MUNDIPHARMA (PTY) LTD	
COSOPT® 20 mg/5 mg	Dorzolamide/timolol Ophthalmic solution

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

COSOPT® Ophthalmic Solution

Active substances

Dorzolamide and timolol

Read all of this leaflet carefully before you start using COSOPT®.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- COSOPT® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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”.

COSOPT® is prescribed to lower raised pressure in the eye in the treatment of glaucoma and ocular hypertension.

Elevated pressure in the eye may damage the optic nerve resulting in deterioration of vision and possible blindness. There generally are few symptoms that you can feel to tell you whether you have elevated pressure within your eye. Your doctor's examination is needed to determine this. If you have raised pressure in your eye, regular eye examinations and measurements of the pressure within your eyes will be necessary.

2. What you need to know before you use COSOPT®

Do not use COSOPT®:

- if you are hypersensitive (allergic) to dorzolamide and/or timolol or any of the other ingredients of COSOPT® (listed in section 6),
- if you have asthma or have ever had asthma,
- if you have chronic obstructive lung disease (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough),
- if you have certain heart diseases such as 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 COSOPT®, contact your doctor or pharmacist.

Warnings and precautions

Take special care with COSOPT®:

Tell your doctor (or pharmacist) about any medical problems you have now or have had in the past, especially:

- breathing problems, asthma or chronic obstructive pulmonary disease.
- 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.
- 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.

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 (e.g. skin rash, or redness and itching of the eye), stop its use 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.

If you wear soft contact lenses, you should consult your doctor before using COSOPT®.

Use in children and adolescents

COSOPT® should not be used in children less than 2 years of age.

There is limited experience with COSOPT® in children between 2 and 6 years of age. However, safety and efficacy data with this solution are insufficient to recommend a safe and effective dose.

Use in 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®

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor about all medicines, including other eye drops, that you are using or plan to use, including those obtained without a prescription. This is particularly important if you are taking medicine to lower blood pressure or to treat heart disease or depression. Also tell your doctor if you are taking large doses of aspirin.

Potentiated systemic beta-blockade (e.g. decreased heart rate) has been reported during combined treatment with quinidine and timolol.

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 breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

Your doctor will decide if you should use COSOPT®. The safety of this medicine in pregnant and lactating women has not been established.

Breastfeeding

Do not use COSOPT® while breastfeeding. If you intend to breastfeed, consult your doctor.

Driving and using machines

There are side effects associated with COSOPT® that may affect your ability to drive and/or operate machinery (see 4. POSSIBLE SIDE EFFECTS). It is not always possible to predict to what extent COSOPT® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which COSOPT® affects them.

COSOPT® contains benzalkonium chloride (0,0075 % *m/v*)

COSOPT® contains the preservative benzalkonium chloride. This preservative may be deposited in soft contact lenses. If you wear contact lenses, consult your doctor before using COSOPT®.

As the possibility of adverse effects on the corneal permeability, and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations cannot be excluded, regular ophthalmological examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

3. How to use COSOPT®

Do not share medicines prescribed for you with any other person.

Always use COSOPT® exactly as your doctor or pharmacist 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 usual dose is one drop in the affected eye(s) in the morning and in the evening.

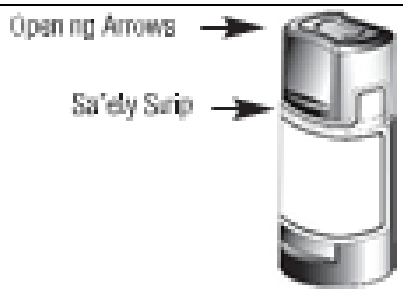
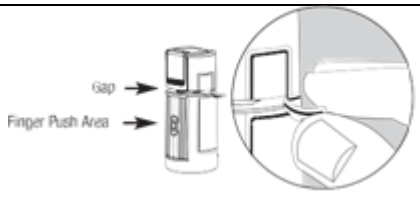
If you are using COSOPT® with another eye drop, the drops should be instilled at least 10 minutes apart.

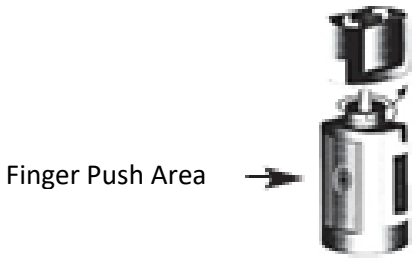
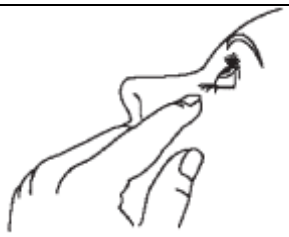
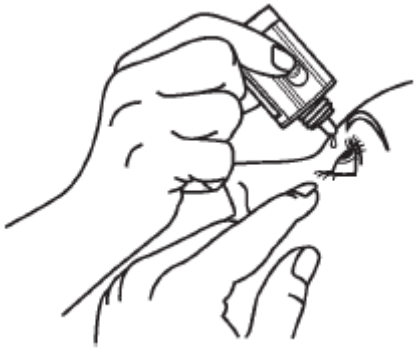
Do not change the dose of the medicine without consulting your doctor. If you must stop treatment, contact your doctor immediately.

