

Package leaflet: information for the user

COSOPT Multi preservative-free 20mg/ml+5mg/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 Multi preservative-free is and what it is used for
2. What you need to know before you use COSOPT Multi preservative-free
3. How to use COSOPT Multi preservative-free
4. Possible side effects
5. How to store COSOPT Multi preservative-free
6. Contents of the pack and other information

1. What COSOPT Multi preservative-free is and what it is used for

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

COSOPT Multi preservative-free eye drops solution is a sterile solution that does not contain a preservative.

2. What you need to know before you use COSOPT Multi preservative-free

Do not use COSOPT Multi 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, difficulty 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 Multi preservative-free if 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.
- any allergies or anaphylactic reactions.
- muscle weakness or have been diagnosed as having myasthenia gravis.
- if you wear soft contact lenses, COSOPT Multi preservative-free has not been studied in patients wearing contact lenses.

If you have a history of contact hypersensitivity to silver, you should not use this medicine as dispensed drops may contain traces of silver from the container closure.

Tell your doctor before you have an operation that you are using COSOPT Multi preservative-free as timolol may change effects of some medicines used during anaesthesia.

When COSOPT Multi preservative-free is instilled into the eye it may affect the entire body.

Talk to your doctor if during the treatment with COSOPT Multi preservative-free you:

- develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids.
- suspect that COSOPT Multi 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.
- develop an eye infection, receive an eye injury, have eye surgery or develop a reaction including new or worsening symptoms.

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 were similar in both elderly and younger patients.

Use in patients with liver impairment

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

Other medicines and COSOPT Multi preservative-free

COSOPT Multi 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 eye drop 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 Multi preservative-free if you are pregnant unless your doctor considers it necessary.

Use in breast-feeding

Do not use COSOPT Multi 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 Multi 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 Multi 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 Multi 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 tip of the multidose container to touch the eye or areas around the eye. It could cause injury to your eye. The eye drops solution 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 multidose container, wash your hands before using this medicine and keep the tip of the multidose container away from contact with any surface.

Instructions for use

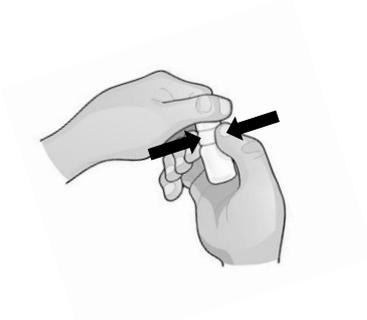
Before instillation of the eye drops:

- Wash your hands before opening the bottle.
- Do not use this medicine if you notice that the tamper-proof seal on the bottle neck is broken before you first use it.
- When using the bottle for the very first time, before delivering a drop to the eye, you should practise using the bottle by squeezing it slowly to deliver one drop away from the eye.
- When you are confident that you can deliver one drop at a time, choose the position that you find most comfortable for the instillation of the drops (you can sit down, lie on your back, or stand in front of a mirror).

- Every time when opening a new bottle, drop one drop to waste to activate the bottle.

Instillation:

1. Hold the bottle directly below the cap and turn the cap to open the bottle. Do not touch anything with the tip of the bottle to avoid contamination of the solution.



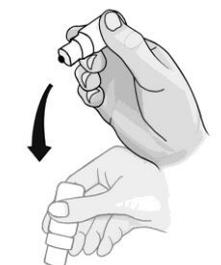
2. Tilt your head backwards and hold the bottle above your eye.
3. Pull the lower eyelid down and look up. Squeeze the bottle gently in the middle and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.



4. 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.



5. Repeat instructions 2 – 4 to deliver a drop into the other eye, if your doctor has instructed you to do this. Sometimes only one eye needs to be treated and your doctor will advise if this applies to you and which eye needs treatment.
6. After each use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid from the tip. This is necessary in order to ensure delivery of subsequent drops.



