SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM

COSOPT® Ophthalmic Solution

COMPOSITION

Each ml of COSOPT® contains 22,26 mg dorzolamide hydrochloride equivalent to 20 mg dorzolamide base and 6,83 mg timolol maleate equivalent to 5,0 mg timolol base and 0,0075 % *m/v* benzalkonium chloride as preservative.

Inactive ingredients: Hydroxyethyl cellulose, mannitol, sodium citrate (dihydrate), sodium hydroxide and water for injection.

PHARMACOLOGICAL CLASSIFICATION

A.15.4 Ophthalmic preparations, other.

PHARMACOLOGICAL ACTION

MECHANISM OF ACTION

COSOPT® is comprised of two components: dorzolamide hydrochloride and timolol maleate. Each of these two components decreases elevated intra-ocular pressure by reducing aqueous humor secretion, but does so by a different mechanism of action.

Dorzolamide hydrochloride is an inhibitor of human carbonic anhydrase II. Inhibition of carbonic anhydrase in the ciliary processes of the eye decreases aqueous humor secretion, presumably by slowing the formation of bicarbonate ions with subsequent reduction in sodium and fluid transport. Timolol maleate is a nonselective beta-adrenergic receptor blocking agent and reduces intra-ocular pressure. The combined effect of these two agents results in additional intra-ocular pressure reduction compared to either component administered alone.

PHARMACOKINETICS/PHARMACODYNAMICS

Dorzolamide Hydrochloride

When topically applied, dorzolamide reaches the systemic circulation. To assess the potential for systemic carbonic anhydrase inhibition following topical administration, agent and metabolite concentrations in RBCs and plasma and carbonic anhydrase inhibition in RBCs were measured. Dorzolamide accumulates in RBCs during chronic dosing as a result of selective binding to CA-II while low concentrations of free drug in plasma are maintained. The parent agent forms a single N-desethyl metabolite that inhibits CA-II less potently than the parent agent but also inhibits a less active isoenzyme (CA-I).

The metabolite also accumulates in RBCs where it binds primarily to CA-I. Dorzolamide binds moderately to plasma proteins (approximately 33 %). Dorzolamide is primarily excreted unchanged in the urine; the metabolite is also excreted in urine. After dosing ends, dorzolamide washes out of RBCs nonlinearly, resulting in a rapid decline of drug concentration initially, followed by a slower elimination phase with a half-life of about four months.

Timolol Maleate

In a study of plasma drug concentration in six subjects, the systemic exposure to timolol was determined following twice daily topical administration of timolol maleate ophthalmic solution 0,5 %. The mean peak plasma concentration following morning dosing was 0,46 ng/ml and following afternoon dosing was 0,35 ng/ml.

Paediatric Use

An ophthalmic solution containing 2 % dorzolamide hydrochloride and 0,5 % timolol has been used in children 2 to 6 years of age whose intraocular pressure could not be controlled on monotherapy with a 2 % dorzolamide hydrochloride solution. However safety and efficacy data with this solution are insufficient to recommend a safe and effective dose.

INDICATIONS

COSOPT® is indicated in the treatment of elevated intra-ocular pressure (IOP) in patients with ocular hypertension, open-angle glaucoma, pseudoexfoliative glaucoma or other secondary open-angle glaucomas when concomitant therapy is appropriate.

CONTRA-INDICATIONS

COSOPT® is contra-indicated in patients with:

- bronchial asthma or a history of bronchial asthma, or severe chronic obstructive pulmonary disease
- sinus bradycardia, second or third degree atrioventricular block, overt cardiac failure, cardiogenic shock
- hypersensitivity to any component of this product.

The above are based on the components and are not unique to the combination.

COSOPT® contains the preservative benzalkonium chloride, which may be deposited in soft contact lenses; therefore, COSOPT® should not be administered while wearing these lenses. The lenses should be removed before application of the drops and not be reinserted earlier than 15 minutes after use (see **WARNINGS AND SPECIAL PRECAUTIONS**).

Pregnancy

There are no adequate and well-controlled studies in pregnant women.

WARNINGS AND SPECIAL PRECAUTIONS

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.

Cardio-respiratory Reactions

COSOPT® may be absorbed systemically. The timolol component is a beta-blocker. Therefore, the same types of adverse reactions found with systemic administration of beta- blockers may occur with COSOPT®.

Because of the timolol maleate component, cardiac failure should be adequately controlled before beginning therapy with COSOPT®. In patients with a history of severe cardiac disease, signs of cardiac failure should be watched for and pulse rates should be checked.

Respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma and rarely death in association with cardiac failure, have been reported following administration of timolol maleate ophthalmic solution.

