

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

ⓇTIMOPTIC-XE®
Timolol maleate ophthalmic gellan solution

Read this carefully before you start taking **TIMOPTIC-XE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TIMOPTIC-XE**.

What is TIMOPTIC-XE used for?

TIMOPTIC-XE lowers the pressure in the eye for conditions such as open-angle glaucoma and ocular hypertension.

How does TIMOPTIC-XE work?

The active ingredient timolol maleate is a beta-blocking drug. It helps lower the pressure in the eye.

What are the ingredients in TIMOPTIC-XE?

Medicinal ingredients: timolol maleate.

Non-medicinal ingredients: gellan gum, mannitol, tromethamine and water for injection.
Benzododecinium bromide is added as preservative.

TIMOPTIC-XE comes in the following dosage forms:

TIMOPTIC-XE is a sterile eye drop containing timolol as the active ingredient. This eye drop also contains a new delivery vehicle which is obtained from a natural substance. This vehicle allows the eye drop to form a clear transparent gel when it contacts the eye.

Ophthalmic Gellan Solution TIMOPTIC-XE, equivalent to 5.0 mg (0.5%) timolol per mL; in 2.5 mL, 5 mL and 7.5 mL dispensers, colour-coded with a dark blue label on the cap.

Do not use TIMOPTIC-XE if:

- you are allergic to any of its components (see **What the ingredients in TIMOPTIC-XE** are section above);
- you have now or have had certain serious breathing problems such as asthma or chronic obstructive lung disease;
- you have certain heart diseases or conditions (such as slow or irregular heartbeats);

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TIMOPTIC-XE. Talk about any health conditions or problems you may have, including:

- If you have any medical problems now or have had any in the past, especially asthma and other lung problems, heart problems or poor blood circulation.
- If you have any allergies
- If you have now or have had in the past, thyroid problems.
- If you have or have had in the past, diabetes or other blood sugar problems.
- If you are planning major surgery, including eye surgery, as using TIMOPTIC-XE may

change the effects of some medicines during anesthesia.

- If you had past eye problems such as choroidal detachment.
- If you had problems or develop problems with blood flow to the brain.
- If you are pregnant or intend to become pregnant.
- If you are breast feeding or intend to breast feed. Timolol has been detected in human breast milk.

TIMOPTIC-XE IS NOT RECOMMENDED FOR CHILDREN.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TIMOPTIC-XE:

- Beta-blockers such as atenolol, epinephrine, quinidine,
- Calcium channel blockers or catecholamine depleting drugs such as reserpine.
- Clonidine
- Epinephrine

How to take TIMOPTIC-XE:

Read the following information carefully. **If you need any explanations, or further information, ask your physician or pharmacist.**

- Do not start taking any other medicines unless you have discussed the matter with your physician or pharmacist.
- If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your physician immediately.
- If you are using TIMOPTIC-XE with another eye drop, the drops should be instilled at least 10 minutes apart.
- Do not change the dosage recommended by your physician. If you must stop treatment, contact your physician immediately.
- 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.
- The contents of the container should not be used for more than one month after the date on which the container is first opened.
- Do not administer while wearing (soft) contact lenses. Remove lenses before application and reinsert no earlier than 15 minutes after use. TIMOPTIC-XE contains benzalkonium chloride as a preservative. This preservative may be absorbed by soft contact lenses.

Instructions for use:

Step 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.

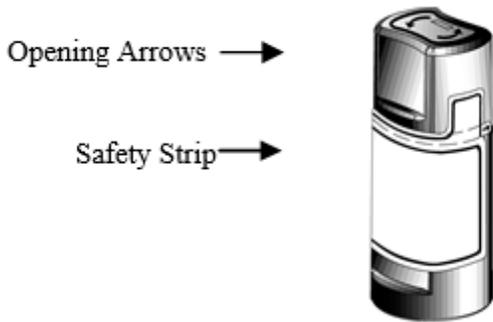


Figure A

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

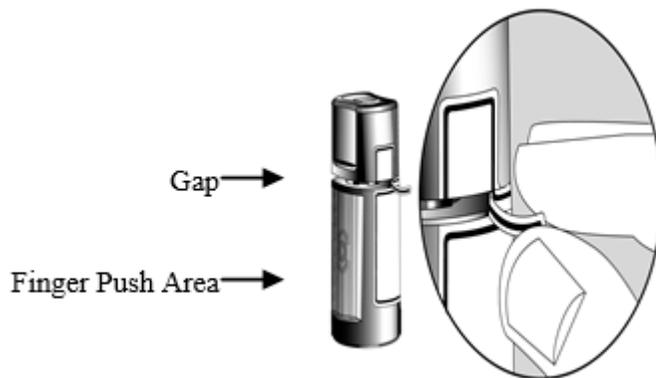


Figure B

Step 3 - Invert the closed bottle and shake ONCE before each use. (It is not necessary to shake the bottle more than once.)

