

Package leaflet: Information for the user
Timolol 0.25% w/v Eye Drops, Solution
Timolol 0.5% w/v Eye Drops, Solution
(timolol maleate)
(referred to as Timolol Eye Drops in the rest of this leaflet)

Read all of this leaflet carefully before you start using 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.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Timolol Eye Drops are and what they are used for

Timolol Eye Drops are available in two strengths: Timolol 0.25% w/v Eye Drops, Solution and Timolol 0.5% w/v Eye Drops, Solution.

Timolol Eye Drops is a member of a group of medicines known as beta-blockers and it is used to reduce the pressure inside your eyeball(s) if you have a condition such as high blood pressure that is affecting your eyes, or glaucoma (high pressure in your eyeball), including glaucoma that developed after you had surgery to remove a cataract from your eye(s).

2. What you need to know before you use Timolol Eye Drops

Do not use Timolol Eye Drops

- if you are allergic to timolol, beta-blockers such as propranolol (used mainly for high blood pressure) or betaxolol (also used for glaucoma) or any of the other ingredients of this medicine (listed in section 6)
- if you have now or have had in 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 the heart rhythm (irregular heart beats)
- if you have 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 talk to your doctor or pharmacist.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Timolol:

- if you have ever had 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 (bradycardia).
- breathing problems, asthma or chronic obstructive pulmonary disease (lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- poor blood circulation disease (peripheral arterial 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
- if you are already taking a different type of beta-blocker such as propranolol (used mainly for high blood pressure) or betaxolol (which is also an eye drop used for glaucoma)
- if you wear soft contact lenses (see the section of this leaflet (Timolol Eye Drops contain benzalkonium chloride and phosphates) Hard contact lenses may generally be worn without problems whilst taking Timolol Eye Drops

If you suspect that Timolol 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 or pharmacist **immediately** if:

- you suffer an eye injury, have eye surgery or get an eye infection whilst you are using Timolol Eye Drops
- a rash develops on your skin or your eyes become dry whilst you are using Timolol Eye Drops.
- your eye problems get worse or you get any new symptoms

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

Children and adolescents

Timolol eye drop solution 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 would be stopped immediately. Contact your doctor as soon as possible. A portable apnoea monitor may also be helpful.

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

Other medicines and Timolol Eye Drops

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. 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 of the following medicines before you use Timolol Eye Drops:

- Adrenaline, used for conditions including asthma and allergic reactions
- Digoxin, used mainly for heart failure or an abnormal heart rhythm
- Quinidine, used to treat heart conditions and some types of malaria
- Fluoxetine and paroxetine, used to treat depression
- Calcium channel blockers such as nifedipine, verapamil or diltiazem, used mainly for angina, high blood pressure, an abnormal heartbeat or Raynaud's syndrome.
- Clonidine or reserpine, used mainly for high blood pressure
- Other beta-blockers such as propranolol, acebutalol, atenolol, bisoprolol, carvedilol, celiprolol, labetalol, metoprolol, nadolol, nebivolol, oxprenalol, pindolol or sotalol, because they belong to the same group of medicines as Timolol and could have an additive effect. This includes beta blockers taken by mouth or used as eyedrops
- Medicines known as catecholamine-depleting agents, such as rauwolfia alkaloids or reserpine, used for high blood pressure.

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 or pharmacist for advice, before using Timolol Eye Drops or any other medicinal product, if you are pregnant, think you are pregnant, are trying to get pregnant or are breastfeeding a baby.

Driving and using machines

Timolol Eye Drops may cause side effects such as dizziness, tiredness and problems with vision, such as blurred vision, drooping of the upper eyelid (making the eye stay half closed), and double vision which may affect your ability to drive or to use tools and machinery. Do not drive or operate tools and machinery whilst you are using Timolol Eye Drops until you feel well and your vision is clear.

Timolol Eye Drops contain benzalkonium chloride and phosphates

This medicine contains benzalkonium chloride as a preservative. 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.

This medicine contains 6.33mg of phosphates in each 1ml of eye drops, which is equivalent to 16.72mg of disodium hydrogen phosphate dodecahydrate and 3.12mg of sodium dihydrogen phosphate dehydrate in 1ml of eye drops (see section 4 possible side effects 'eyes' for further information)

3. How to use Timolol Eye Drops

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Always wash your hands before using Timolol Eye Drops.