Immunology and Hypersensitivity

COSOPT® may be absorbed systemically. The dorzolamide component is a sulfonamide. Therefore, the same types of adverse reactions found with systemic administration of sulfonamides may occur with COSOPT®. If signs of serious reactions or hypersensitivity occur, discontinue use of this preparation.

In clinical studies, local ocular adverse effects, primarily conjunctivitis and lid reactions, were reported with chronic administration of dorzolamide hydrochloride ophthalmic solution. Some of these reactions had the clinical appearance and course of an allergic-type reaction that resolved upon discontinuation of therapy. Similar reactions have been reported with COSOPT®. If such reactions are observed, discontinuation of treatment with COSOPT® should be considered.

While taking beta-blockers, including timolol, patients with a history of atopy or a history of severe anaphylactic reaction to a variety of allergens may be more reactive to accidental, diagnostic, or therapeutic repeated challenge with such allergens. Such patients may be unresponsive to the usual doses of epinephrine used to treat anaphylactic reactions.

Renal and Hepatic Impairment

COSOPT® has not been studied in patients with severe renal impairment (CrCl less than 30 milliliter/min). Because dorzolamide hydrochloride and its metabolite are excreted predominantly by the kidney, COSOPT® is not recommended in such patients.

COSOPT® has not been studied in patients with hepatic impairment.

Concomitant Therapy

There is a potential for an additive effect on the known systemic effects of carbonic anhydrase inhibition in patients receiving oral and topical carbonic anhydrase inhibitors concomitantly. The concomitant administration of COSOPT® and oral carbonic anhydrase inhibitors has not been studied and is not recommended.

Patients who are already receiving a beta-adrenergic blocking agent systemically and who are given COSOPT® should be observed for a potential additive effect either on the intra-ocular pressure or on the known systemic effects of beta-blockade. The use of two topical beta-adrenergic blocking agents is not recommended.

Use in the Elderly

Of the total number of patients in clinical studies of COSOPT®, 49 % were 65 years of age and over, while 13 % were 75 years of age and over. No overall differences in effectiveness or safety were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Other

The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. COSOPT® has not been studied in patients with acute angle-closure glaucoma.

Choroidal detachment has been reported with administration of aqueous suppressant therapy (e.g. timolol, acetazolamide, dorzolamide) after filtration procedures.

There is an increased potential for developing corneal edema in patients with low endothelial cell counts. Precautions should be used when prescribing COSOPT® to this group of patients.

INTERACTIONS

Specific interaction studies have not been performed with COSOPT®.

In clinical studies, COSOPT® was used concomitantly with the following systemic medications without evidence of adverse interactions: ACE-inhibitors, calcium channel blockers, diuretics, non-steroidal anti-inflammatory drugs including aspirin, and hormones (e.g. estrogen, insulin, thyroxine).

However, the potential exists for additive effects and production of hypotension and/or marked bradycardia when timolol maleate ophthalmic solution is administered together with oral calcium channel blockers, catecholamine-depleting drugs or beta-adrenergic blocking agents.

Potentiated systemic beta-blockade (e.g. decreased heart rate, depression) has been reported during combined treatment with CYP2D6 inhibitors (e.g. quinidine, selective serotonin uptake inhibitors) and timolol.

The dorzolamide component of COSOPT® is a carbonic anhydrase inhibitor and although administered topically, is absorbed systemically. In clinical studies, dorzolamide hydrochloride ophthalmic solution was not associated with acid-base disturbances. However, these disturbances have been reported with oral carbonic anhydrase inhibitors and have in some instances, resulted in interactions (e.g. toxicity associated with high-dose salicylate therapy). Therefore, the potential for such interactions should be considered in patients receiving COSOPT®.

Oral beta-adrenergic blocking agents may exacerbate the rebound hypertension which can follow the withdrawal of clonidine.

PREGNANCY AND LACTATION

The safety of this medicine in pregnant and lactating woman has not been established (see **CONTRA-INDICATIONS, Pregnancy**).

It is not known whether dorzolamide hydrochloride is excreted in human milk. Timolol maleate does appear in human milk. Because of the potential for serious adverse reactions on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug.

DOSAGE AND DIRECTIONS FOR USE

The dose is one drop of COSOPT® in the affected eye(s) two times daily.

When substituting COSOPT® for another ophthalmic antiglaucoma agent(s), discontinue the other agent(s) after proper dosing on one day, and start COSOPT® on the next day.

If another topical ophthalmic agent is being used, COSOPT® and the other agent should be administered at least ten minutes apart.

Safety and efficacy in paediatric patients below the age of 2 years have not been established. Although COSOPT® has been used in children 2 to 6 years of age, however data on safety and efficacy are insufficient to recommend a safe and effective dose (see **Paediatric Use**).

