

PACKAGE LEAFLET: INFORMATION FOR THE USER

Timolol 0.25% w/v Eye Drops Solution Timolol 0.5% w/v Eye Drops Solution

(timolol)

Read all of this leaflet carefully before you start taking this medicine. because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Timolol is and what it is used for
2. What you need to know before you use Timolol
3. How to use Timolol
4. Possible side effects
5. How to store Timolol
6. Contents of the pack and other information

1. What Timolol is and what it is used for

Timolol Eye Drops contain a substance called timolol which belongs to a group of medicines called beta-blockers. Timolol lowers the pressure in your eye(s). It is used to treat glaucoma, when the pressure in the eye is raised.

2. What you need to know before you use Timolol

Do not use Timolol Eye Drops if:

- you are allergic (hypersensitive) to timolol , beta-blockers or any of the other ingredients of timolol (see section 6: Contents of the pack and other information)
- you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- you have heart problems
- slow heart beat
- disorders of heart rhythm (irregular heart beats)
- heart failure .
 - “cardiogenic shock” – a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and lightheadedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness.

If you are not sure whether you should use Timolol Eye Drops talk to your doctor or pharmacist.

Warning and precautions:

Talk to your doctor before taking Timolol eye drops if you have now or have had in the past

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure.
- low blood pressure.
- disturbances of heart rate such as slow heart beat.

- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes as Timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as Timolol may mask signs and symptoms
- you wear soft contact lenses. Your eye drops contain a preservative which can be deposited on soft contact lenses. It is important that your lenses are removed before using your eye drops and not put back into your eyes for at least 15 minute.

Tell your doctor before you have an operation that you are using Timolol Eye Drops as Timolol may change effects of some medicines used during anaesthesia.

If your eye becomes irritated or any new eye problems come on, talk to your doctor straight away. Eye problems could include redness of the eye or swelling of the eyelids (see Section 4: Possible Side Effects).

If you suspect that Timolol Eye Drops is causing an allergic reaction or hypersensitivity (for example, skin rash, or redness and itching of the eye), stop using timolol and contact your doctor immediately.

Tell your doctor if:

- you get an eye infection
- you injure your eye or have an operation on it
- your eye problems get worse or you get any new symptoms.

Children and adolescents

There is only very limited data available on the use of timolol in infants and children. For example, in one small clinical study, timolol, the active ingredient in Timolol eye drops, has been studied in infants and children aged 12 days to 5 years, who have elevated pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

Timolol should generally be used with caution in young patients. In newborns, infants and younger children Timolol should be used with extreme caution. If coughing, wheezing, abnormal breathing or abnormal pauses in breathing (apnoea) occur, the use of the medication should be stopped immediately. Contact your doctor as soon as possible. A portable apnoea monitor may also be helpful.

Other medicines and Timolol Eye drops

Timolol Eye Drops can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including other eye drops or medicines obtained without prescription.

It is important to tell your doctor before using Timolol Eye Drops if you are taking one or more of the following medicines:

- a calcium antagonist, such as nifedipine, verapamil or diltiazem, often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud's syndrome
- digoxin, a medicine used to relieve heart failure or treat abnormal heartbeat
- medicines known as catecholamine-depleting agents, such as rauwolfia alkaloids or reserpine, used for high blood pressure
- medicines called pressor amines, such as adrenaline used to treat severe allergic reaction
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine.
- clonidine, a medicine used to treat high blood pressure
- other beta-blockers taken by mouth or used as eye drops, because they belong to the same group of medicines as Timolol and could have an additive effect.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine

Use in pregnancy

Do not use Timolol if you are pregnant unless your doctor considers it necessary.

Use in breast-feeding

Do not use Timolol if you are breast-feeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines

There are possible side effects associated with Timolol Eye Drops, such as dizziness, tiredness and changes in your eyesight, such as blurred vision, drooping of the upper eyelid (making the eye stay half closed), double vision which may affect your ability to drive and/or operate machinery. Do not drive and/or operate machinery until you feel well and your vision is clear.

Timolol Eye Drops contains the preservative benzalkonium chloride.

This medicine contains 0.1 mg benzalkonium chloride in each ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Timolol

Always use Timolol Eye Drops solution exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. The doctor will decide how many drops you should take each day and how long you should use them.

The recommended dose is one drop in the affected eye(s) twice each day:

- one in the morning
- one in the evening.

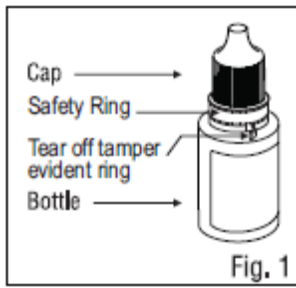
Do not change your usual dose without talking to your doctor.

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 infection 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.