Timolol Eye Drops are for ocular use only (to be used as eye drops only) – **do not** swallow.

Posology

Adults

Always use Timolol eye drops solution exactly as your doctor has told you. 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 Timolol Eye Drops bottle to touch your eyes or around your eyes, do not touch the tip of the bottle with your fingers, and replace the screw cap tightly onto the bottle every time you finish using Timolol Eye Drops.

This will stop Timolol Eye Drops becoming contaminated with bacteria that can cause eye infections which, in turn, can lead to serious eye damage, possibly resulting in loss of vision. 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.

Use Timolol Eye Drops as follows:

1. Before opening a bottle of Timolol Eye Drops for the first time, check that the tamper-evident seal on the cap is not broken – if it is, **do not** use the timolol contained within it and tell your doctor or pharmacist immediately.
2. To open the bottle, unscrew the cap by turning it anticlockwise.
3. Tilt your head back so you are looking at the ceiling and gently pull the lower eyelid of the affected eye down, so there is a pocket between your eyelid and your eye and hold it there whilst you put the drops in. For paediatric populations, one drop only of Timolol should be instilled per dosing time.
4. Turn the bottle upside down and squeeze to release a drop into your eye. **Make sure you do not touch your eye or eye lid or anything else with the dropper tip.**
5. After using Timolol Eye Drops, press a finger into the corner of your eye, by the nose, for 2 minutes. This helps to stop timolol maleate getting into the rest of the body. For paediatric populations, after instillation keep the eyes closed for as long as possible (e.g. 3-5 minutes).

6. Repeat steps three and four above for the other eye if you have been told to do so by your doctor.
7. Replace and tighten the bottle cap by turning it clockwise until it is firmly closed, straight away after use. Do not over-tighten the cap.

Use in children and adolescents

A detailed medical examination should precede the use of Timolol. Your doctor will carefully evaluate the risks and benefits when considering treatment with Timolol. If the benefits outweigh the risks, it is recommended to use the lowest active agent concentration available once daily. With regard to “the use in children”, the 0.1% active agent concentration may be sufficient to control pressure within the eye. If the pressure is not sufficiently controlled with this dosage, a twice daily application at 12-hourly intervals may be necessary. Patients, especially newborn, should be closely observed for one to two hours after the first dose and careful monitoring for adverse events should be carried out until surgery is performed.

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 instillation keep the eyes closed for as long as possible (e.g. 3 – 5 minutes) and apply pressure to the corner of the eye closest to the nose to prevent the eye drops spreading throughout the 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 think you have used more Timolol Eye Drops than you should have done, or you accidentally swallow any Timolol Eye Drops, see a doctor or go to the nearest hospital casualty department immediately, taking the bottle of Timolol Eye Drops and this leaflet with you, even if you feel well. Signs that you or somebody else has used too much Timolol Eye Drops can include: dizziness, headache, shortness of breath, chest pain, a slower than normal heartbeat, difficulty breathing or heart attack (resulting in severe chest pain).

If you forget to use Timolol Eye Drops

If you forget to use Timolol Eye Drops, use it again as soon as you remember. . However, if it is almost time for your next dose by the time you remember, skip the dose that you have missed completely and wait until it is time for your next dose before you use Timolol Eye Drops again. Do not use a double dose of Timolol Eye Drops to make up for a forgotten dose.

If you stop using Timolol Eye Drops

If you stop using Timolol Eye Drops for any reason, contact your doctor or pharmacist immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Timolol Eye Drops without speaking to your doctor.

Like other medicines applied into the 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 ocular 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 suffer from any of the following at any time during your treatment stop taking the medicine and seek immediate medical help:

- generalised allergic reactions including swelling beneath the skin that can occur in areas such as the face, lips, mouth, tongue, throat or limbs, and can obstruct the airway which may cause difficulty swallowing or breathing (angiodema), hives or itchy rash, localized and generalised rash, itchiness, severe sudden life-threatening allergic reaction. systemic lupus erythematosus (also known as “SLE” or “Lupus”), symptoms of which can include painful swollen joints, muscle pain, unexplained fever or a red rash
- severe sudden life-threatening allergic reaction (anaphylactic reaction).
- wheezing, difficulty breathing (bronchospasm), particularly if you already have a disease affecting your lungs such as asthma. This may be serious enough to cause death (usually in patients with pre-existing bronchospastic disease)
- a reduced blood supply to the brain (cerebral ischemia) (the symptoms of these can include problems moving, speaking, seeing or thinking clearly)
- heart attack (cardiac arrest) (symptoms of which can include severe chest pain)
- heart (cardiac) failure (symptoms of which can include shortness of breath)

Possible side effects are listed below under the parts of the body that might be affected.

