

TIMOPTOL-XE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TIMOPTOL-XE?

TIMOPTOL-XE contains the active ingredient timolol maleate. TIMOPTOL-XE is used to lower raised pressure in the eye and to treat glaucoma.

For more information, see Section [1. Why am I using TIMOPTOL-XE?](#) in the full CMI.

2. What should I know before I use TIMOPTOL-XE?

Do not use if you have ever had an allergic reaction to TIMOPTOL-XE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

Tell your doctor if you have a heart condition or any breathing conditions including asthma, emphysema or chronic obstructive pulmonary disease (COPD).

For more information, see Section [2. What should I know before I use TIMOPTOL-XE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TIMOPTOL-XE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TIMOPTOL-XE?

- Your doctor will tell you how many drops you need to use each day.
- Use TIMOPTOL-XE every day, at about the same time each day, unless your doctor tells you otherwise.

More instructions can be found in Section [4. How do I use TIMOPTOL-XE?](#) in the full CMI.

5. What should I know while using TIMOPTOL-XE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using TIMOPTOL-XE.• Have your eye pressure checked when your eye specialist says, to make sure TIMOPTOL-XE is working.• Remove contact lenses before using TIMOPTOL-XE drops
Things you should not do	<ul style="list-style-type: none">• Do not stop using TIMOPTOL-XE without first talking to your doctor• Do not give TIMOPTOL-XE to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how TIMOPTOL-XE affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your TIMOPTOL-XE drops in a cool place below 30°C away from direct light• Do not leave the lid off the bottle for any length of time to avoid contaminating your eye drops• Dispose of any remaining solution after four weeks

For more information, see Section [5. What should I know while using TIMOPTOL-XE ?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using TIMOPTOL-XE.

Common side effects include: temporary blurred or double vision, irritated or watery eyes, headache, tiredness, change in mood, upset stomach, dry mouth, cold hands or feet, tingling fingers or toes.

Serious side effects are rare, and may include: fast or irregular heart beat, dizziness, fainting, shortness of breath.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TIMOPTOL-XE[®] (tim-opt-ol ex-ee)

Active ingredient(s): *timolol maleate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TIMOPTOL-XE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TIMOPTOL-XE.**

Where to find information in this leaflet:

- [1. Why am I using TIMOPTOL-XE?](#)
- [2. What should I know before I use TIMOPTOL-XE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TIMOPTOL-XE?](#)
- [5. What should I know while using TIMOPTOL-XE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using TIMOPTOL-XE?

TIMOPTOL-XE contains the active ingredient timolol maleate. TIMOPTOL-XE belongs to a family of medicines called beta-blockers.

TIMOPTOL-XE is used, either alone or in combination with other eye drops or medicines, to lower raised pressure within your eye(s) and to treat glaucoma.

Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Also, some people with raised eye pressure may not have glaucoma.

This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye. There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist.

If glaucoma is not treated it can lead to serious problems. You may have no symptoms but eventually glaucoma can lead to total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

Although TIMOPTOL-XE helps control your glaucoma it does not cure it.

For more information about glaucoma, contact Glaucoma Australia Inc., PO Box 420, Crows Nest 1585, telephone 1800 500 880, or at www.glaucoma.com.au

2. What should I know before I use TIMOPTOL-XE?

Warnings

Do not use TIMOPTOL-XE if:

- you are allergic to timolol maleate, or any of the ingredients listed at the end of this leaflet**
- Always check the ingredients to make sure you can use this medicine
- you have, or have had in the past certain serious breathing problems such as asthma, a history of asthma, chronic obstructive lung disease (COPD), emphysema, or other breathing problems**
- you have certain heart conditions, such as a slow heart rate, an irregular heart beat, or heart failure**
- the seal around the cap is broken**
- the bottle shows signs of tampering**
- the expiry date on the pack has passed.** If you use this medicine after the expiry date has passed, it may not work

Check with your doctor if you:

- have any other medical conditions**, especially the following:
 - heart problems (such as coronary heart disease, heart failure or low blood pressure)
 - heart rate disturbances (such as slow or irregular heart beats)
 - 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
- are already using another beta-blocker eye drop.** It is not recommended to use two beta-blockers at the same time.
- have a history of allergic problems including eczema, hives or hay fever**
- you have had an allergy to any other medicines or any other substances, including foods, preservatives or dyes.**
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible

risks and benefits of using TIMOPTOL-XE during pregnancy and a decision can be made if you should or should not use it.

Do not use TIMOPTOL-XE if you are breast-feeding or intend to breastfeed. Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

Using TIMOPTOL-XE with contact lenses

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in TIMOPTOL-XE (benzalkonium chloride) may be deposited in soft contact lenses. Wait at least 15 minutes after you have used TIMOPTOL-XE before you put your soft contact lenses back into your eyes.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and TIMOPTOL-XE may interfere with each other. These include:

- medicines for high blood pressure or heart conditions, including a group of medicines called betablockers
- digoxin, a medicine used to treat heart failure
- quinidine, a medicine used to treat irregular heart beats
- medicines to treat depression
- medicines to treat diabetes

These medicines may be affected by TIMOPTOL-XE, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TIMOPTOL-XE.

4. How do I use TIMOPTOL-XE?

How much to use

- **Follow the instructions provided by your doctor and use TIMOPTOL-XE until your doctor tells you to stop.**
- The usual dose for adults is one drop of TIMOPTOL-XE a day, in either one or both eyes.

