

DISCLAIMER

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COSOPT® PF

PATIENT INFORMATION

CO-SOPT® PF (CO-sopt PEA EHF)

(dorzolamide hydrochloride-timolol maleate ophthalmic solution) 2%/0.5%

Read this information before you start using COSOPT PF and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is COSOPT PF?

COSOPT PF is a prescription sterile eye drop solution that contains 2 medicines, dorzolamide hydrochloride (a sulfonamide carbonic anhydrase inhibitor) and timolol maleate (a beta-adrenergic blocker). COSOPT PF is used to lower the pressure in the eye (intraocular pressure) in people with open-angle glaucoma or ocular hypertension, when their eye pressure is too high and beta-adrenergic blocker medicines alone have not adequately lowered the pressure.

It is not known if COSOPT PF is safe and effective in children under 2 years of age.

Who should not use COSOPT PF?

Do not use COSOPT PF if you:

- have or have had asthma
- have or have had severe lung problems (chronic obstructive pulmonary disease)
- have heart problems, including slow or irregular heartbeat or heart failure
- are allergic to dorzolamide hydrochloride, timolol maleate, or any of the ingredients in COSOPT PF. See the end of this leaflet for a complete list of ingredients in COSOPT PF.

Talk to your healthcare provider before taking this medicine if you have any of these conditions.

What should I tell my doctor before using COSOPT PF?

Before you use COSOPT PF, tell your doctor if you:

- have problems with muscle weakness (myasthenia gravis)
- have diabetes or problems with low blood sugar (hypoglycemia)
- have thyroid, kidney, or liver problems
- are planning to have surgery
- are allergic to sulfa drugs
- have or have had eye problems, including any surgery on your eye or eyes, or are using any other eye medicines
- have any other medical problems
- are pregnant or plan to become pregnant. It is not known if COSOPT PF will harm your unborn baby. If you become pregnant while using COSOPT PF talk to your doctor right away.
- are breastfeeding or plan to breastfeed. It is not known whether dorzolamide passes into your breast milk however, timolol has been detected in breast milk. Talk to your doctor about the best way to feed your baby if you use COSOPT PF.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

COSOPT PF and other medicines may affect each other causing side effects. COSOPT PF may affect the way other medicines work, and other medicines may affect how COSOPT PF works.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use COSOPT PF?

Read the Instructions for Use at the end of this Patient Information leaflet for additional instructions about the right way to use COSOPT PF.

- Use COSOPT PF exactly as your doctor tells you.
- **Use 1 drop of COSOPT PF in your eye (or eyes) in the morning and 1 drop in the evening.**
- If you use other medicines in your eye, wait at least 5 minutes between using COSOPT PF and your other eye medicines.
- Use your COSOPT PF right away after opening. Each COSOPT PF single-use container is sterile and is to be used 1 time then thrown away.
- Do not save any COSOPT PF that may be left over after you use a single-use container. Using COSOPT PF that is not sterile may cause other eye problems.

What are the possible side effects of COSOPT PF?

COSOPT PF may cause serious side effects including:

- **severe breathing problems.** These breathing problems can happen in people who have asthma, chronic obstructive pulmonary disease, or heart failure and can cause death. Tell your doctor right away if you have breathing problems while taking COSOPT PF.
- **heart failure.** This can happen in people who already have heart failure and in people who have never had heart failure before.

Tell your doctor right away if you get any of these symptoms of heart failure while taking COSOPT PF:

- shortness of breath
- irregular heartbeat (palpitations)
- swelling of your ankles or feet
- sudden weight gain
- **severe allergic reactions.** These allergic reactions can happen the first time you use COSOPT PF or after you have been using COSOPT PF for a while and may cause death. **Stop taking COSOPT PF and call your doctor right away or get emergency help if you get any of these symptoms of an allergic reaction:**
 - swelling of your face, lips, mouth, or tongue

- trouble breathing
- wheezing
- severe itching
- skin rash, redness, or swelling
- dizziness or fainting
- fast heartbeat or pounding in your chest (tachycardia)
- sweating
- **worsening muscle weakness.** COSOPT PF can cause muscle weakness to get worse in people who already have problems with muscle weakness (myasthenia gravis).
- **kidney problems.** Your doctor may do tests to check your kidney function while you use COSOPT PF.
- **swelling of your eye (cornea)**

The most common side effects of COSOPT PF include:

- a bitter, sour, or unusual taste in your mouth after using COSOPT PF
- burning, stinging, redness, or itching of the eye
- blurred vision
- painful, red, watery eyes with increased sensitivity (superficial punctate keratitis)

Tell your doctor if you have any new eye problems while using COSOPT PF including:

- an eye injury
- an eye infection
- a sudden loss of vision
- eye surgery
- swelling and redness of and around your eye (conjunctivitis)
- problems with your eyelids

Tell your doctor if you have any other side effects that bother you.

These are not all the possible side effects of COSOPT PF. For more information, ask your doctor or pharmacist.

Call your doctor about medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I do in case of an overdose?

If you swallow the contents of the container, 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 PF?

- Store COSOPT PF at room temperature between 68°F to 77°F (20°C to 25°C). Do not freeze.
- Keep the COSOPT PF single-use containers in their original foil pouch to protect from light.
- Write down the date you open the foil pouch in the space provided on the pouch.
- Throw away all unused COSOPT PF single-use containers 15 days after first opening the pouch.

Keep COSOPT PF and all medicines out of the reach of children.

General information about the safe and effective use of COSOPT PF.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use COSOPT PF for a condition for which it was not prescribed. Do not give COSOPT PF to other people, even if they have the same symptoms you have. It may harm them. This Patient Information leaflet summarizes the most important information about COSOPT PF. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about COSOPT PF that is written for health professionals.

What are the ingredients in COSOPT PF?

Active ingredients: dorzolamide hydrochloride and timolol maleate

Inactive ingredients: sodium citrate, hydroxyethyl cellulose, sodium hydroxide, mannitol, and water for injection.

Instructions for Use

Read these instructions before using your COSOPT PF and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

Important:

- **COSOPT PF is for the eye only. Do not swallow COSOPT PF.**
- COSOPT PF single-use containers are packaged in a foil pouch.
- Write down the date you open the foil pouch in the space provided on the pouch.

Every time you use COSOPT PF:

Step 1. Wash your hands.

Step 2. Take the strip of single-use containers from the pouch.

Step 3. Pull off 1 single-use container from the strip.

Step 4. Put the remaining strip of single-use containers back in the pouch and fold the edge to close the pouch.

Step 5. Hold the single-use container upright. Make sure that the solution is in the bottom part of the single-use container **(See Figure A)**.



(Figure A)

Step 6. Open the single-use container by twisting off the tab **(See Figure B)**.



(Figure B)

Step 7. Tilt your head backwards. If you are unable to tilt your head, lie down.

Step 8. Place the tip of the single-use container close to your eye. Be careful not to touch your eye with the tip of the single-use container **(See Figure C)**.



(Figure C)

Step 9. Pull the lower eyelid downwards and look up.

Step 10. Gently squeeze the container and let 1 drop of COSOPT PF fall into the space between your lower eyelid and your eye. If a drop misses your eye, try again **(See Figure D)**.



(Figure D)

Step 11. Blot any excess solution from the skin around the eye with a tissue.

- If your doctor has told you to use drops in both eyes, repeat steps 7 to 11 for your other eye.
- There is enough COSOPT PF in 1 single-use container for 1 or both of your eyes.
- **Throw away the opened single-use container with any remaining COSOPT PF right away.**

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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