

TIMOPTOL-XE[®]

timolol maleate

2.5 mL ophthalmic solution

What is in this leaflet

This leaflet answers some common questions about TIMOPTOL-XE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using TIMOPTOL-XE against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What TIMOPTOL-XE is used for

TIMOPTOL-XE is used to lower raised pressure in the eye 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.

Glaucoma is usually caused by a build up of the fluid, which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. 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 New Zealand, Department of Ophthalmology, Private Bag 92019, Auckland. Telephone 09 373 8779, email: info@glaucoma.org.nz

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

TIMOPTOL-XE lowers pressure in the eye by reducing the production of fluid.

TIMOPTOL-XE belongs to a family of medicines called beta-blockers.

TIMOPTOL-XE is not addictive.

Before you use TIMOPTOL-XE

When you must not use it

Do not use TIMOPTOL-XE if you have an allergy to TIMOPTOL-XE or any of the ingredients listed at the end of this leaflet.

Do not use TIMOPTOL-XE if:

- you have asthma, or a history of asthma, chronic obstructive lung disease (emphysema), or other breathing problems
- you have certain heart conditions, such as a very slow heart rate, an irregular heartbeat, or heart failure.

Do not use TIMOPTOL-XE if you are breastfeeding or plan to breastfeed.

Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

Do not use TIMOPTOL-XE if:

- 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.

If you are not sure whether you should start using TIMOPTOL-XE, talk to your doctor.

Do not use TIMOPTOL-XE in a child.

The safety and effectiveness of TIMOPTOL XE in children have not been established.

Before you start to use it

Tell your doctor if:

1. 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.
2. you have any medical conditions, especially the following:
 - heart disease
 - lung disease
3. you are already using another beta-blocker eye drop
It is not recommended to use two beta-blocker eye drops at the same time.
4. you have a history of allergic problems, including eczema, hives or hay fever
5. if you wear soft contact lenses you should consult your doctor before using TIMOPTOL-XE

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6. if you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you use TIMOPTOL-XE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any 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 beta-blockers
- digoxin, a medicine used to treat heart failure
- quinidine, a medicine used to treat irregular heart beats
- medicines to treat depression

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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using TIMOPTOL-XE.

How to use TIMOPTOL-XE

How much to use

Your doctor will tell you how many drops you need to use each day. Use TIMOPTOL-XE only when prescribed by your doctor.

The usual dose for adults is one drop of TIMOPTOL-XE once a day, in either one or both eyes.

TIMOPTOL-XE contains a new delivery vehicle, gellan gum. This vehicle allows the eye drop to form a clear gel when it contacts the eye. This gel increases the contact time of timolol maleate with the eye. This means TIMOPTOL-XE needs to be administered only once a day.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Use TIMOPTOL-XE once a day, every day, at about 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.

If your doctor recommends that you use TIMOPTOL-XE with another eye drop, use the other medicine at least 10 minutes before TIMOPTOL-XE.

Before opening the bottle for the first time make sure the two safety seals joining the cap

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to the bottle are not broken. If they are, do not use the bottle and return it to your pharmacist.

You will notice a small space between the cap and the bottle. This is normal.

How to use it

Before opening the bottle for the first time, make sure the two safety seals joining the cap to the bottle are not broken. If they are, do not use the bottle and return it to your pharmacist.

You will notice a small space between the cap and the bottle – this is normal.

You may find it easier to put drops in your eye while you are sitting or lying down.

If you are wearing contact lenses, remove them before putting the drops in your eye.

1. Wash your hands well with soap and water.
2. To open the bottle for the first time, hold the bottle upright, and turn the cap in the direction of the arrows until you can lift it off. This will break the two safety seals.
3. Locate the “finger press” area on the side of the bottle between the vertical lines.
4. Hold the bottle upside down in one hand, with your thumb or index finger over the “finger press” area and place the other finger on the other side of the bottle. Do not insert fingers into base of bottle.
5. Using your other hand, gently pull down your lower eyelid to form a pouch.
6. Tilt your head back and look up.
7. Hold the bottle **vertically** and put the tip close to your lower eyelid. Do not let it touch your eye.
8. Release one drop into the pouch formed between your eye and eyelid by **gently** pressing on the “finger press” area.
9. Close your eye and keep it closed for a couple of minutes. While your eye is still closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Do not blink or rub your eye.
10. Replace the cap. Turn it clockwise until firm resistance is felt (approximately one full turn). **Do not over tighten the cap.**
11. Wash your hands again with soap and water to remove any residue.

