

SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM

TIMOPTOL® 0,25 % Ophthalmic Solution

TIMOPTOL® 0,5 % Ophthalmic Solution

COMPOSITION

TIMOPTOL® 0,25 % Ophthalmic Solution: Each ml contains 2,5 mg of timolol base (present as timolol maleate) and 0,10 mg benzalkonium chloride (0,01 % *m/v*) as preservative.

TIMOPTOL® 0,5 % Ophthalmic Solution: Each ml contains 5,0 mg of timolol base (present as timolol maleate) and 0,10 mg benzalkonium chloride (0,01 % *m/v*) as preservative.

PHARMACOLOGICAL CLASSIFICATION

A.15.4 Ophthalmic Preparations, other.

PHARMACOLOGICAL ACTION

Timolol maleate ophthalmic solution reduces elevated and normal intraocular pressure whether or not associated with glaucoma. Onset of action of timolol maleate is usually rapid, occurring approximately 20 minutes after topical application to the eye. Maximum reduction of intraocular pressure occurs in 1 to 2 hours. Significant lowering of intraocular pressure has been maintained for as long as 24 hours with 0,25 % or 0,50 % timolol maleate ophthalmic solution.

Timolol maleate is a non-selective beta-adrenergic receptor blocking agent that does not have significant intrinsic sympathomimetic, direct myocardial depressant or local anaesthetic (membrane stabilising) activity.

The precise mechanism of action of timolol maleate in lowering intraocular pressure is not clearly established at this time, although a fluorescein study and tonography studies indicate that its predominant action may be related to reduced aqueous formation.

However, in some studies a slight increase in outflow facility was also observed. Timolol maleate reduces intraocular pressure with little or no effect on accommodation or pupil size.

INDICATIONS

TIMOPTOL® ophthalmic solution is indicated for the reduction of elevated intraocular pressure in:

- patients with ocular hypertension
- patients with chronic open-angle glaucoma
- aphakic patients with glaucoma
- some patients with secondary glaucoma

Patients with narrow angles and a history of spontaneous or iatrogenically induced narrow-angle closure in the opposite eye, in whom reduction of intraocular pressure is necessary (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

TIMOPTOL® is also indicated as concomitant therapy in patients with paediatric glaucoma, who are inadequately controlled with other anti-glaucoma therapy.

CONTRA-INDICATIONS

Sinus bradycardia, sino-arterial block, second- or third-degree atrioventricular block, overt cardiac failure, cardiogenic shock.

Reactive airway disease, bronchial asthma or with a history of bronchial asthma, or severe chronic obstructive pulmonary disease.

Hypersensitivity to TIMOPTOL® ophthalmic solution.

WARNINGS AND SPECIAL PRECAUTIONS

As the possibility of adverse effects on the 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.

Particular caution should be exercised with patients suffering from the following: Asthma, bronchitis, chronic respiratory diseases, second- and third-degree heart block and sinus bradycardia less than 50 per minute, peripheral vascular diseases and Raynaud's phenomenon.

In the peri-operative period it is generally unwise to reduce the dosage.

A patient's normal tachycardiac response to hypovolaemia or blood loss may be obscured during or after surgery. Particular caution should be taken in this regard.

TIMOPTOL® ophthalmic solution may be absorbed systemically.

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

The same adverse reactions found with systemic administration of beta-adrenergic blocking agents may occur with topical administration.

Cardio-Respiratory Reactions

TIMOPTOL® ophthalmic solution should be used with caution in patients with known contra-indications to systemic use of beta-adrenergic receptor blocking agents. These include sinus bradycardia and greater than first-degree heart block, cardiogenic shock, diabetes, especially labile diabetes.

Cardiac failure should be adequately controlled before beginning therapy with TIMOPTOL®. In patients with a history of severe cardiac disease, signs of cardiac failure should be watched for and pulse rates should be checked.

Due to its negative effect on conduction time, beta blockers should be given with caution to patients with first-degree heart block.

In patients with mild/moderate chronic obstructive pulmonary disease (COPD), TIMOPTOL® should be used with caution, and only if the potential benefit outweighs the potential risk.

Vascular disorders

Patients with severe peripheral circulatory disturbance/disorders (e.g. severe forms of Raynaud's disease or Raynaud's syndrome) should be treated with caution.

Masking of hypoglycemic symptoms in patients with Diabetes Mellitus

Beta-adrenergic blocking agents should be administered with caution in patients subject to spontaneous hypoglycemia or to diabetic patients (especially those with labile diabetes) who are receiving insulin or oral hypoglycemic agents. Beta-adrenergic blocking agents may mask the signs and symptoms of acute hypoglycemia.

