PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

TIMOPTOL-XE® 0,50 % Sterile Ophthalmic Gellan Solution

Active substance(s)

Timolol

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

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

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

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

Each millilitre of TIMOPTOL-XE® 0,5% contains 5 mg timolol as the active ingredient.

TIMOPTOL-XE® is a beta-blocking medicine that is prescribed to lower raised pressure in the eye and to treat glaucoma.

If you want to learn more about TIMOPTOL-XE® and increased eye pressure or glaucoma, you may obtain further information from your doctor or pharmacist, who has more detailed information about TIMOPTOL-XE® and your eye condition.

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

Do not use TIMOPTOL-XE®

- if you are hypersensitive (allergic) to timolol or any of the other ingredients of TIMOPTOL-XE® (listed in section 6)
- if you have now or have had in the past certain breathing problems such as asthma or chronic obstructive lung disease
- if you have certain heart problems (such as slow or irregular heartbeats, or heart failure)
- if you have advanced peripheral arterial insufficiency (symptoms include painful cramping in your hip, thigh or calf muscles after certain activities, such as walking or climbing stairs)
- if you have Raynaud's Syndrome (symptoms include numbness of fingers and toes)
- if you wear contact lenses

If you are not sure whether you should use TIMOPTOL-XE®, 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-XE® 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-XE®, as it may change the effects of some medicines during your anaesthetic.

If you suspect that TIMOPTOL-XE® is causing an allergic reaction (for example, 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 TIMOPTOL-XE®.

Children and adolescents

Safety and effectiveness in children have not been established.

Other medicines and TIMOPTOL-XE®

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

This is particularly important if you are taking medicine:

- to lower blood pressure (such as calcium channel blockers or beta-blockers)
- to treat heart disease (such as digoxin, diltiazem, verapamil or nifedipine)
- to treat diabetes
- to treat depression (such as fluoxetine or paroxetine)

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-XE® 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-XE® while breastfeeding. If you intend to breastfeed, consult your doctor. If you are using TIMOPTOL-XE® you should not breastfeed your baby.

Driving and using machines

Your vision may be temporarily blurred for 30 seconds to 5 minutes immediately after putting TIMOPTOL-XE® in your eyes. Make sure that your vision is clear before you drive a motor vehicle or operate machinery. There are additional side effects associated with the use of TIMOPTOL-XE® that may affect your ability to drive or operate machinery (see Section 4).

3. How to use TIMOPTOL-XE®

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

Always use TIMOPTOL-XE® 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 starting dose is one drop of TIMOPTOL-XE® 0,5 % in the affected eye(s) once a day.

If your doctor recommends that you use TIMOPTOL-XE® with another eye drop, this other medicine should be administered at least 10 minutes before TIMOPTOL-XE®.

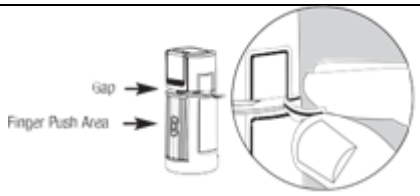
Do not change the dosage recommended by your doctor. If you must stop treatment, consult your doctor immediately.

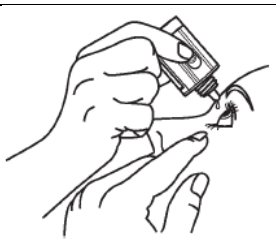
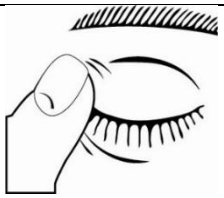
If you have the impression that the effect of TIMOPTOL-XE® is too strong or too weak, talk to your doctor or pharmacist.

Instructions for use

Invert the closed container and shake once before each use. It is not necessary to shake the container more than once.

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. Invert the closed bottle and shake ONCE before each use (it is not necessary to shake the bottle more than once). 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. TIMOPTOL-XE®, 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 TIMOPTOL-XE®, press a finger into the corner of your eye, by the nose (as shown) for 2 minutes. This helps keep TIMOPTOL-XE® 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 direction as indicated by the arrows on 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-XE® left in the bottle. You should not be concerned since an extra amount of TIMOPTOL-XE® has been added and you will get	

the full amount of TIMOPTOL-XE® that your doctor prescribed. Do not attempt to remove excess medicine from the bottle.

If you use more TIMOPTOL-XE® than you should

If you put too many drops in your eye or swallow the contents of the bottle of TIMOPTOL-XE®, among other effects, you may become light-headed, have difficulty breathing or feel that your heart rate has slowed. You should 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-XE®

Use TIMOPTOL-XE® as prescribed by your doctor. If you miss a dose of TIMOPTOL-XE®, 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-XE®

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

4. Possible side effects

TIMOPTOL-XE® can have side effects. Not all side effects reported for TIMOPTOL-XE® are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

Serious side effects

If any of the following happens, stop using TIMOPTOL-XE® 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-XE®. 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, stinging, itching, tearing and redness of the eye
- dry eyes

Less frequent side effects

- a condition called lupus (systemic lupus erythematosus)
- stroke, reduced blood supply to the brain
- 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
- muscle pain
- nausea, diarrhoea, upset stomach, dry mouth
- hair loss
- rash
- less desire to have sex

Frequency not known

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

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-XE®.

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

5. How to store TIMOPTOL-XE®

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light. Avoid freezing.
- Do not use this medicine after the month and year of Expiry on the container.
- Do not use more than 30 days after opening.

- To avoid possible contamination, keep the tip of the container away from contact with any surface.
- 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-XE® contains

TIMOPTOL-XE® is a sterile eye drop. The active substance is timolol.

Each ml of TIMOPTOL-XE® 0,5 % contains 5 mg timolol.

The other ingredients are benzododecinium bromide (0,012 % *m/v*), gellan gum, mannitol, tromethamine, and water for injection. Benzododecinium bromide is added as a preservative.

What TIMOPTOL-XE® looks like and contents of the pack

TIMOPTOL-XE® 0,5 % is a sterile, colourless to nearly colourless, slightly opalescent, slightly viscous, aqueous ophthalmic solution. The label on the cap of the Ocumeter™ container is dark blue.

TIMOPTOL-XE® is supplied in an Ocumeter™ containing 2,5 ml solution.

Holder of Certificate of Registration

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7441

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Registration number

South Africa: S3

TIMOPTOL-XE® 0,50 %: 29/15.4/0231

Namibia: NS2

TIMOPTOL-XE® 0,50 %: 13/15.4/0009

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

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