



BROWN & BURK

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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, 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.

In this leaflet:

1. What Timolol is and what it is used for
2. 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. Before you use Timolol

Do not use Timolol Eye Drops:

- if you are allergic to timolol maleate, beta-blockers or any of the other ingredients
- if you have now or have had in the past respiratory problems such as severe asthma, severe chronic obstructive bronchitis (severe lung condition which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- if you have a slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats).

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

Take special care with Timolol Eye Drops:

Before you use this medicine, tell your doctor 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 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
- Contact lenses. These should be removed before treatment with Timolol and not put back into your eyes until 15 minutes after using the eye drops.

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 these drops 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.

Use in children

Timolol Eye Drops are not recommended for use in children and adolescents.

Using other medicines

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 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

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

Do not use Timolol Eye Drops 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 and changes in your eyesight, 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.

Benzalkonium chloride may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses.

3. How to use Timolol

Always use Timolol Eye Drops exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

- one in the morning
- one in the evening.

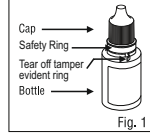
Do not change your usual dose without talking to your doctor.

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.

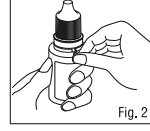
Instructions for use:

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).

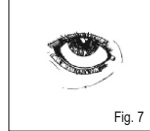


6. To open the bottle, remove the cap by turning it in the counterclockwise direction (Fig. 6).



Using your eye drops

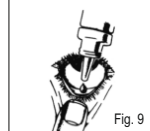
7. Wash your hands, tilt your head back and look at the ceiling (Fig. 7).



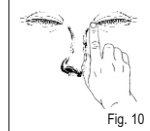
8. Gently pull the lower eyelid down to form a small pocket between the eyelid and the eye. (Fig. 8).



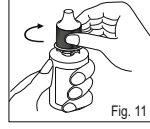
9. Turn the bottle upside down and squeeze it gently to release one drop into each eye that needs treatment. Do not touch your eye or eyelid with the dropper tip (Fig. 9). If a drop misses your eye, try again.



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).



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



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

13. 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.

Eye medications, if handled improperly, can become contaminated by common bacteria to cause infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated eye medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately. Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

After using Timolol Eye drops, press a finger into the corner of your eye, by the nose (see figure 5) for 2 minutes. This helps to stop timolol getting into the rest of the body.

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
- 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. If they do occur, you may need medical attention.

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.

The frequency of possible side effects listed below is defined using the following convention
Very common (affects more than 1 user in 10)
Common (affects 1 to 10 users in 100)
Uncommon (affects 1 to 10 users in 1,000)
Rare (affects 1 to 10 users in 10,000)

Not known (frequency cannot be estimated from the available data)

If you experience the following, stop using Timolol Eye Drops and tell your doctor immediately or go to the casualty department of your nearest hospital:

- Allergic reactions, which may be severe and cause swelling of your face, tongue and throat resulting in difficulty breathing.
- In some patients these may include:
 - The possible side effects relating to your heart are:
 - a slower than normal heart rate
 - an abnormal heart rhythm
 - heart block (a problem with the electrical conduction system of your heart)
 - heart failure (symptoms of which can include shortness of breath)
 - palpitations
 - heart attack (symptoms of which can include severe chest pain)
 - worsening of angina and associated chest pain
 - swelling of parts of the body
 - worsening of pre-existing circulation problems
 - cold hands and feet
 - The possible side effects relating to your ears are:
 - ringing noises in the ears
 - dizziness
 - The possible side effects relating to your eyes are:
 - eye irritation including a feeling of burning and stinging in the eyes
 - inflammation of parts of your eyes or eyelids making them itchy, red, sticky or swollen
 - painful eyes or poorer than normal eyesight
 - loss of blinking reaction to objects near the eye
 - drooping eyelids
 - dry eyes
 - changes in vision including double vision
 - structural damage to the eye (possibly resulting in the appearance of flashes of light or "floaters" in vision, or loss of vision) following eye surgery has also been reported if timolol was being used after the surgery.
 - The possible side effects relating to your digestive system are:
 - feeling sick
 - being sick
 - diarrhoea
 - indigestion including stomach ache, feeling bloated or "full"
 - dry mouth
 - poor appetite
 - weight loss
 - stomach pains.
 - Possible side effects relating to your joints and muscles are:
 - a lack of strength and weakness generally or when exercising
 - weakness of particular muscles
 - extreme tiredness
 - chest pain
 - pain in the fingers and toes
 - joint pain
 - difficulty in walking.
 - The possible side effects relating to your immune system are:
 - itching
 - local or generalized rash
 - systemic lupus erythematosus (also known as "SLE" or "Lupus"), symptoms of which can include painful or swollen joints, muscle pain, unexplained fever or a red rash.
 - The possible side effects relating to your skin are:
 - baldness
 - red, itchy, flaky rash or worsening of pre-existing psoriasis
 - itching
 - peeling of skin
 - purple-coloured spots and patches on the skin
 - sweating
 - The possible side effects relating to your metabolism are:
 - higher than normal blood sugar levels (symptoms of which can include a great thirst, a dry mouth or the need to pass water often)
 - lower than normal blood sugar levels (symptoms of which can include feeling sick, sweating, weakness, faintness, confusion or coma).
 - The possible side effects relating to your nervous system are:
 - stroke
 - dizziness
 - headache
 - fainting
 - a feeling of pins and needles
 - worsening of a disorder called myasthenia gravis which affects the muscles and causes weakness and tiredness.
 - The possible side effects relating to your brain are:
 - depression
 - difficulty sleeping
 - an increased number of dreams
 - nightmares
 - memory loss
 - lack of concentration.
 - The possible side effects relating to your reproductive system are:
 - a reduced sex drive
 - "Peyronie's disease" (men, causing the penis to bend when erect)
 - impotence
 - Difficulty passing water
 - The possible side effects relating to your lungs are:
 - difficulty breathing, particularly if you already have a disease affecting your lungs such as asthma. This may be serious enough to cause death
 - breathlessness
 - cough
 - fluid in the lungs
 - failure of the lungs to function normally (symptoms of which can include bluish skin, confusion or sleepiness).
 - The possible side effects relating to your circulatory system are:
 - abnormally low blood pressure
 - a reduced blood supply to the brain (the symptoms of these can include problems moving, speaking, seeing or thinking clearly)
 - pain in your legs on walking
 - redness and flushing caused by increased blood flow to the skin
 - Raynaud's phenomenon (which causes the fingers and/or toes

to turn white, blue or red in hot or cold temperatures).

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' as applicable 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:

Generalized 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, seroiticness, severe sudden life-threatening allergic reaction.

Low blood glucose levels.
Difficulty sleeping (insomnia), depression, nightmares, memory loss.

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

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, Raynaud's phenomenon, cold hands and feet.

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

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

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

Muscle pain not caused by exercise.
Sexual dysfunction, decreased libido.

Muscle weakness/tiredness.

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

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 look 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 Maryat 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 approved on 04/2017

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.)

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