Masking of Thyrotoxicosis

Beta-adrenergic blocking agents may mask certain clinical signs of hyperthyroidism (e.g., tachycardia). Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta-adrenergic blocking agents which might precipitate a thyroid storm.

Surgical anaesthesia

The necessity or desirability of withdrawal of beta-adrenergic blocking agents prior to major surgery is controversial. If necessary during surgery, the effects of beta-adrenergic blocking agents may be reversed by sufficient doses of adrenergic agonists.

Other

Patients who are already receiving a beta-adrenergic receptor blocking agent systemically and who are given TIMOPTOL® should be observed for a potential additive effect, either on the intraocular pressure or on the known systemic effects of beta blockade.

In patients with angle-closure glaucoma, the immediate objective of treatment is to reopen the angle. This requires constricting the pupil with a miotic. TIMOPTOL® has little or no effect on the pupil. When TIMOPTOL® is used to reduce elevated intraocular pressure in angle-closure glaucoma it should be used with a miotic and not alone.

The preservative in TIMOPTOL® may be deposited in soft contact lenses; therefore TIMOPTOL® should not be used while wearing these lenses. The lenses should be removed before application of the drops and not be reinserted earlier than 15 minutes after use.

Risk from Anaphylactic Reaction

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

INTERACTIONS

Although TIMOPTOL® used alone has little or no effect on pupil size, mydriasis resulting from concomitant therapy with TIMOPTOL® and adrenaline has been reported.

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

The potential exists for additive effects and production of hypotension and/or marked bradycardia when TIMOPTOL® is administered together with an oral calcium entry blocker, catecholamine-depleting medicines, antiarrhythmics, parasympathomimetics, or beta-adrenergic blocking agents.

While no side effects of the oculo-cutaneous syndrome type have been described with this product, the possibility of their development with prolonged usage has not been excluded, and regular ophthalmic examination is required.

TIMOPTOL® should be administered with care in patients suffering from myasthenia gravis. Deterioration in myasthenia has been reported after application of the ophthalmic solution.

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

Special note

Digitalisation of patients receiving long-term TIMOPTOL® therapy may be necessary if congestive cardiac failure is likely to develop. This combination can be considered despite the potentiation of negative chronotropic effect of the two medicines. Careful control of dosages and of the individual patient's response (and notably pulse rate) is essential in this situation.

Abrupt discontinuation of therapy may cause exacerbation of angina pectoris in patients suffering from ischaemic heart disease.

Discontinuation of therapy should be gradual, and patients should be advised to limit the extent of their physical activity, during the period that the medicine is being discontinued.

Patients with pheochromocytoma usually require treatment with an alpha-adrenergic blocker.

PREGNANCY AND LACTATION

Use in Pregnancy

Safety in pregnancy has not been established. The use of TIMOPTOL® requires that the anticipated benefit be weighed against possible hazards.

Nursing Mothers

TIMOPTOL® is detectable in human milk. Because of the potential for serious adverse reactions from TIMOPTOL® in infants, a decision should be made whether to discontinue nursing or to discontinue the medicine, taking into account the importance of the medicine to the mother.

DOSAGE AND DIRECTIONS FOR USE

The usual starting dose is one drop of 0,25 % solution in the affected eye(s) twice a day.

If clinical response is not adequate, dosage may be changed to one drop of 0,5 % solution in each affected eye twice a day.

If needed, concomitant therapy with other agent(s) for lowering intraocular pressure may be given with TIMOPTOL®. The use of two topical beta-adrenergic blocking agents is not recommended (see "WARNINGS AND SPECIAL PRECAUTIONS").

Since in some patients the pressure-lowering response to TIMOPTOL® may require a few weeks to stabilise, evaluation should include a determination of intraocular pressure after approximately 4 weeks of treatment with TIMOPTOL®.

If the intraocular pressure is maintained at satisfactory levels, many patients can be placed on once-a-day therapy. Because of naturally occurring diurnal variations in intraocular pressure, satisfactory response is best determined by measuring the intraocular pressure at different times during the day.

When using nasolacrimal occlusion or closing the eyelids for 2 minutes, the systemic absorption is reduced. This may result in an increase in local activity.

How to transfer patients from other therapy

When a patient is transferred from another topical ophthalmic beta-adrenergic blocking agent, that agent should be discontinued after proper dosing on one day and treatment with TIMOPTOL® started on the following day with one drop of 0,25 % TIMOPTOL® in

the affected eye twice a day. The dose may be increased to one drop of 0,5 % TIMOPTOL® twice a day if the clinical response is not adequate.

