

TIMOPTOL-XE®

Timolol maleate

Consumer Medicine Information

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 Australia Inc., PO Box 420, Crows Nest 1585, telephone 1800 500 880, or at www.glaucoma.com.au.

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 now or have had in the past serious breathing problems such as asthma, chronic obstructive lung disease (emphysema), or other breathing problems**
- **you have certain heart conditions, such as a slow heart rate, an irregular heart beat, or heart failure.**

Do not use TIMOPTOL-XE if you are breast-feeding or plan to breast-feed.

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 now or have had any 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

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

TIMOPTOL-XE has not been studied in people wearing contact lenses.

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
- 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.

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.

How to use it

Please refer to the instruction leaflet inside the TIMOPTOL-XE pack for directions on how to use your eye drops.

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.

Wait at least 15 minutes before replacing your contact lenses.

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 Poisons Information Centre (telephone 13 11 26) 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.

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

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

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.

Side 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 side effects in a few people. All medicines can have side effects. Sometimes they are

serious, most of the time they are not. You may need medical treatment if you get some of the side 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
- conjunctivitis
- irritation or feeling of having something in the eye, dry eyes
- watering of the eyes or discharge
- pain in the eye
- 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
- dry mouth
- abdominal pain

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

sexual dysfunction

**muscle weakness or muscle pain,
not caused by exercise.**

These are usually mild side 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 side effects.

You may need urgent medical attention.

Serious side 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 nettlerash

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

Other side 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 side 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 25°C.

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

TIMOPTOL-XE is supplied in Australia by:

Mundipharma Pty Limited

88 Phillip Street

Sydney NSW 2000

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TIMOPTOL-XE 0.25% - AUST R 50304

TIMOPTOL-XE 0.5% - AUST R 50306

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