hypertension. It is used when a beta-blocker eyedrop alone is not adequate to control eye pressure.

What should I know about high pressure in the eye?

People with open-angle glaucoma or ocular hypertension have pressures in one or both of their eye(s) that are too high for them.

High pressure in the eye may damage the optic nerve. This may lead to loss of vision and possible blindness. There generally are few symptoms that you can feel to tell you whether you have high pressure within your eye. Your doctor needs to examine your eyes to determine this. If you have high pressure in your eye, you will need your pressure checked and your eyes examined regularly.

Who should not use COSOPT?

Do not use COSOPT if you have:

- asthma or have ever had asthma,
- severe lung problems,
- slow or irregular heartbeat or heart failure,
- allergies to any of its ingredients. See the list at the end of the leaflet.

If you are not sure whether you should use COSOPT, contact your doctor or pharmacist.

What should I tell my doctor before and during treatment with COSOPT?

Tell your doctor:

- if you are pregnant or plan to become pregnant,
- if you are breast-feeding or intend to breast-feed,
- about any medical problems you have now or had in the past, especially heart problems or breathing problems including asthma,
- if you now have or had in the past kidney or liver problems,
- if you have diabetes, thyroid disease or muscle weakness,
- about all medicines that you are taking or plan to take, including those you can get without a prescription,
- about any allergies including allergies to any medications, especially sulfa drugs,

¹Registered trademark of MERCK & CO., Inc.
COPYRIGHT © 2005 MERCK & CO., Inc.
All rights reserved

NDA 20-869/S-030

Page 4

- if you develop an eye infection, develop a red or swollen eye or eyelid, receive an eye injury, have eye surgery, or develop new or worsening eye symptoms,
- if you plan on having any type of surgery.

How should I use COSOPT?

COSOPT is an eyedrop. The usual dose is one drop in the morning and one drop in the evening. Your doctor will tell you if just one or both eyes are to be treated.

If you are using COSOPT with another eyedrop, the eyedrops should be used at least 10 minutes apart. It is very important to use your medication exactly as directed by your doctor. If you stop using your medicine, contact your doctor immediately.

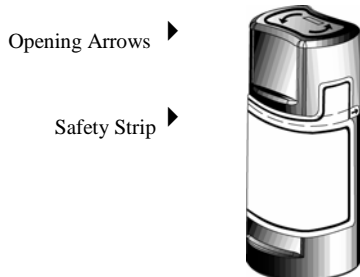
COSOPT contains a preservative called benzalkonium chloride. This preservative may be absorbed by soft contact lenses. Contact lenses should be removed before using COSOPT. The lenses can be placed back into your eyes 15 minutes after using the eyedrops.

Do not allow the tip of the bottle to touch the eye or areas around the eye. The bottle may become contaminated with bacteria. This can cause eye infections leading to serious damage to the eye, even loss of vision. Keep the tip of the bottle away from contact with any surface to avoid contamination.

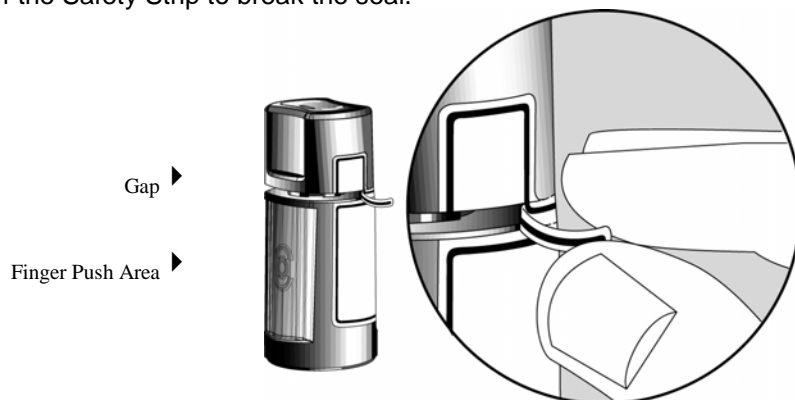
INSTRUCTIONS FOR USE

Please follow these instructions carefully when using COSOPT. Use COSOPT as prescribed by your doctor.

1. If you use other topically applied ophthalmic medications, they should be administered at least 10 minutes before or after COSOPT.
2. Wash hands before each use.
3. Before using the medication for the first time, be sure the Safety Strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.



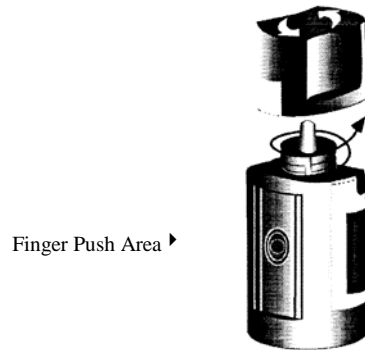
4. Tear off the Safety Strip to break the seal.