When a patient is transferred from a single anti-glaucoma agent, continue the agent already being used and add one drop of 0,25 % TIMOPTOL® in each affected eye twice a day. On the following day, discontinue the previously used anti-glaucoma agent completely and continue with TIMOPTOL®. If a higher dose of TIMOPTOL® is required, substitute one drop of 0,50 % solution in each affected eye twice a day.

Use in Children

The usual starting dose is one drop of 0,25 % TIMOPTOL® in the affected eye(s) every 12 hours, in addition to other anti-glaucoma medication. The dosage may be increased to one drop of 0,5 % solution in the affected eye(s) every 12 hours if necessary. The use of TIMOPTOL® is not recommended in premature infants or neonates.

SIDE EFFECTS

TIMOPTOL® ophthalmic solution is usually well tolerated. The following adverse reactions have been reported with ocular administration of this or other timolol maleate formulations, either in clinical trials or since the medicine has been marketed.

Very Common: ($\geq 1/10$), Common: ($\geq 1/100$, $< 1/10$), Uncommon: ($\geq 1/1\ 000$, $< 1/100$), and Rare: ($\geq 1/10\ 000$, $< 1/1\ 000$)

Blood and lymphatic system disorders

Rare: Systemic lupus erythematosus

Nervous system and psychiatric disorders

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

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

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

Rare: Tinnitus

Cardiac and vascular disorders

Uncommon: Bradycardia, syncope

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

Respiratory, thoracic, and mediastinal disorders

Uncommon: Dyspnoea

Rare: Bronchospasm (predominantly in patients with pre-existing bronchospastic disease), respiratory failure, cough

Gastrointestinal disorders

Uncommon: Nausea, dyspepsia

Rare: Diarrhoea, dry mouth

Unknown: Abdominal pain

Skin and subcutaneous tissue disorders

Rare: Alopecia, psoriasiform rash or exacerbation of psoriasis

Renal disorders

None reported

Reproductive system and breast disorders

Rare: Peyronie's disease

General disorders and administration site disorders

Uncommon: Asthenia/fatigue

Rare: Signs and symptoms of allergic reactions including anaphylaxis, angiooedema, urticaria, localised and generalised rash

Urogenital

Unknown: Sexual dysfunction

Musculoskeletal

Unknown: Myalgia

Respiratory reactions and cardiac reactions, including death due to bronchospasm in cardiac failure have been reported following administration of TIMOPTOL®. The frequency of these events has not been determined.

Aphakic cystoid macular oedema, nasal congestion, anorexia, CNS effects (e.g. behavioural changes including confusion, hallucinations, anxiety, disorientation, nervousness, somnolence, and other psychic disturbances), hypertension, retroperitoneal fibrosis and pseudo pemphigoid have been reported, although a causal relationship to TIMOPTOL® has not been established.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

The most common signs and symptoms to be expected with overdosage with administration of a systemic beta-adrenergic receptor blocking agent are symptomatic bradycardia, hypotension, bronchospasm and acute cardiac failure.

The following therapeutic measures should be considered:

1. **Gastric lavage:** If ingested. Studies have been shown that timolol does not dialyse readily.
2. **Symptomatic bradycardia:** Use atropine sulphate intravenously in a dosage of 0,25 to 2 mg to induce vagal blockade. If bradycardia persists, intravenous isoproterenol hydrochloride should be administered cautiously. In refractory cases the use of a transvenous cardiac pacemaker may be considered.
3. **Hypotension:** Use sympathomimetic pressor medicine therapy, such as dopamine, dobutamine or levarterenol. In refractory cases the use of glucagon hydrochloride has been reported to be useful.
4. **Bronchospasm:** Use isoproterenol hydrochloride. Additional therapy with aminophylline may be considered.
5. **Acute cardiac failure:** Conventional therapy with digitalis, diuretics and oxygen should be instituted immediately. In refractory cases the use of intravenous aminophylline is suggested. This may be followed if necessary by glucagon hydrochloride which has been reported to be useful.
6. **Heart block (second- or third-degree):** Use isoproterenol hydrochloride or a transvenous cardiac pacemaker.

IDENTIFICATION

TIMOPTOL® Ophthalmic Solution is a colourless to light yellow, clear aqueous solution.

The label on the cap of the TIMOPTOL® 0,25 % Ocumeter™ is pink and that of the TIMOPTOL® 0,5 % Ocumeter™ is lilac.

PRESENTATION

TIMOPTOL® Ophthalmic Solution is supplied in Ocumeter™ bottles containing 5 ml solution.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light.