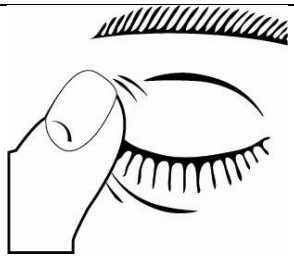
If you have the impression that the effect of COSOPT® is too strong or too weak, talk to your doctor or pharmacist.

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, keep the tip of the container away from contact with any surface.

Instructions for use

1. Before using the medication for the first time, be sure the Safety Strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.	
2. Tear off the Safety Strip to break the seal.	

3. To open the bottle, unscrew the cap by turning as indicated by the arrows on the top of the cap. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.	
4. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.	
5. Invert the bottle and press lightly with the thumb or index finger over the "Finger Push Area" (as shown) until a single drop is dispensed into the eye as directed by your doctor. DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP. Ophthalmic medications, if handled improperly, can become contaminated by common bacteria known to cause eye infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated ophthalmic medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.	 

6. After using COSOPT®, press a finger into the corner of your eye, by the nose (as shown) for 2 minutes. This helps keep COSOPT® in your eye.	
7. If drop dispensing is difficult after opening for the first time, replace the cap on the bottle and tighten (DO NOT OVERTIGHTEN) and then remove by turning the cap in the opposite directions as indicated by the arrows on the top of the cap.	
8. Repeat steps 4, 5 and 6 with the other eye if instructed to do so by your doctor.	
9. Replace the cap by turning until it is firmly touching the bottle. The arrow on the left side of the cap must be aligned with the arrow on the left side of the bottle label for proper closure. Do not over tighten or you may damage the bottle and cap.	
10. The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.	
11. After you have used all doses, there will be some COSOPT® left in the bottle. You should not be concerned since an extra amount of COSOPT® has been added and you will get the full amount of COSOPT® that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.	

If you take more COSOPT® than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you put too many drops in your eye or swallow any of the contents of the bottle, 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 COSOPT® 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 forgotten individual doses.

If you stop using COSOPT®

If you want to stop using this medicine talk to your doctor first.

4. Possible side effects

COSOPT® can have side effects.

Serious side effects:

If any of the following happens, stop using COSOPT® and contact your doctor or go to the casualty department at your nearest hospital.

- 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.

Not all side effects reported for COSOPT® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COSOPT®, please consult your health care provider for advice.

Frequent side effects:

- bitter taste in the mouth;
- burning and stinging of the eyes, blurred vision, itchy eyes, tearing, redness 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;

- headache;
- sinusitis (feeling of tension or fullness in the nose);
- feeling sick, also called nausea;
- weakness/tiredness, and fatigue.

Less frequent side effects:

- dizziness, fainting;
- depression;
- inflammation of the iris;
- slowing of your heart rate, shortness of breath, irregular heartbeat;
- increase of your heart rate;
- visual disturbances including refractive changes (in some cases due to withdrawal of medication to treat excessive contraction of the pupil of the eye);
- indigestion;
- kidney stones;
- 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;
- detachment of the layer below the retina that contains blood vessels following from filtration surgery which may cause visual disturbances;

- eyelid crusting, swelling of the cornea (with symptoms of visual disturbances);
- ringing noises in your ear;
- low blood pressure;
- high 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;
- nose bleed;
- constriction of the airways in the lungs causing difficulty in breathing, cough, throat irritation, dry mouth;
- diarrhoea;
- contact dermatitis, skin rash with white silvery coloured appearance (psoriasiform rash);
- hair loss;
- 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:

Frequency not known:

Low blood glucose levels, heart failure, a type of heart rhythm disorder, 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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of COSOPT®.

Alternatively report to the following e-mail address: ZADrugsafety@mundipharma.co.za.

5. How to store COSOPT®

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Protect from light.
- Do not use this medicine after the month and year of expiry on the container.
- Do not use more than 30 days after opening.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COSOPT® contains:

- COSOPT® is a sterile eye drop.
- The active substances are dorzolamide and timolol. Each ml of COSOPT® contains 20 mg dorzolamide and 5 mg timolol.
- The other ingredients are benzalkonium chloride (0,0075 % m/v), hydroxyethyl cellulose, mannitol, sodium citrate dihydrate, sodium hydroxide and water for injection.

What COSOPT® looks like and contents of the pack

COSOPT® Ophthalmic Solution is a clear, colourless to nearly colourless, slightly viscous solution.

COSOPT® Ophthalmic Solution is available in OCUMETER™ Plus Ophthalmic Dispensers containing 5 ml solution.

Tamper evidence is provided by a safety strip on the container label.

Holder of Certificate of Registration

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South Africa: S3

32/15.4/0525

Namibia: NS2

04/15.4/1161

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

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