

# Cozopt SUD

Dorzolamide 2% & Timolol 0.5%  
Ophthalmic Solution

(Preservative-free single-unit dose vial)

## Composition:

**Cozopt SUD Preservative-free Ophthalmic Solution:** Each ml contains Dorzolamide Hydrochloride USP equivalent to Dorzolamide 20 mg & Timolol Maleate BP equivalent to Timolol 5 mg.

## Pharmacology:

Dorzolamide Hydrochloride and Timolol Maleate which reduce intraocular pressure (IOP) by combined action. Dorzolamide is human carbonic anhydrase II inhibitor which decreases aqueous humor secretion by slowing the formation of bicarbonate ions with subsequent reduction in sodium and fluid transport. Timolol is a non-selective beta adrenergic receptor blocker that does not have significant intrinsic sympathomimetic, direct myocardial depressant, or local anesthetic (membrane stabilizing) activity. It lowers IOP by decreasing the formation of aqueous humor in the ciliary epithelium.

## Indications:

Cozopt SUD Preservative-free Ophthalmic Solution is indicated for the treatment of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta blockers.

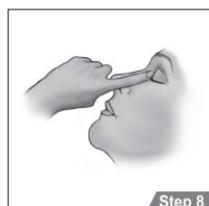
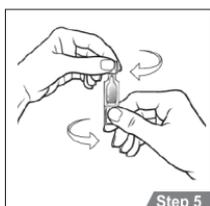
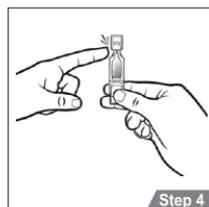
## Dosage and Administration:

Instill one drop in the conjunctival sac of the affected eye(s) twice daily.

## How to use Cozopt SUD Preservative-free ophthalmic solution:

Always use Cozopt SUD preservative-free ophthalmic solution as described in this leaflet or as directed by the physician. Make sure that the single-unit dose vial is intact before use. The solution should be used immediately after opening. The contents of one single-unit dose vial are sufficient for both eyes. Apply Cozopt SUD Preservative-free ophthalmic solution in the following way (Steps 1 to 8 pictures below)

- Step 1:** Take a pillow pack out of the Cozopt SUD box. Open the pillow pack and remove the strip of single-unit dose vial.
- Step 2:** Pull off one single-unit dose vial from the strip. Put the remaining strip of single-unit dose vials back in the pillow pack
- Step 3:** Hold the Cozopt SUD vial upright.
- Step 4:** Tap the top of the vial until all of the solution is in the bottom part of the vial.
- Step 5:** Open the Cozopt SUD single-unit dose vial by twisting off the cap. Make sure that the tip of the single-unit dose vial does not touch anything, to avoid contamination.
- Step 6:** Tilt your head backwards. If you are not able to tilt your head, lie down. Gently pull your lower eyelid downwards and look up.
- Step 7:** Place the tip of the Cozopt SUD single-unit dose vial close to your eye, but be careful not to touch your eye with it. Gently squeeze the single-unit dose vial and let one drop of Cozopt SUD Preservative-free ophthalmic solution fall inside the lower eyelid.
- Step 8:** Close your eye for a moment. Press the inner corner of the eye with your index finger for about one minute.



## Contraindications:

Contraindicated in patients who are hypersensitive to any of the components of this preparation.

## Side-effects:

Since Dorzolamide & Timolol are PRESERVATIVE-FREE, it avoids the potential risks caused by the preservatives. Mild burning, ocular hyperemia, blurred vision may occur.

## Precaution:

- For ophthalmic use only.
- Wash your hands before use.
- To avoid contamination or possible eye injury, do not let the open end of the single-unit dose vial touch your eye or anything else.
- If you wear contact lenses - take out your lenses before using eye drops and then wait for at least 15 minutes after using this drops before putting your lenses back in.
- If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.

## Use in special group:

**Use in pregnancy:** There are no adequate and well-controlled studies in pregnant women. Dorzolamide & Timolol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Use in lactation:** Caution should be exercised when Dorzolamide & Timolol is administered to a nursing mother.

**Use in children:** Safety and effectiveness in children below the age of 2 years have not been established.

**Use in elderly patients:** No overall differences in safety and effectiveness have been observed between elderly and other adult patients.

## Storage:

- Store below 30°C temperature in a dry place, protect from light.
- Discard after use.
- Keep out of the reach of children.

## Packing:

**Cozopt SUD Preservative-free Ophthalmic Solution:** Each Alu-Alu pillow pack contains 10 single-unit dose vials (SUD's). Each single-unit dose vial contains 0.2 ml of sterile eye drops.