Keep out of reach of children.

DO NOT USE MORE THAN 30 DAYS AFTER OPENING.

REGISTRATION NUMBERS

South Africa 

TIMOPTOL® 0,25 %: K/15.4/339

TIMOPTOL® 0,5 %: K/15.4/340

Namibia 

TIMOPTOL® 0,25 %: 13/15.4/0007

Botswana 

TIMOPTOL® 0,25 %: B9316020

TIMOPTOL® 0,5 %: B9315915

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

Mundipharma (Pty) Ltd
Block D, Grosvenor Square
Park Lane, Century City
Cape Town
7441
South Africa
www.mundipharma.co.za

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15 January 2009

DATE OF REVISION OF THE TEXT

23 November 2019

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OCUMETER™ (TM): OCUMETER is a Trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., U.S.A., used under license.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TIMOPTOL® 0,25 % Ophthalmic Solution

TIMOPTOL® 0,5 % Ophthalmic Solution

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- TIMOPTOL® 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 TIMOPTOL® CONTAINS

Timoptol® is a sterile eye drop.

Each ml of solution contains either 2,5 mg or 5 mg of timolol as the active ingredient.

The other ingredients are: sodium hydroxide, sodium phosphate dibasic anhydrous, sodium phosphate monobasic and water for injection. Benzalkonium chloride is added as preservative.

2. WHAT TIMOPTOL® IS USED FOR

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

Elevated pressure in the eye may damage the optic nerve resulting in deterioration of vision and possible blindness. There are generally 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 TIMOPTOL®

Do not use TIMOPTOL®

- If you are hypersensitive (allergic) to timolol or any of the other ingredients of TIMOPTOL®
- If you have now or have had certain serious breathing problems such as asthma
- If you have chronic obstructive lung disease
- If you have certain heart problems (such as slow or irregular heartbeats)

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

Take special care with TIMOPTOL®

Tell your doctor about any medical problems you have now or have had in the past:

- Heart problems (such as coronary heart disease, heart failure or low blood pressure)
- Heart rate disturbances (such as slow or irregular heartbeats)
- Poor blood circulation problems (such as Raynaud's syndrome)
- Lung or breathing problems (such as asthma or chronic obstructive lung disease)
- Diabetes or other blood sugar problems
- Thyroid disease

Tell your doctor before you have an operation that you are using TIMOPTOL®, as it may change the effect of some medicines during anaesthesia.

Also tell your doctor if you have allergies to any medications.

If you suspect that TIMOPTOL® is causing an allergic reaction (e.g. skin rash or redness and itching of the eye), stop its use and contact your doctor at once.

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 TIMOPTOL®.

PREGNANCY AND BREASTFEEDING

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Use in Pregnancy

Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will decide if you should use TIMOPTOL®.

Use in Breastfeeding

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

Use in children

TIMOPTOL® may be used in children, if prescribed by your doctor, but is not recommended in newborns and infants. The usual dosage in children is one drop of TIMOPTOL® 0,25 % or 0,5 % (whichever your doctor prescribes) every 12 hours in the affected eye(s).

Driving and using machinery

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

Taking other medicines with TIMOPTOL®

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, diabetes or depression.

Important information about some of the ingredients of TIMOPTOL®

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

4. HOW TO USE TIMOPTOL®

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

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

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

Your doctor will establish the appropriate dose and duration of treatment.

The usual starting dose is one drop of 0,25 % TIMOPTOL® in the affected eye(s) in the morning and in the evening. If your response is not adequate, your doctor may increase the dosage to one drop of TIMOPTOL® 0,5 % in the affected eye(s) in the morning and in the evening.

For some patients, if pressure in the eye is maintained at satisfactory levels, your doctor may prescribe TIMOPTOL® to be used once a day.

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

In some cases, your doctor may prescribe another medication, including other eye drops, to use with TIMOPTOL® to help lower the pressure in your eye(s).

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 infection 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 this medicine 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.