When to use TIMOPTOL-XE

- **TIMOPTOL-XE should be used once a day, every day at the same time each day unless your doctor tells you otherwise.** Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

How to use TIMOPTOL-XE drops

- Please refer to the instruction leaflet inside the TIMOPTOL-XE box for directions on how to use your eye drops.
- You may find it easier to put drops in your eye(s) while you are sitting or lying down.
- If using TIMOPTOL-XE with another eye drop, use the other eye drop at least 10 minutes before using TIMOPTOL-XE.
- **If you are wearing contact lenses remove them before putting the drops in your eye(s), and wait at least 15 minutes after you have used the drops before putting your contact lenses back in.**
- **Be careful not to touch the dropper against eye, eyelid or anything else to avoid contaminating the eye drops.** Contaminated eye drops may give you an eye infection.
- You may experience blurred vision in the eye(s) for 30 seconds to 5 minutes immediately after using TIMOPTOL-XE drops.

If you forget to use TIMOPTOL-XE

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use the drops as soon as you remember and then go back to using them as you would normally.

If you are not sure whether to skip a dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose you missed.

If you have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much TIMOPTOL-XE

If you think that you have used too much TIMOPTOL-XE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TIMOPTOL-XE?

Things you should do

Have your eye pressure checked when your eye specialist says, to make sure TIMOPTOL-XE is working.

Tell your doctor before you have an operation that you are using TIMOPTOL-XE. TIMOPTOL-XE may change the effects of some medicines during anaesthesia.

Remind any doctor, dentist or pharmacist you visit that you are using TIMOPTOL-XE.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using TIMOPTOL-XE.

Call your doctor straight away if you:

- Develop an eye infection, receive an eye injury or have eye surgery. Your doctor may tell you to use a new bottle of TIMOPTOL-XE because of possible contamination of the old one, or may advise you to stop your treatment with TIMOPTOL-XE.

Things you should not do

- Do not stop using TIMOPTOL-XE without first talking with your doctor. If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.
- Do not give TIMOPTOL-XE to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TIMOPTOL-XE affects you.

TIMOPTOL-XE generally does not cause any problems with your ability to drive a car or operate machinery. However, TIMOPTOL-XE may cause temporary blurred vision or dizziness in some people. Make sure you know how you react to TIMOPTOL-XE and that your vision is clear before driving a car or operating machinery.

Looking after your medicine

Store TIMOPTOL-XE drops below 30°C .

Keep the drops away from direct light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.
- In the pockets of your clothes

Keep it where young children cannot reach it.

Do not leave the lid off the bottle for any length of time to avoid contaminating the eye drops.

When to discard your medicine

Write the date on the bottle when you open the eye drops and throw out any remaining solution after 4 weeks.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Problems with your eyes such as:</p> <ul style="list-style-type: none"> • temporary blurred vision, double vision or other visual problems • allergic reactions including redness, swelling and/or itching of the eye(s) • burning or stinging of the eye(s) • conjunctivitis • watering of eye(s) or discharge • pain in the eye(s) • irritation or feeling like there is something in the eye(s), dry eye(s) • drooping of eyelid(s) <p>Difficulty thinking or working because of:</p> <ul style="list-style-type: none"> • headache • a feeling of tiredness, weakness • ringing or buzzing in the ears • difficulty sleeping, nightmares • change to your mood such as depression • memory loss <p>Stomach or bowel problems such as:</p> <ul style="list-style-type: none"> • feeling sick (nausea), upset stomach • diarrhoea • dry mouth • abdominal pain <p>Changes to the ways your hands and feet feel such as:</p> <ul style="list-style-type: none"> • cold hands or feet • numbness, tingling or colour change (white, blue then red) in fingers when exposed to the cold (Raynaud's Phenomenon) • numbness or tingling in the fingers or toes <p>Other effects:</p> <ul style="list-style-type: none"> • cough • hair loss or thinning • less desire for sex • sexual dysfunction • muscle weakness or muscle pain not caused by exercise 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are usually mild side effects of TIMOPTOL-XE</p>

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(inactive ingredients)	tromethamine benzododecinium bromide (as preservative)
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Serious side effects

Serious side effects	What to do
<p>Heart related:</p> <ul style="list-style-type: none"> fast or irregular heart beats, also called palpitations dizziness and light-headedness, which may be due to low blood pressure slow pulse, chest pain fainting <p>Skin or allergy related:</p> <ul style="list-style-type: none"> skin rash, itching swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing or swallowing severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash <p>Breathing-related:</p> <ul style="list-style-type: none"> wheezing or shortness of breath difficulty breathing <p>Circulation-related:</p> <ul style="list-style-type: none"> swelling of the hands, feet. Ankles or legs 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>Serious side effects are rare.</p>

Do not use TIMOPTOL-XE eye drops if you are allergic to any of these ingredients.

What TIMOPTOL-XE looks like

TIMOPTOL-XE is a clear colourless solution in a plastic 5 mL bottle. It comes in 2 strengths : 0.25% and 0.5%.

TIMOPTOL-XE 0.25% - AUST R 50304

TIMOPTOL-XE 0.5% - AUST R 50306

Who distributes TIMOPTOL-XE

Mundipharma Pty Limited
10 Carrington Street
Sydney NSW 2000

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TIMOPTOL-XE contains

Active ingredient (main ingredient)	timolol maleate
Other ingredients	gellan gum mannitol