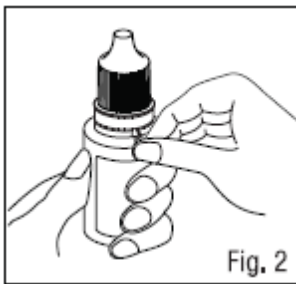
Instructions for use:

Opening the bottle for the first time

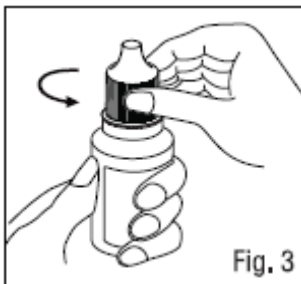
1. Before using the medication for the first time, check that the tear-off tamper evident ring is intact and also that the safety ring connection with the cap has not been broken (Fig.1). You must not use the bottle if the tamper-evident rings on the bottle neck are broken or removed.



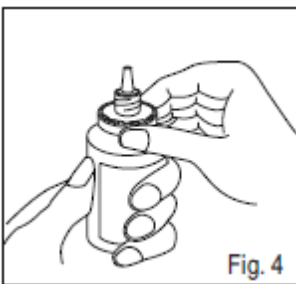
2. Before opening the bottle for the first time, tear off the tamper evident ring to break the seal (Fig.2).



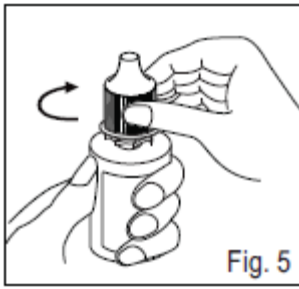
3. To open the bottle, remove the cap by turning it in the counterclockwise direction (Fig.3).



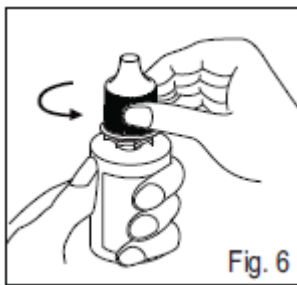
4. After opening the cap remove the safety ring gently (Fig. 4).



5. Place the cap and tighten the cap on the nozzle completely by turning clockwise. The spike in the cap will pierce the tip of the bottle (Fig.5).

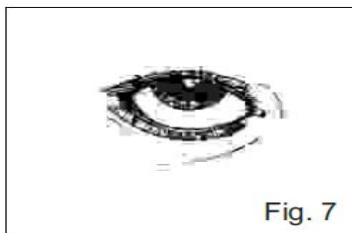


6. To open the bottle, remove the cap by turning it in the counterclockwise direction (Fig.6).

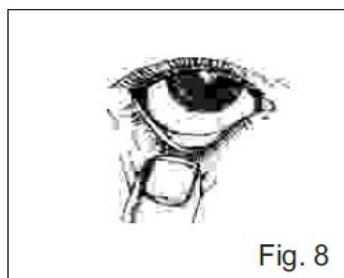


Using your eye drops

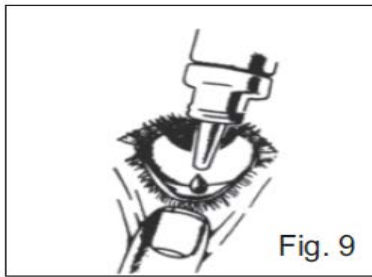
7. Wash your hands, tilt your head back and look at the ceiling (Fig.7).



8. Gently pull the lower eyelid down to form a small pocket between the eyelid and the eye (Fig.8).

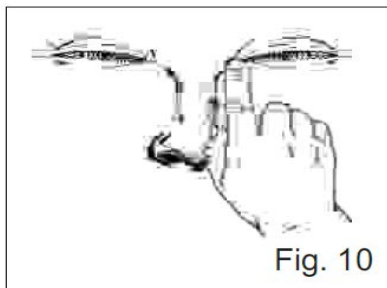


9. Turn the bottle upside down and squeeze it gently to release one drop into each eye that needs treatment. Do not touch your eye or eyelid with the dropper tip (Fig. 9). If a drop misses your eye, try again.



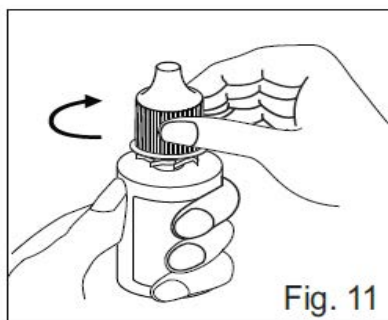
10. Let go of the lower lid, and close your eye For 2 minutes, by pressing the finger into the corner of your eye, by the nose (Fig.10). This helps to stop timolol getting into the rest of your body.

Ophthalmic medications, if handled improperly, can become contaminated by common bacteria known to cause 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 doctor immediately concerning continued use of this bottle.



