PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

TIMOPTOL® 0,5 % Ophthalmic Solution

Active substance(s)

Timolol

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, pharmacist, nurse or other health care provider.
- 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.

What is in this leaflet

1. What TIMOPTOL® is and what it is used for
2. What you need to know before you use TIMOPTOL®
3. How to use TIMOPTOL®
4. Possible side effects
5. How to store TIMOPTOL®
6. Contents of the pack and other information

1. What TIMOPTOL® is and what it is used for

TIMOPTOL® is a sterile eye drop containing timolol as the active ingredient.

Each milliliter of TIMOPTOL 0,5 % contains 5 mg timolol as the active ingredient.

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.

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

Do not use TIMOPTOL®

- if you are hypersensitive (allergic) to timolol or any of the other ingredients of TIMOPTOL® (listed in section 6);
- if you have now or have had in the past certain 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.

Warnings and precautions

Tell your doctor about any medical problems you have now or have had in the past, and about any allergies to any medications.

Take special care with TIMOPTOL® if you have:

- 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 effects 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 (for example, 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®.

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 older than 3 years of age is one drop of TIMOPTOL® 0,5 % every 12 hours in the affected eye(s).

Other medicines and TIMOPTOL®

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, diabetes or depression.

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®.

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

Do not use TIMOPTOL® if you are pregnant. Tell your doctor if you are pregnant or intend to become pregnant. The safety of this medicine in pregnant and lactating women has not been established.

Breastfeeding

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

Driving and using machines

There are side effects associated with TIMOPTOL® that may affect your ability to drive or operate machinery (see Section 4).

3. How to use TIMOPTOL®

Do not share medicines prescribed for you with any other person.
Always use TIMOPTOL® exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

The usual dose is 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.

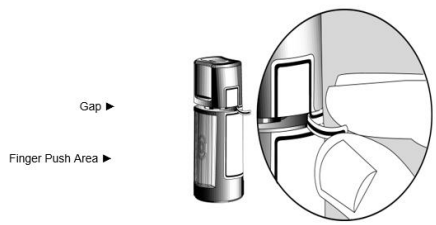
Do not change the dose of the medicine without consulting your doctor. If you must stop treatment, contact your doctor immediately.

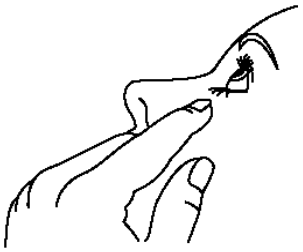
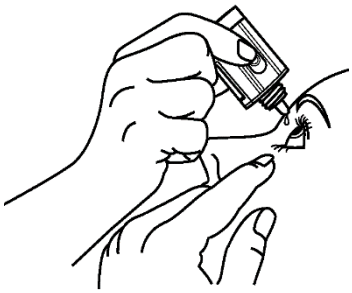
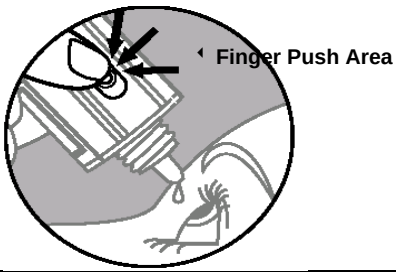
In some cases, your doctor may prescribe another medication, including other eye drops, to use with TIMOPTOL® to help lower the pressure in your eye(s).

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

Instructions for use

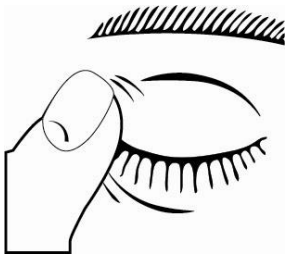
Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from contact with any surface.

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. When opening the bottle for the first time, do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your container 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 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 medications. 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 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 and 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 excess medicine from the bottle	

If you use more TIMOPTOL® than you should

If you put too many drops in your eye or swallow the contents of the bottle of TIMOPTOL®, 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 an overdosage, 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 take a double dose to make up for forgotten individual doses.

If you stop using TIMOPTOL®

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

4. Possible side effects

TIMOPTOL® can have side effects.

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.

Serious side effects

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

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TIMOPTOL®. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Headache;

- eye irritation, such as burning and stinging, redness of the eye;
- dry eyes.

Less frequent side effects

- A condition called lupus (systemic lupus erythematosus);
- palpitations, irregular heartbeat, a slowing of your heart rate;
- swelling or coldness of your hands and feet;
- shortness of breath, cough, chest pain;
- depression, insomnia, nightmares;
- memory loss, tingling, dizziness, fainting;
- visual changes such as double vision;
- ringing in your ears;
- tiredness;
- nausea, diarrhoea, upset stomach, dry mouth;
- hair loss;
- less desire to have sex.

Frequency not known

- itching or other more severe allergic-type reactions;
- hallucination, decreased concentration, increased dreaming
- blurred vision, corneal erosion (damage to the front layer of the eyeball);
- heart failure;
- taste disturbances, vomiting;
- stomach pain;
- muscle pain;
- sexual dysfunction (impotence);
- difficulty in passing urine;
- low blood sugar levels, high blood sugar levels.

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TIMOPTOL®. Alternatively report to the following e-mail address: ZADrugsafety@mundipharma.co.za

5. How to store TIMOPTOL®

- Store all medicines out of reach of children.
- Store 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).

6. Contents of the pack and other information

What TIMOPTOL® contains

- The active substance is timolol.
- Each ml of TIMOPTOL® 0,5 % contains 5 mg timolol.
- The other ingredients are sodium hydroxide, sodium phosphate dibasic anhydrous, sodium phosphate monobasic and water for injection. Benzalkonium chloride is added as preservative (0,01 % *m/v*).

What TIMOPTOL® looks like and contents of the pack

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

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

The label on the cap of the TIMOPTOL® 0,5 % is lilac.

Holder of Certificate of Registration

Mundipharma (Pty) Ltd

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Cape Town

7441

This leaflet was last revised in

6 December 2022

Registration number

South Africa S3

TIMOPTOL® 0,5 %: K/15.4/340

Botswana S2

TIMOPTOL® 0,5 %: B9315915

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

TIMOPTOL® (R): TIMOPTOL is a Registered Trademark of Mundipharma.

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