TIMOPTOL-XE(R)

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.

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 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

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.

Glaucosa 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 the Glaucoma Foundation of Australia (PO Box 420, Crows Nest 2065, telephone 02 9906 6640).

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.
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**
   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.

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.

**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.

* medicine at least 10 minutes before TIMOPTOL-XE.
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.

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
  - 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
  - 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 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 nettle rash
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.

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:
Merck Sharp & Dohme (Australia) Pty Limited
A.B.N. 14 000 173 508
54-68 Ferndell Street
South Granville NSW 2142
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TIMOPTOL-XE 0.5% - AUST R 50306
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