11. Repeat steps 8 , 9 & 10 with the other eye if instructed to do so by your doctor.

12. Reclose the bottle after use (Fig.11). The next time you need to apply the drops follow steps 7-12



13. The dispenser tip is designed to provide a pre-measured drop; therefore, do NOT enlarge the hole of the dispenser tip.

14. After you have used all doses, there will be some eye drops solution left in the bottle. You should not be concerned since an extra amount of solution has been added and you will get the full amount of Timolol that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

Use in children and adolescents

Before you or your child starts to take Timolol, your doctor or your child's doctor will have carried out a detailed medical examination and decided whether or not this medicine is suitable. You or your child, especially a newborn, should be closely monitored for one to two hours after the first dose and carefully monitored for any signs of side effects until surgery is carried out.

Method of administration:

One drop only of Timolol should be instilled into the affected eye(s) each time. Follow the “Instructions for Use” above when administering the eye drops. After using Timolol, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop timolol getting into the rest of your body.

Duration of treatment:

Your doctor or your child’s doctor will decide for how long the eye drops will be needed.

If you use more Timolol Eye Drops than you should

If you put too many drops in your eye or swallow any of the drops, you may:

- have a headache
- feel dizzy or light-headed
- have difficulty breathing
- chest pain
- feel that your heart rate has slowed down.

If this happens, contact your doctor immediately.

If you forget to use Timolol Eye Drops

It is important to take Timolol as prescribed by your doctor.

- If you miss a dose, use the drops as soon as possible.
- If it is almost time for the next dose, skip the missed dose and take the next dose at the usual time.
- Do not take a double dose to make up for the forgotten dose.

If you stop using Timolol Eye Drops

If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines Timolol Eye Drops can cause side effects, although not everybody gets them. You can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop using Timolol Eye drops without speaking to your doctor.

Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with intravenous and/or oral beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions.

If you develop allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction, stop taking your eyes drops and seek medical attention immediately.

Low blood glucose levels.

Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucination.

Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like tingling or pins and needles, and headache.

Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed) double vision, sensitivity to light, discharge from the eye, pain in the eye.

Ringing sound in the ears,

Slow heart rate, chest pain, palpitations, oedema (fluid build up), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build up), a type of heart rhythm disorder, heart attack, heart failure.

Low blood pressure, fainting, interference with the blood supply to the brain which may lead to a stroke, Raynaud's phenomenon, cold hands and feet, limping because there is a reduced blood supply to your legs.

Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, shortness of breath, wheezing, cough.

Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.

Sexual dysfunction, decreased sex drive, decreased libido. In men a condition which affects your penis called Peyronie's disease. The signs may be abnormal curve, pain or hardening of the tissue of your penis.

Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash, itching.

Muscle weakness/tiredness, muscle pain not caused by exercise.

A condition called lupus (systemic lupus erythematosus).

Ask your doctor or pharmacist for more information about the side effects. Both have a more complete list of side effects.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How To Store Timolol

Keep your eye drops out of the sight and reach of children.

- This medicinal product does not require any special storage condition before first opening.
- Do not store your eye drops above 25°C after first opening. Store the bottle in the outer carton.
- You can use Timolol for 28 days after first opening the bottle. Discard the opened bottle with any remaining solution after that time.

Do not use Timolol Eye Drops after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Timolol contains

The active substance is timolol maleate.

The other ingredients are:

- benzalkonium chloride as preservative
- disodium phosphate dodecahydrate (E339)
- sodium dihydrogen phosphate dihydrate (E339)
- sodium hydroxide
- water for injections.

What Timolol Eye Drops looks like and contents of the pack

Timolol is a clear colourless to light yellow sterile eye drops solution available in two strengths:

- 0.25% w/v solution of timolol
- 0.5% w/v solution of timolol

Timolol is available in bottles containing 5 ml of sterile eye drops solution. Timolol 0.5% w/v is additionally available in a 10ml bottle size.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Ltd
5 Marryat Close
Hounslow West
Middlesex
TW4 5DQ
UK.

This medicinal product is authorised in the Member States of the EEA under the following names:

UK & IE: Timolol 0.25% w/v & 0.5% w/v Eye Drops Solution

This leaflet was last revised on 01/2020

This leaflet gives the most important patient information about Timolol. If you have any questions after you have read it, ask your doctor or pharmacist who will give you further information.

Further information about glaucoma is available from:

International Glaucoma Association (IGA)
15A Highpoint Business Village
Henwood, Ashford
Kent, TN24 8DH
Tel: 01233 648170
E-mail: info@iga.org.uk
Registered Charity number 274681.

(The IGA is an independent charity organisation which helps glaucoma patients and their relatives, and is not associated with Brown & Burk UK Ltd.)

Alternatively, if you or someone you know has problems with their vision, and you require further advice or information, please phone the Royal National Institute for the Blind (RNIB) Helpline on 0845 776 9999, Monday to Friday 9am to 5 pm, calls charged at local rates.
(The RNIB is an independent UK charity and is not associated with Brown & Burk UK Ltd.)