7. Wipe off any excess solution from the skin around the eye.
8. At the end of the 2 months in-use shelf life of the medicine, there will be some COSOPT Multi preservative-free left in the bottle. Do not attempt to use the excess medicine remaining in the bottle after you have completed the course of treatment. Do not use the eye drops for longer than 2 months after first opening the bottle.

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

If you use more COSOPT Multi 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 Multi preservative-free

It is important to use COSOPT Multi 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 use a double dose to make up for the forgotten dose.

If you stop using COSOPT Multi 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.

Rare (may affect up to 1 in 1,000 people):

- chest pain, oedema (fluid build up), 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), cardiac arrest, heart block, low blood pressure, cerebral ischaemia (reduced blood supply to the brain), stroke
- shortness of breath, respiratory failure, constriction of the airways in the lungs
- signs and symptoms of systemic allergic reactions, including angioedema, urticaria, pruritus, rash, anaphylaxis
- severe skin reactions, including swelling beneath the skin

Other side effects:

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

The following adverse reactions have been reported with COSOPT Multi 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):

- Effects in the eye: 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 (getting something in the eye and not feeling it), eye pain, dry eyes, blurred vision.
- General side effects: headache, sinusitis (feeling of tension or fullness to the nose), nausea, weakness/tiredness, fatigue.

Uncommon (may affect up to 1 in 100 people):

- Effects in the eye: inflammation of the iris, visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases).
- General side effects: dizziness, depression, slow heartbeat, fainting, shortness of breath, indigestion, kidney stones.

Rare (may affect up to 1 in 1,000 people):

- Effects in the eye: 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.
- General side effects: forceful heartbeat that may be rapid or irregular (palpitations), 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), cough, throat irritation, dry mouth, insomnia, nightmares, memory loss, tingling or numbness of the hands or feet, an increase in signs and symptoms of myasthenia gravis (muscle disorder), decreased sex drive, systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs), ringing noises in your ear, rhinitis, nose bleed, 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.

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, abdominal pain, vomiting, muscle pain not caused by exercise, sexual dysfunction, hallucination and foreign body sensation in eye (feeling that there is something in your eye).

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 via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store COSOPT Multi preservative-free

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 carton and bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

After first opening the bottle, the solution can be used for **2 months**. The bottle must be kept tightly closed.

Do not use this medicine if you notice that the seal is broken the first time you use 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 Multi 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 hydroxyethylcellulose, mannitol, sodium citrate, sodium hydroxide, and water for injections.

What COSOPT Multi preservative-free looks like and contents of the pack

COSOPT Multi preservative-free is a clear, colourless to nearly colourless slightly viscous solution, practically free from visible particles provided in a white plastic bottle with a white Novelia dropper applicator and a white plastic tamper-proof screw cap.

Pack sizes: 1, 2 or 3 bottles in a carton

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Santen Oy
Niittyhaankatu 20
33720 Tampere
Finland

Manufacturer

Tubilux Pharma SpA
Via Costarica 20/22
00071 Pomezia (Roma)
Italy

OR

Santen Oy
Kelloportinkatu 1
33100 Tampere
Finland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Bulgaria, Croatia, Cyprus,	COSOPT iMulti
-------------------------------------	---------------

Greece, Portugal, Spain	
Belgium, Luxembourg	COSOPT Sine Conservans
Czech Republic	COSOPT Multi Dose bez konzervačních přísad
Denmark	COSOPT sine ukonservet
Estonia, Finland, France, Germany, Iceland, Norway, Sweden	COSOPT sine
Hungary	COSOPT Multi
Ireland	COSOPT Multi preservative-free
Italy	COSOPT
Latvia, Lithuania	COSOPT PF
Poland	COSOPT PF Multi
Romania	COSOPT fara conservant
Slovak Republic	COSOPT Multi Dose Free
Slovenia	COSOPT brez konzervansa
The Netherlands	COSOPT Multidose conserveermiddelvrij
United Kingdom	COSOPT Multi Preservative Free

This leaflet was last revised in 03/2020.