Opening Arrows ▶

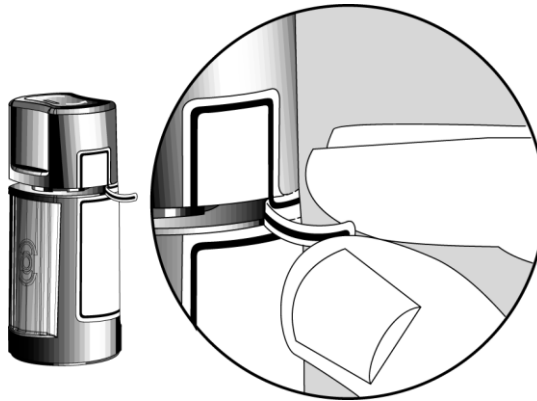
Safety Strip ▶



2. Tear off the Safety Strip to break the seal.

Gap ▶

Finger Push Area ▶

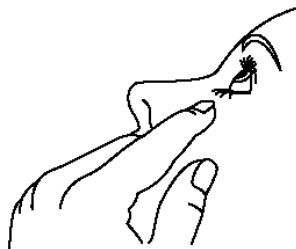


3. To open the bottle, unscrew the cap by turning as indicated by the arrows on the top of the cap. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent the dispenser from operating properly.

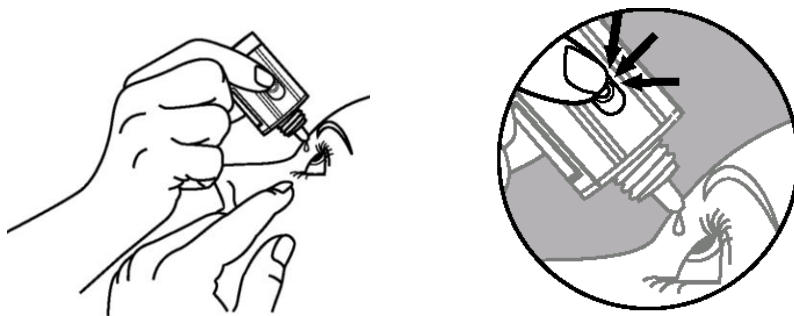
Finger Push Area ▶



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 medicine such as TIMOPTOL[®], 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 medicines. If you think your medicine may be contaminated or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

6. After using TIMOPTOL[®], press a finger into the corner of your eye, by the nose (as shown) for 2 minutes. This helps keep TIMOPTOL[®] 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 OVER TIGHTEN), and then remove by turning the cap in the opposite direction as indicated by the arrows on the top of the cap.
8. Repeat steps 4 & 5 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 TIMOPTOL[®] left in the bottle. You should not be concerned since an extra amount of TIMOPTOL[®] has been added and you will get the full amount of TIMOPTOL[®] that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

If you use more TIMOPTOL[®] than you should

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.

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

If you forget to use TIMOPTOL[®]

Use TIMOPTOL[®] 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.

5. POSSIBLE SIDE EFFECTS

TIMOPTOL[®] may have unintended or undesirable effects, so-called side effects. Although not all these side effects may occur, if they do occur, you may need medical attention.

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

You may experience eye irritation, such as burning and stinging, dry eyes, redness of the eye, or visual changes such as double vision. In addition, the following side effects may occur: Ringing in your ears, headache, tiredness, dizziness, depression, insomnia, nightmares, memory loss, tingling, nausea, diarrhoea, upset stomach, dry mouth, chest pain, fainting, palpitations, irregular heartbeat, a slowing of your heart rate, swelling or coldness of your hands and feet, shortness of breath, cough, hair loss, rash, itching or other more severe allergic-type reactions, muscle pain, sexual dysfunction, and less desire to have sex.

Other side effects may also occur rarely, and some of these may be serious. 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 or any other unusual symptoms.

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

6. STORING AND DISPOSING OF TIMOPTOL®

Store all medicines out of reach of children.

Store TIMOPTOL® at or below 25 °C. Protect from light.

Do not use this medicine after the month and year following EXP: on the label of 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).

7. PRESENTATION OF TIMOPTOL®

TIMOPTOL® Ophthalmic Solution is supplied in Ocumeter™ containers containing 5 ml solution.

8. IDENTIFICATION OF TIMOPTOL®

TIMOPTOL® Ophthalmic Solution is a colourless to light yellow, clear aqueous solution.

The label on the cap of the TIMOPTOL® 0,25 % is pink and that of the TIMOPTOL® 0,5 % is lilac.

9. REGISTRATION NUMBERS

South Africa S3

TIMOPTOL® 0,25 %: K/15.4/339

TIMOPTOL® 0,5 %: K/15.4/340

Namibia NS2

TIMOPTOL® 0,25 %: 13/15.4/0007

Botswana S2

TIMOPTOL® 0,25 %: B9316020

TIMOPTOL® 0,5 %: B9315915

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

Mundipharma (Pty) Ltd
Block D, Grosvenor Square
Park Lane, Century City,
Cape Town
7441
South Africa
www.mundipharma.co.za

11. THIS LEAFLET WAS LAST REVISED IN

23 November 2019

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