Step 4 - 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.

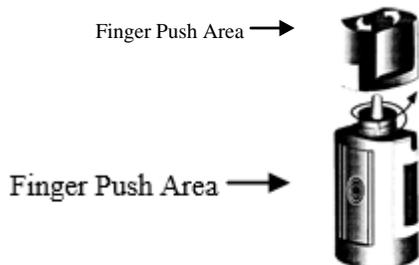


Figure C

Step 5 - Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.



Figure D

Step 6 - 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 physician.

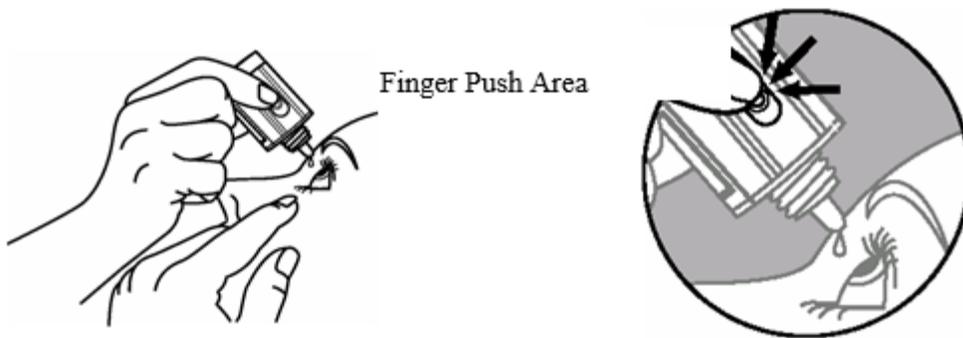


Figure E

Step 7 - After using TIMOPTIC-XE, press a finger into the corner of your eye, by the nose (as shown) for 2 minutes. This helps keep TIMOPTIC-XE in your eye.

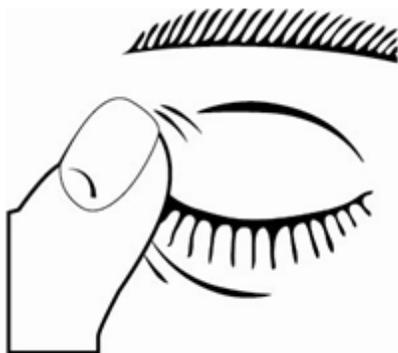


Figure F

Step 8 - 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 the top of the cap.

Step 9 - Repeat steps 5 & 6 with the other eye if instructed to do so by your physician.

Step 10 - Replace the cap by turning until it is firmly touching the bottle. Do not overtighten or you may damage the bottle and cap.

Step 11 - The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.

Step 12 - After you have used all doses, there will be some TIMOPTIC-XE left in the bottle. You should not be concerned since an extra amount of TIMOPTIC-XE has been added and you will get the full amount of TIMOPTIC-XE that your physician prescribed. Do not attempt to remove excess medicine from the bottle.

Usual adult dose:

One drop in the affected eye(s) once a day. Your doctor may change your dose based on your condition.

Overdose:

If you put too many drops in your eye or swallow any of the contents of the bottle, you should contact your physician immediately.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

It is important to apply TIMOPTIC-XE as prescribed by your physician. If you miss a dose, apply 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 double dose.

What are possible side effects from using TIMOPTIC-XE?

These are not all the possible side effects you may feel when taking TIMOPTIC-XE. If you experience any side effects not listed here, contact your healthcare professional.

You may experience:

- muscle pain
- abdominal pain
- nausea
- vomiting
- eye symptoms such as itching, burning and stinging, dry eyes, redness of the eye, foreign body sensation or visual changes, such as double vision.

Other side effects may also occur rarely, and some of these may be serious. These may include shortness of breath.

Timolol has been reported rarely to increase muscle weakness in some patients with myasthenia gravis.

Your vision may be temporarily blurred for 30 seconds to 5 minutes immediately after putting TIMOPTIC-XE in your eye. Make sure that your vision is clear before you drive a motor vehicle or operate machinery.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Slow heartbeat			✓
RARE			
Heart effects such as irregular heartbeat, heart block, low blood pressure			✓
Allergic reactions with symptoms such as swelling of the mouth and throat, shortness of breath, hives, severe itching and rash			✓

This is not a complete list of side effects. For any unexpected effects while taking TIMOPTIC-XE, contact your physician or pharmacist.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

- Store at room temperature 15°C - 25°C.
- Protect from light.
- Avoid freezing.
- Do not use this medicine for more than one month after the container was first opened.
- Keep out of the sight and reach of children.

If you want more information about TIMOPTIC-XE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website <http://www.elvium.ca>, or by calling 1-833-744-0005.

This leaflet was prepared by Elvium Life Sciences.

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