Package leaflet: Information for the user

COSOPT Preservative-Free 20 mg/ml + 5 mg/ml eye drops, solution in single-dose container
(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 Preservative-Free is and what it is used for
2. What you need to know before you use COSOPT Preservative-Free
3. How to use COSOPT Preservative-Free
4. Possible side effects
5. How to store COSOPT Preservative-Free
6. Contents of the pack and other information

1. What COSOPT Preservative-Free is and what it is used for

COSOPT Preservative-Free 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 Preservative-Free 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 Preservative-Free

Do not use COSOPT Preservative-Free

- 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, dificulty in breathing and/or long-standing cough).
- if you have a slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats).
- 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 Preservative-Free**

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 heart beat.
- 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 Preservative-Free as timolol may change effects of some medicines used during anaesthesia.

Also tell your doctor about any allergies or anaphylactic reactions.

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 Preservative-Free 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 Preservative-Free is instilled into the eye it may affect the entire body.

COSOPT Preservative-Free has not been studied in patients wearing contact lenses.
If you wear soft contact lenses, you should consult your doctor before using this medicine.

Use in children
There is limited experience with COSOPT (preserved formulation) in infants and children.

Use in elderly
In studies with COSOPT (preserved formulation), the effects of COSOPT (preserved formulation) 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 Preservative-Free
COSOPT Preservative-Free 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 eyedrop that contains a beta-blocker.
- taking another carbonic anhydrase inhibitor such as acetazolamide.
- taking monoamine oxidase inhibitors (MAOIs).
- 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
Ask your doctor or pharmacist for advice before taking any medicine.

Use in pregnancy
Do not use COSOPT Preservative-Free if you are pregnant unless your doctor considers it necessary.

Use in breast-feeding
Do not use COSOPT Preservative-Free if you are breast-feeding. Timolol may get into your milk. 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 Preservative-Free, 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.

3. How to use COSOPT Preservative-Free

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The appropriate dosage and duration of treatment will be established by your doctor.

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

If you are using COSOPT Preservative-Free 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.

If you have difficulty administering your eye drops, seek the assistance of a family member or carer.

Do not allow the single dose container to touch the eye or areas around the eye. It could cause injury to your eye. It may also 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 single dose container, wash your hands before using this medicine and keep the tip of the single dose container away from contact with any surface. A new single dose container should be opened immediately prior to each use;

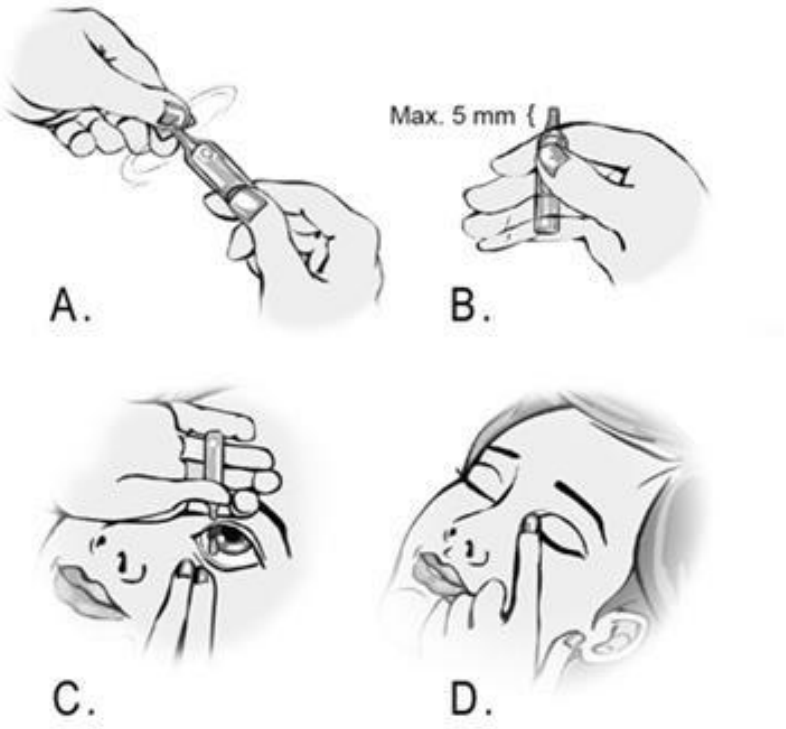
there is enough solution in each container for both eyes if your doctor has told you to use the drops in both eyes.

Discard the opened container with any remaining contents immediately after use.

Instructions for use

Open the foil sachet which contains the individual single dose containers. Write the date of first opening on the sachet.

