Package leaflet: information for the user
COSOPT® 20 mg/ml + 5 mg/ml eye drops, solution
dorzolamide / timolol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What COSOPT is and what it is used for
2. What you need to know before you use COSOPT
3. How to use COSOPT
4. Possible side effects
5. How to store COSOPT
6. Contents of the pack and other information

1. What COSOPT is and what it is used for

COSOPT contains two medicines: dorzolamide and timolol.
- Dorzolamide belongs to a group of medicines called “carbonic anhydrase inhibitors”.
- Timolol belongs to a group of medicines called “beta blockers”.

These medicines lower the pressure in the eye in different ways.

COSOPT is prescribed to lower raised pressure in the eye in the treatment of glaucoma when beta-blocker eyedrop medicine used alone is not adequate.

2. What you need to know before you use COSOPT

Do not use COSOPT
- if you are allergic to dorzolamide hydrochloride, timolol maleate or any of the other ingredients of this medicine (listed in section 6).
- if you have now or had in the past respiratory problems, such as asthma or severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- if you have a slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats).
- if you have severe kidney disease or problems, or a prior history of kidney stones.
- if you have excess acidity of the blood caused by a build up of chloride in the blood (hyperchloraemic acidosis).

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

Warnings and precautions
Talk to your doctor before using COSOPT.
Tell your doctor about any medical or eye problems you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness, or choking), heart failure, low blood pressure.
- disturbances of heart rate such as slow heartbeat.
- breathing problems, asthma or chronic obstructive pulmonary disease.
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome).
- diabetes as timolol may mask signs and symptoms of low blood sugar.
- overactivity of the thyroid gland as timolol may mask signs and symptoms.

Tell your doctor before you have an operation that you are using COSOPT as timolol may change effects of some medicines used during anaesthesia.
Also, tell your doctor about any allergies or allergic reactions including hives, swelling of the face, lips, tongue, and/or throat, which may cause difficulty in breathing or swallowing.

Tell your doctor if you have muscle weakness or have been diagnosed as having myasthenia gravis.

If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately.

If you suspect that COSOPT is causing an allergic reaction or hypersensitivity (for example, skin rash, severe skin reaction, or redness and itching of the eye), stop using this medicine and contact your doctor immediately.

Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, or develop a reaction including new or worsening symptoms.

When COSOPT is instilled into the eye, it may affect the entire body.

Children
There is limited experience with COSOPT in infants and children.

Elderly
In studies with COSOPT, the effects of this medicine were similar in both elderly and younger patients.

Use in patients with liver impairment
Tell your doctor about any liver problems you now have or have suffered from in the past.

Other medicines and COSOPT
COSOPT can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are:

- taking medicine to lower blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers or digoxin).
- taking medicines to treat a disturbed or irregular heartbeat such as calcium channel blockers, beta-blockers or digoxin.
- using another eye drop that contains a beta-blocker.
- taking another carbonic anhydrase inhibitor such as acetazolamide.
- taking monoamine oxidase inhibitors (MAOIs) which are used to treat depression.
- taking a parasympathomimetic medicine which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which is sometimes used to help restore normal movements through the bowel.
- taking narcotics such as morphine used to treat moderate to severe pain.
- taking medicines to treat diabetes.
- taking antidepressants known as fluoxetine and paroxetine.
- taking a sulfa medicine.
- taking quinidine (used to treat heart conditions and some types of malaria).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not use COSOPT if you are pregnant unless your doctor considers it necessary.
Do not use COSOPT if you are breast-feeding. Timolol may get into breastmilk. Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines
No studies on the effects on the ability to drive or use machines have been performed. There are side effects associated with COSOPT, such as blurred vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until you feel well or your vision is clear.

COSOPT contains benzalkonium chloride
This medicine contains approximately 0.002 mg benzalkonium chloride in each drop which is equivalent to 0.075 mg/ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.
Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use COSOPT

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will establish the appropriate dosage and duration of treatment.

The recommended dose is one drop in the affected eye(s) in the morning and in the evening.

If you are using this medicine with another eye drop, the drops should be instilled at least 10 minutes apart.

Do not change the dose of the medicine without consulting your doctor.

Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, wash your hands before using this medicine and keep the tip of the container away from contact with any surface. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this container.

Instructions for use

Do not use the container if the plastic safety strip around the neck is missing or broken. When opening the container for the first time, tear off the plastic safety strip.

Every time you use COSOPT:

1. Wash your hands.
2. Open the container. Take special care that the tip of the dropper container does not touch your eye, the skin around your eye or your fingers.
3. Tilt your head backwards and hold the container upside down over the eye.

4. Pull the lower eyelid downwards and look up. Hold and gently squeeze the container on the flattened sides of the container and let one drop fall into the space between the lower eyelid and the eye.

5. Close your eye and press the inner corner of the eye with your finger for about two minutes. This helps to stop the medicine from getting into the rest of the body.
6. Repeat steps 3 to 5 with the other eye if instructed to do so by your doctor.
7. Put the cap back on and close the container tightly.

If you use more COSOPT than you should

If you put too many drops in your eye or swallow any of the contents of the container, among other effects, you may become light-headed, have difficulty breathing, or feel that your heart

rate has slowed. Contact your doctor immediately.

If you forget to use COSOPT
It is important to use this medicine as prescribed by your doctor.
If you miss a dose, use 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 use a double dose to make up for the forgotten dose.

If you stop using COSOPT
If you want to stop using this medicine talk to your doctor first.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects:
If you experience any of the following side effects, stop using this medicine and seek immediate medical advice as these could be signs of a reaction to the medicine.