Wait at least 15 minutes before replacing your contact lenses.

These eye drops should be used at least 10 minutes before or after using any other eye preparation. Store the bottle away from direct sunlight, preferably in a cool place where the temperature stays below 30°C.

At the end of use, you will notice a small quantity of solution remaining in the bottle. This retained solution cannot be removed and is normal.

Discard any remaining solution 4 weeks after opening the bottle.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.

Contaminated eye drops may give you an eye infection.

You may feel a slight burning sensation in the eye shortly after using the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

How long to use it

TIMOPTOL-XE helps control your condition but does not cure it. Therefore TIMOPTOL-XE must be used every day. Continue using TIMOPTOL-XE for as long as your doctor prescribes.

If you forget to use it

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 the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

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

If you use too much (overdose)

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of TIMOPTOL-XE, or used too many drops, immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If TIMOPTOL-XE is accidentally swallowed, or if you use too many drops, you may feel light-headed or dizzy, you may faint, have a very slow pulse rate, or have wheezing or difficulty breathing.

While you are using TIMOPTOL-XE

Things you must do

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

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of TIMOPTOL-XE because of possible contamination of the old one, or may advise you to stop your treatment with TIMOPTOL-XE.

If you become pregnant while using TIMOPTOL-XE tell your doctor.

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

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Things you must not do

Do not give TIMOPTOL-XE to anyone else, even if they have the same condition as you.

Do not stop using TIMOPTOL-XE without first talking to your doctor.

If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving or operating machinery until you know how TIMOPTOL-XE affects you.

TIMOPTOL-XE may cause temporary blurred vision for 30 seconds to 5 minutes immediately after using the drops. Make sure that your vision is clear before driving a car or operating machinery.

Adverse Effects

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

TIMOPTOL-XE helps most people with high eye pressure and glaucoma, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

Problems with your eye/s such as:

- blurred vision which generally lasts from 30 seconds to 5 minutes
- double vision
- allergic reactions including redness, swelling and/or itching of the eye
- burning and stinging of the eyes
- irritation or feeling of having something in the eye, dry eyes
- discharge
- drooping of eyelid/s

Difficulty thinking or working because of:

- headache
- tiredness, weakness
- ringing or buzzing in the ears
- difficulty sleeping, nightmares
- changes in mood such as depression, memory loss

Stomach or bowel problems:

- feeling sick (nausea), upset stomach
- diarrhoea

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- dry mouth

Changes in the way your hands and feet feel such as:

- cold hands or feet
- numbness, tingling and colour change (white, blue then red) in fingers when exposed to the cold (Raynaud's Phenomenon)
- numbness or tingling in the fingers or toes

Cough

Hair loss or thinning

Less desire for sex.

These are usually mild adverse effects of TIMOPTOL-XE.

Tell your doctor immediately if you notice any of the following:

- fast or irregular heart beats, also called palpitations
- dizziness and light-headedness, which may be due to low blood pressure
- skin rash, itching
- swelling of the hands, feet, ankles or legs

These may be serious adverse effects. You may need urgent medical attention. Serious adverse effects are rare.

If any of the following happen, stop using TIMOPTOL-XE and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- wheezing, difficulty in breathing, shortness of breath
- very slow pulse, chest pain
- fainting
- 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

These are serious adverse effects. You may need urgent medical attention. These adverse effects are rare.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using TIMOPTOL-XE

Storage

Keep your eye drops in a cool dry place where the temperature stays below 30°C.

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Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Do not carry the eye drops in pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep the eye drops away from direct light.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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

Disposal

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

Eye drops contain a preservative, which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

How does it come?

TIMOPTOL-XE comes as eye drops in a 2.5 mL dropper pack. It is available in two strengths.

Ingredients

Active ingredient:

- TIMOPTOL-XE 0.25% - timolol maleate, equivalent to timolol 0.25%
- TIMOPTOL-XE 0.5% - timolol maleate, equivalent to timolol 0.5%

Inactive ingredients:

- gellan gum
- mannitol
- tromethamine
- benzododecinium bromide as preservative

Supplier

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TIMOPTOL-XE is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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