Every time you use COSOPT Preservative-Free



1. Wash your hands.
2. Take the strip of containers from the sachet.
3. Detach one single-dose container from the strip.
4. Put the remaining strip back in the sachet and fold the edge to close the sachet.
5. If the solution is not in the tip of the container, tap the unopened container a few times with your finger keeping the dispensing end downwards in order to get the solution to the tip.
6. To open the container, twist off the tab. (Picture A).

7. Hold the container between your thumb and index finger. Note that the tip of the container must not show more than 5 mm above the edge of your index finger. (Picture B).

8. Tilt your head backwards or lie down. Place your hand on your forehead. Your index finger should be aligned with your eyebrow or resting on the bridge of the nose. Look up. Pull the lower eyelid downwards with the other hand. Do not allow any part of the container to touch your eye or any area around your eye. Gently squeeze the container to let one drop fall into the space between the lid and the eye (Picture C). Do not blink while applying the drop to your eye. Each single dose container contains enough solution for both eyes.

9. 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. (Picture D)

10. Wipe off any excess solution from the skin around the eye.

If your doctor has told you to use drops in both eyes, repeat the previously mentioned steps for your other eye.

After putting the drop into the eye(s), throw away the used single dose container even if there is solution remaining to avoid contamination of the preservative free solution.

Store the remaining containers in the foil sachet; the remaining containers must be used within 15 days after opening of the sachet. If there are any containers left 15 days after opening the sachet they should be safely thrown away and a fresh sachet opened. It is important to continue to use the eye drops as prescribed by your doctor.

If you are not sure how to administer your medicine, ask your doctor, pharmacist or nurse.

If you use more COSOPT Preservative-Free 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 Preservative-Free
It is important to take COSOPT Preservative-Free 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 take a double dose to make up for the forgotten dose.

If you stop using COSOPT Preservative-Free
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.

Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing, shortness of breath, hives or itchy rash, localized and generalized 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 Preservative-Free without speaking to your doctor.

The following adverse reactions have been reported with COSOPT Preservative-Free 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, taste perversion

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 realizing of getting something in the eye and not feeling pain), eye pain, dry eyes, blurred vision, headache, sinusitis (feeling of tension or fullness to the nose), 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 (due to withdrawal of miotic therapy in some cases), slow heartbeat, fainting, shortness of breath, indigestion, and kidney stones

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, insomnia, 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, respiratory failure, rhinitis, nose bleed, constriction of the airways in the lungs, 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 Johnsons 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, pharmacist or nurse. 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.
Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
Malta: ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

5. How to store COSOPT Preservative-Free

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

Do not use the unopened sachets of COSOPT Preservative-Free after the expiry date shown by the six digits following EX (or EXP) on the foil package. The first two digits indicate the month; the last four digits indicate the year. The expiry date refers to the last day of that month.

Do not store above 25°C.
Store in the original foil sachet in order to protect from light.
You can use COSOPT Preservative-Free 15 days after first opening the sachet.
Discard any unused single dose containers after that time.
Discard the opened single dose container with any remaining solution immediately after first use.

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 Preservative-Free 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.

What COSOPT Preservative-Free looks like and contents of the pack
COSOPT Preservative-Free is a clear, colourless to nearly colourless slightly viscous solution. Each foil sachet contains 15 or 10 low density polyethylene single dose containers containing 0.2 ml of solution.

Pack sizes:

30 x 0.2 ml (2 sachets with 15 single dose containers or 3 sachets with 10 single-dose containers)
60 x 0.2 ml (4 sachets with 15 single dose containers or 6 sachets with 10 single-dose containers)
120 x 0.2 ml (8 sachets with 15 single dose containers or 12 sachets with 10 single-dose containers)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Santen Oy, Niittyhaankatu 20, 33720 Tampere, Finland.

Manufacturer: Fareva Mirabel, Route de Marsat, Riom, 63963 Clermont-Ferrand, Cedex 9, France.
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:

Cosopt	Finland, France, Lithuania, Portugal, Sweden
Cosopt brez konzervansa	Slovenia
Cosopt Conserveermiddelvrij	Netherlands
Cosopt fără conservant	Romania
Cosopt Free	Slovakia
Cosopt Free bez konzervačních přísad	Czech Republic
Cosopt monodose	Italy
Cosopt PF	Bulgaria, Latvia, Poland
Cosopt PF "Χωρίς συντηρητικό"	Greece
Cosopt Preservative-free	Ireland, United Kingdom (Northern Ireland), Malta
Cosopt-S	Germany
Cosopt sine	Austria
Cosopt Ukonserveret	Denmark
Cosopt Unit Dose	Belgium, Luxemburg
Cosopt Uno	Hungary

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