SIDE EFFECTS

During clinical studies, 1 035 patients were treated with COSOPT®. Approximately 2,4 % of all patients discontinued therapy with COSOPT® because of local ocular adverse reactions, approximately 1,2 % of all patients discontinued because of local adverse reactions suggestive of allergy or hypersensitivity.

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

[Very Common: (greater than 1/10), Common: (greater than 1/100, less than 1/10), Uncommon: (greater than 1/1 000, less than 1/100) and Rare: (greater than 1/10 000, less than 1/1 000)]

*Adverse reactions marked with an asterisk (*) were also observed with COSOPT® during post-marketing experience.

Blood and lymphatic system disorders:

Timolol maleate ophthalmic solution:

Rare: systemic lupus erythematosus

Nervous system and psychiatric disorders:

Dorzolamide hydrochloride ophthalmic solution:

Common: headache

Rare: dizziness, paraesthesia

Timolol maleate ophthalmic solution:

Common: headache

Uncommon: dizziness, depression

Rare: insomnia, nightmares, memory loss, paraesthesia, increase in signs and symptoms of myasthenia gravis, decreased libido, cerebrovascular accident

Eye disorders:

COSOPT®:

Very Common: burning and stinging

Common: conjunctival injection, blurred vision, corneal erosion, ocular itching, tearing

Dorzolamide hydrochloride ophthalmic solution:

Common: eyelid inflammation, eyelid irritation, superficial punctuate keratitis

Uncommon: iridocyclitis

Rare: eyelid crusting, transient myopia (which resolved upon discontinuation of therapy), choroidal detachment (following filtration surgery)*, signs and symptoms of local reactions including palpebral reaction

Timolol maleate ophthalmic solution:

Common: signs and symptoms of ocular irritation including blepharitis, keratitis, decreased corneal sensitivity, dry eyes, conjunctivitis

Uncommon: visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases)

Rare: ptosis, diplopia, choroidal detachment (following filtration surgery)*

Ear and labyrinth disorders:

Timolol maleate ophthalmic solution:

Rare: tinnitus

Cardiac and vascular disorders:

Timolol maleate ophthalmic solution:

Uncommon: bradycardia*, syncope

Rare: hypotension, chest pain, palpitation, edema, arrhythmia, congestive heart failure, heart block*, cardiac arrest, cerebral ischaemia, claudication, Raynaud's phenomenon, cold hands and feet

Respiratory, thoracic, and mediastinal disorders:

COSOPT®:

Rare: respiratory failure*

Dorzolamide hydrochloride ophthalmic solution:

Rare: epistaxis

Timolol maleate ophthalmic solution:

Uncommon: dyspnoea*

Rare: bronchospasm (predominantly in patients with pre-existing bronchospastic disease), cough

Gastro-intestinal disorders:

COSOPT®:

Very Common: taste perversion

Dorzolamide hydrochloride ophthalmic solution:

Common: nausea*

Rare: dry mouth

Timolol maleate ophthalmic solution:

Uncommon: nausea*, dyspepsia

Rare: diarrhoea, dry mouth

Skin and subcutaneous tissue disorders:

COSOPT®:

Rare: contact dermatitis*

Dorzolamide hydrochloride ophthalmic solution:

Rare: rash

Timolol maleate ophthalmic solution:

Rare: alopecia, psoriasiform rash or exacerbation of psoriasis

Renal disorders:

COSOPT®:

Uncommon: urolithiasis

Reproductive system and breast disorders:

Timolol maleate ophthalmic solution:

Rare: Peyronie's disease

General disorders and administration site disorders:

Dorzolamide hydrochloride ophthalmic solution:

Common: asthenia/fatigue

Rare: systemic allergic reactions including angio-oedema, urticaria, bronchospasm and pruritus

Timolol maleate ophthalmic solution:

Uncommon: asthenia/fatigue

Rare: signs and symptoms of allergic reactions including anaphylaxis, angioedema, urticaria, localised and generalised rash

Laboratory Findings

COSOPT® was not associated with clinically meaningful electrolyte disturbances.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

No data is available with regard to human overdosage by accidental or deliberate ingestion of COSOPT®.

There have been reports of inadvertent overdosage with timolol maleate ophthalmic solution resulting in systemic effects similar to those seen with systemic beta-adrenergic blocking agents such as dizziness, headache, shortness of breath, bradycardia, bronchospasm, and cardiac arrest. The most common signs and symptoms to be expected with overdosage of dorzolamide are electrolyte imbalance, development of an acidotic state, and possibly central nervous system effects (see **SIDE EFFECTS**).

