

## IMPORTANT: PLEASE READ

### CONSUMER INFORMATION

## TIMOPTIC-XE®

### timolol maleate ophthalmic gellan solution

This leaflet is part III of a three-part “Product Monograph” published when TIMOPTIC-XE® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TIMOPTIC-XE®. Contact your physician or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

TIMOPTIC-XE® is the brandname for the medication timolol maleate ophthalmic gellan solution. TIMOPTIC-XE® is an ophthalmic solution of a beta-blocking drug which lowers the pressure in the eye for conditions such as glaucoma and ocular hypertension and is only available through a prescription by your physician.

**Remember** - This medicine is prescribed for the particular condition that you have. **Do not give this medicine to other persons, nor use it for any other condition.**

##### What it does:

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

##### When it should not be used:

Do not use TIMOPTIC-XE® if you:

- are allergic to any of its components
- have asthma or have ever had asthma
- have chronic obstructive lung disease
- have certain heart diseases or conditions
- are breast feeding or intend to breast feed.

##### What the medicinal ingredient is:

Timolol maleate.

##### What the important nonmedicinal ingredients are:

gellan gum, mannitol, tromethamine and water for injection. Benzododecinium bromide is added as preservative.

##### What dosage forms it comes in:

TIMOPTIC-XE® is a sterile eye drop containing timolol as the active ingredient. This eyedrop 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 2.5 mg (0.25%) timolol per mL; in 5 mL dispensers, colour-coded with a light blue label on the cap.

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

#### WARNINGS AND PRECAUTIONS

This medicine may not be suitable for some patients. So, tell your physician if you think **any** of the following applies to you:

- If you have any medical problems now or have had any in the past, especially asthma and other lung problems or heart problems;
- If you have any allergies to any medications;
- TIMOPTIC-XE® contains the preservative benzododecinium bromide. If you wear contact lenses, you should consult your physician or pharmacist before using TIMOPTIC-XE®. Do not administer while wearing (soft) contact lenses. Remove lenses before application and reinsert no earlier than 15 minutes after use.
- If you had past thyroid problems.
- 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. Discuss with your physician.

#### TIMOPTIC-XE® IS NOT RECOMMENDED FOR CHILDREN.

#### INTERACTIONS WITH THIS MEDICATION

Your physician also needs to know about drugs (including eye drops) that you are using or plan to use, including drugs obtained without a prescription. This is particularly important if you are taking medicine to lower blood pressure or to treat heart disease or depression including beta-blockers such as atenolol, epinephrine, quinidine, calcium channel blockers or catecholamine depleting drugs such as reserpine.

#### PROPER USE OF THIS MEDICATION

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 suspect that TIMOPTIC-XE® is causing an allergic reaction (for example, skin rash or itching), stop its use and contact your physician as soon as possible.
- 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 eyedrop, 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.
- Contact your physician without delay if you have ocular surgery or develop a condition that was not present at the time this medication was prescribed (e.g., trauma, an infection, etc.).
- The contents of the container should not be used for more than one month after the date on which the container is first opened.

Usual Adult dose:

The appropriate dosage and duration of treatment will be established by your physician.

The usual dose is one drop in the affected eye(s) once a day.

Overdose

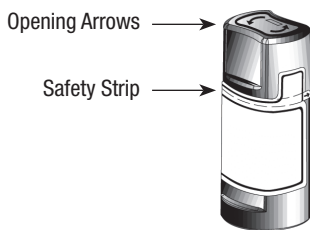
If you put too many drops in your eye or swallow any of the contents of the bottle, you should contact your physician immediately.

Missed Dose:

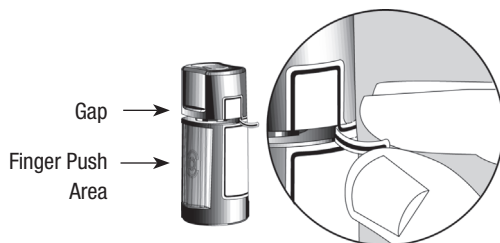
It is important to apply TIMOPTIC-XE® as prescribed by your physician. If you miss a dose, apply it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not double dose.

**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.

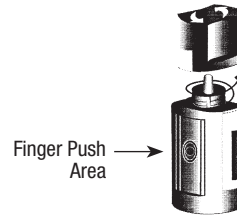


2. Tear off the Safety Strip to break the seal.

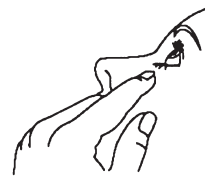


3. Invert the closed bottle and shake ONCE before each use. (It is not necessary to shake the bottle more than once.)

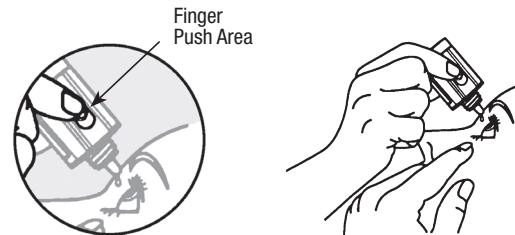
4. To open the bottle, unscrew the cap by turning as indicated by the arrows on the top of the cap. When opening the bottle for the first time, do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your container from operating properly.



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



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.



**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 physician immediately concerning continued use of this bottle.

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 the top of the cap.
8. Repeat steps 5 & 6 with the other eye if instructed to do so by your physician.
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 overtighten 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 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.
12. Tell your physician if you wear contact lenses. Depending on the type of lense, your physician may advise that you re-insert your contact lenses not earlier than 15 minutes after application of TIMOPTIC-XE®.

#### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- Any medicine may have unintended or undesirable effects, so-called side effects. Although not all of these side effects may occur, if they do occur, you may need medical attention.
- You may experience 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 myasthenic gravis.
- Your physician or pharmacist has a complete list of the possible side effects from this medication. Please tell your physician or pharmacist promptly about any unusual symptom.
- 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
		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.***

#### HOW TO STORE IT

**Store at room temperature 15° - 25°C. Protect from light. Avoid freezing.**

Do not use this medicine after the date shown on the container.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

#### REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

Toll-free telephone: 1-866-234-2345

Toll-free fax: 1-866-678-6789

By email: [cadmp@hc-sc.gc.ca](mailto:cadmp@hc-sc.gc.ca)

By regular mail:

National AR Centre  
Marketed Health Products Safety  
and Effectiveness Information Division  
Marketed Health Products Directorate  
Tunney's Pasture, AL 0701C  
Ottawa, ON K1A 0K9

or Merck Frosst Canada Ltd. by:

Toll-free telephone: 1-800-567-2594

Toll-free fax: 1-877-428-8675

By regular mail:

Merck Frosst Canada Ltd.  
P.O. Box 1005  
Pointe-Claire - Dorval, QC H9R 4P8

***NOTE: Before contacting Health Canada or Merck Frosst, you should contact your physician or pharmacist.***

#### MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.merckfrosst.com>

or by contacting the sponsor, Merck Frosst Canada Ltd., at: 1-800-567-2594.

This leaflet was prepared by Merck Frosst Canada Ltd.

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[www.merckfrosst.com](http://www.merckfrosst.com)



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