Generalised allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airways which may cause difficulty swallowing, shortness of breath, hives or itchy rash, localised and generalised rash, itchiness, severe sudden life-threatening allergic reaction.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using COSOPT without speaking to your doctor.

The following side effects have been reported with COSOPT or one of its components either during clinical trials or during post-marketing experience:

Very Common (may affect more than 1 in 10 people):
Burning and stinging of the eyes, unusual taste.

Common (may affect up to 1 in 10 people):
Redness in and around the eye(s), watering or itching of the eye(s), corneal erosion (damage to the front layer of the eyeball), swelling and/or irritation in and around the eye(s), feeling of having something in the eye, decreased corneal sensitivity (not realising of getting something in the eye and not feeling pain), eye pain, dry eyes, blurred vision, headache, sinusitis (feeling of tension or fullness in the nose), feeling sick, also called nausea, weakness/tiredness and fatigue.

Uncommon (may affect up to 1 in 100 people):
Dizziness, depression, inflammation of the iris, visual disturbances including refractive changes (in some cases due to withdrawal of medication to treat excessive contraction of the pupil of the eye), slow heartbeat, fainting, shortness of breath, indigestion, and kidney stones (often marked by a sudden onset of excruciating, cramping pain in their low back and/or side, groin, or abdomen).

Rare (may affect up to 1 in 1,000 people):
Systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs), tingling or numbness of the hands or feet, trouble sleeping, nightmares, memory loss, an increase in signs and symptoms of myasthenia gravis (muscle disorder), decreased sex drive, stroke, temporary short sightedness which may resolve when treatment is stopped, detachment of the layer below the retina that contains blood vessels following from filtration surgery which may cause visual disturbances, drooping of the eyelids (making the eye stay half closed), double vision, eyelid crusting, swelling of the cornea (with symptoms of visual disturbances), low pressure in the eye, ringing noises in your ear, low blood pressure, changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of feet and legs due to fluid build up), oedema (fluid build up), cerebral ischaemia (reduced blood supply to the brain), chest pain, forceful heartbeat that may be rapid or irregular (palpitations), heart attack, Raynaud's phenomenon, swelling or coldness of your hands and feet and reduced circulation in your arms and legs, leg cramps and/or leg pain when walking (claudication), shortness of breath, feeling out of breath, runny or stuffed nose, nose bleed, constriction of the airways in the lungs causing difficulty in breathing, cough, throat irritation, dry mouth, diarrhoea, contact dermatitis, hair loss, skin rash with white silvery coloured appearance (psoriasiform rash), Peyronie's disease (which may cause a curvature of the penis), allergic type reactions such as rash, hives, itching, in rare cases possible swelling of the lips, eyes and mouth, wheezing, or severe skin reactions (Stevens Johnson syndrome, toxic epidermal necrolysis).

Like other medicines applied into your eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with oral beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected.

Listed additional side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

Not known (frequency cannot be estimated from the available data):
Low blood glucose levels, heart failure, a type of heart rhythm disorder, abdominal pain, vomiting, muscle pain not caused by exercise, sexual dysfunction, hallucination, foreign body sensation in eye (feeling that there is something in your eye), abnormal sensitivity of the eyes to light, increased heart rate and increased blood pressure.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.
United Kingdom (Northern Ireland): Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Ireland: HPRA Pharmacovigilance, website: www.hpra.ie.

5. How to store COSOPT

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container label and the carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Keep the container in the outer carton in order to protect from light.

You can use COSOPT for 28 days after first opening the container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What COSOPT contains

- The active substances are dorzolamide and timolol.
- Each ml contains 20 mg of dorzolamide (as 22.26 mg dorzolamide hydrochloride) and 5 mg of timolol (as 6.83 mg timolol maleate).
- The other ingredients are hydroxyethyl cellulose, mannitol, sodium citrate, sodium hydroxide, and water for injections. Benzalkonium chloride is added as a preservative.

What COSOPT looks like and contents of the pack
COSOPT is a clear, colourless to nearly colourless slightly viscous solution.

Cosopt is filled into container consisting of a white translucent plastic container with 5 ml of solution. The plastic container is closed with a white screw cap.
Tamper evidence is provided by a safety strip on the container label.

Pack sizes:
1 x 5 ml (single 5-ml container)
3 x 5 ml (three 5-ml containers)
6 x 5 ml (six 5-ml containers)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder in UK and Ireland: Santen Oy, Niittyhaankatu 20, 33720 Tampere, Finland

Manufacturer: Santen Oy, Kelloportinkatu 1, 33100 Tampere, Finland.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, Spain, Sweden, United Kingdom (Northern Ireland):

COSOPT

This leaflet was last revised in January 2026.

HOW CAN YOU OBTAIN MORE INFORMATION ABOUT COSOPT, INCREASED EYE PRESSURE OR GLAUCOMA?

This leaflet gives you the most important information about COSOPT. If you have any questions after you have read it, ask your doctor or pharmacist, who can give you more information about COSOPT and your eye condition.

Further information about glaucoma is available from:
International Glaucoma Association (IGA)
Woodcote House
15 Highpoint Business Village
Henwood,
Ashford
Kent, TN24 8DH
Tel: 01233 648170
Registered Charity number 274681.

Alternatively, if you or someone you know has problems with their vision, and you require further advice or information, please phone the Royal National Institute for the Blind (RNIB) Helpline on 0303 123 9999.

(The IGA and RNIB are independent UK charities and are not associated with Santen Oy.)