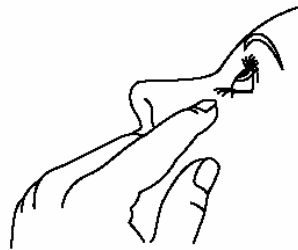
NDA 20-869/S-030

Page 5

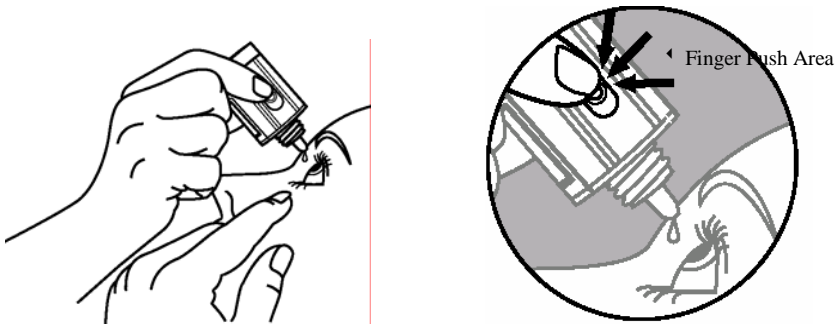
- To open the bottle, unscrew the cap by turning as indicated by the arrows on the top of the cap. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.



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



- 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 as directed by your doctor.



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

Ophthalmic medications, if handled improperly, can become contaminated by common bacteria known to cause eye infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated ophthalmic medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

- If drop dispensing is difficult after opening for the first time, replace the cap on the bottle and tighten (DO NOT OVERTIGHTEN) and then remove by turning the cap in the opposite direction as indicated by the arrows on the top of the cap.
- Repeat steps 6 & 7 with the other eye if instructed to do so by your doctor.

NDA 20-869/S-030

Page 6

10. Replace the cap by turning until it is firmly touching the bottle. The arrow on the left side of the cap must be aligned with the arrow on the left side of the bottle label for proper closure. Do not overtighten or you may damage the bottle and cap.
11. The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.
12. 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 and you will get the full amount of COSOPT that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

Can I use COSOPT with other medicines?

Tell your doctor or pharmacist about all drugs that you are using or plan to use. This includes other eyedrops and drugs obtained without a prescription. This is particularly important if you are taking medicine to lower blood pressure or to treat heart disease, or if you are taking large doses of aspirin.

Ask your doctor's advice about taking COSOPT if you are also using:

- oral carbonic anhydrase inhibitors (for example, acetazolamide, Diamox®)
- oral beta-blockers (for example, propranolol, Inderal®)
- calcium antagonists (for example, nifedipine, Procardia®)
- catecholamine-depleting drugs (for example, reserpine)
- digitalis in combination with calcium antagonists (for example, Lanoxin® with Procardia®)
- quinidine (for example, Cardioquin®)
- clonidine (for example, Catapres®)
- injectable epinephrine (for example, EpiPen®).
- SSRIs (for example Prozac®)

Your doctor or pharmacist can tell you if any of the drugs you are using are in the above list.

What are the possible side effects of COSOPT?

Any medicine may have unintended or undesirable effects. These are called side effects. Side effects may not occur, but if they do occur, you may need medical attention. The most common side effects you may experience are:

- eye symptoms such as burning and stinging, redness of the eye(s), blurred vision, tearing or itching.
- a bitter, sour or unusual taste after putting in your eyedrops.

Other side effects may occur rarely, and some of these may be serious. Tell your doctor right away if you experience:

- shortness of breath
- visual changes
- an irregular heartbeat and/or a slowing of your heart rate.

The above list is NOT a complete list of side effects reported with COSOPT. Your doctor can discuss with you a more complete list of side effects. Please tell your doctor [or pharmacist] promptly about any of these or any other unusual symptom.

What should I do in case of an overdose?

If you swallow the contents of the bottle, contact your doctor immediately. Among other effects, you may feel light-headed, have difficulty breathing, or feel your heart rate has slowed.

How should I store COSOPT?

NDA 20-869/S-030

Page 7

Keep your medicine in a safe place where children cannot reach it. Store COSOPT at room temperature (59-86°F, 15-30°C). Protect the bottle from light. Do not use your medicine after the expiration date on the bottle.

What else should I know about COSOPT?

Do not use COSOPT for a condition for which it was not prescribed. Do not give COSOPT to other people, even if they have the same condition you have. It may harm them.

Inactive ingredients:

The inactive ingredients of COSOPT are sodium citrate, hydroxyethylcellulose, sodium hydroxide, mannitol, water for injection and benzalkonium chloride added as a preservative.

Issued January 2006
541A-12/05 511880Z

MERCK & CO., Inc.
Whitehouse Station, NJ 08889, USA