Treatment should be symptomatic and supportive. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored. Studies have shown that timolol does not dialyse readily.

IDENTIFICATION

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

PRESENTATION

COSOPT® Ophthalmic Solution is available in containers containing 5 ml solution.

The OCUMETER™ Plus Ophthalmic Dispenser consists of a translucent, high density polyethylene container with a sealed dropper tip, a flexible fluted side area which is depressed to dispense the drops, and a 2-piece cap assembly. The opaque, white, 2-piece cap mechanism punctures the dropper tip seal upon initial use, then locks to provide a single cap during the usage period. Tamper evidence is provided by a safety strip on the container label.

STORAGE INSTRUCTIONS

Store at or below 30 ºC. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

DO NOT USE MORE THAN 30 DAYS AFTER OPENING.

REGISTRATION NUMBER

South Africa: S3

32/15.4/0525

Namibia: NS2

04/15.4/1161

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

COSOPT® Ophthalmic Solution

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 or your pharmacist.
- 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.

1. 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, water for injection.

2. WHAT COSOPT® IS USED FOR

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.

3. 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®,
- if you have asthma or have ever had asthma,
- if you have chronic obstructive lung disease,
- if you have certain heart diseases,
- if you are allergic to dorzolamide or timolol or any of the other ingredients of COSOPT®.

If you are not sure whether you should use COSOPT®, contact your doctor or pharmacist.

Take special care with COSOPT®

Tell your doctor (or pharmacist) about any medical problems you have now or have had in the past, especially asthma and other lung problems or heart problems, and about any allergies to any medications.

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

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.

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Use in pregnancy

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

Use in breast-feeding

Do not use COSOPT® while breast-feeding. If you intend to breast-feed, consult your doctor.

Use in patients with significant kidney or liver impairment

Tell your doctor if you now have or have had in the past kidney or liver problems.

Driving and using machinery

There are side effects associated with COSOPT® that may affect your ability to drive and/or operate machinery (see **POSSIBLE SIDE EFFECTS**).

Important information about some of the ingredients of COSOPT®

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.

Taking other medicines with COSOPT®

Always tell your healthcare professional if you are taking any other medicine. (This includes 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.

4. HOW TO USE COSOPT®

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

Always take COSOPT® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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.

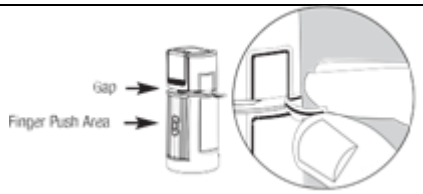
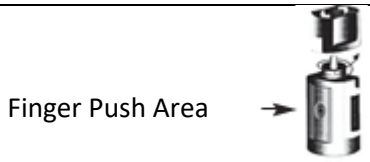
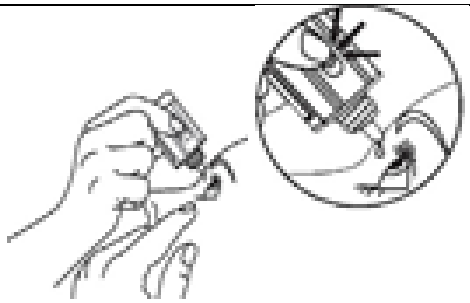
If you are using COSOPT® with another eye drop, the drops should be instilled at least 10 minutes apart.

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. 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.	
7. Repeat steps 4 and 5 with the other eye if instructed to do so by your doctor.	
8. 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.	
9. The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.	
10. 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 use 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 control 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 the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

COSOPT® can have side effects.

Not all side effects reported for COSOPT® are included in this leaflet. Should your general health worsen or if you experience any untoward side effects while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Very Frequent:

- burning and stinging of the eyes
- bitter taste in the mouth.

Frequent:

- blurred vision,
- itchy eyes,
- tearing,
- redness of the eye(s).

Less Frequent:

- slowing of your heart rate,
- shortness of breath,
- visual changes.

Rare:

- irregular heartbeat.

Ask your doctor or pharmacist for more information about side effects. Both have a more complete list of side effects. Please tell your doctor (or pharmacist) about any of these side effects or any other unusual symptoms.

6. STORING AND DISPOSING OF COSOPT®

Store all medicines out of reach of children.

Store COSOPT® at or below 30 ºC. Protect from light.

Do not use this medicine after the month and year following EXP 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 the sewerage system (e.g. toilets).

7. PRESENTATION OF COSOPT®

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

8. IDENTIFICATION OF COSOPT®

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

9. REGISTRATION NUMBERS

South Africa: S3

32/15.4/0525

Namibia: NS2

04/15.4/1161

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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