Heart:

- a slower than normal heart rate (bradycardia)
- changes in the rhythm or speed of the heart beat (arrhythmia)
- heart condition (atrioventricular block) (a problem with the electrical conduction system of your heart)
- palpitations
- worsening of angina and associated chest pain
- heart disease with shortness of breath and swelling of parts of the body (feet and legs) due to fluid build up (congestive heart failure)
- fluid build up (oedema)
- worsening of pre-existing circulation problems
- cold hands and feet.

Ears:

- ringing noises in the ears
- dizziness.

Eyes:

- eye irritation including a feeling of burning, stinging, itching, tearing, and redness in the eyes
- inflammation of parts of your eyes or eyelids including the cornea making them itchy, red, sticky (discharge) or swollen
- swollen eyelid (blepharitis)
- irritation or feeling of having something in the eye (keratitis)
- painful eyes or poorer than normal eyesight
- loss of blinking reaction to objects near eye
- drooping of the upper or lower eyelids (ptosis)
- dry eyes
- changes in vision including double vision (diplopia) and sensitivity to light
- decreased corneal sensitivity
- damage to the front layer of the eyeball (corneal erosion)
- 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. This includes blurred vision and detachment of the layer below the retina that contains blood vessels, low eye pressure, and visual disturbances after an eye operation (choroidal detachment following filtration surgery).
- If you suffer from severe damage to the clear layer at the front of eye (the cornea), phosphates may cause in very cases cloudy patches on the cornea due to calcium build-up during treatment.

Digestive system:

- feeling sick
- being sick
- diarrhoea
- indigestion (dyspepsia) including stomach ache, feeling bloated or 'full'
- dry mouth
- taste disturbances (dysgeusia)
- stomach pain.

Other parts of your body:

- a lack of strength and weakness generally or when exercising
- Muscle weakness/tiredness (asthenia)
- Muscle pain not caused by exercise (myalgia)
- extreme tiredness (fatigue)
- chest pain
- pain in the fingers and toes.

Immune system:

- hives (urticaria) or itchy rash
- itchiness (pruritus)
- local or generalised rash

Metabolism:

- 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 (or glucose) levels (hypoglycaemia) (symptoms of which can include feeling sick, sweating, weakness, faintness, confusion or coma).

Skeleton:

- joint pain.

Nervous system:

- stroke (cerebrovascular accident)
- reduced blood supply to the brain
- dizziness
- headache
- fainting (syncope)
- unusual sensations like a feeling of pins and needles (paraesthesia)
- increases in signs and symptoms of, or worsening of a disorder called myasthenia gravis which affects the muscles and causes weakness and tiredness.

Brain:

- depression
- difficulty sleeping (insomnia)
- an increased number of dreams
- nightmares
- memory loss
- hallucination
- lack of concentration.

Reproductive system:

- a reduced sex drive (sexual dysfunction, decreased libido)
- ‘Peyronie’s disease’ in men, causing the penis to bend when erect. The signs may be abnormal curve, pain or hardening of the tissue of your penis
- Impotence
- difficulty passing water.

Lungs:

- breathlessness (dyspnoea)
- cough
- fluid in the lungs
- failure of the lungs to function normally (symptoms of which can include bluish skin, confusion or sleepiness).

Skin:

- hair loss (alopecia)
- red, itchy, flaky rash or worsening of pre-existing psoriasis
- itching
- peeling of skin
- purple-coloured spots and patches on the skin
- sweating
- skin rash with white silvery coloured appearance (psoriasiform rash).

Circulatory system:

- abnormally low blood pressure (hypotension)
- pain in your legs on walking
- redness and flushing caused by increased blood flow to the skin
- poor blood circulation - Raynaud's phenomenon (which causes the fingers and/or toes to turn white, blue or red in hot or cold temperatures).

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 via the national reporting systems listed below.

United Kingdom

Yellow Card Scheme

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

Malta

ADR Reporting

www.medicinesauthority.gov.mt/adrportal

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

5. How to store Timolol Eye Drops

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the outer carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the bottle in the original outer cardboard carton in order to protect from light.

You can use Timolol Eye Drops for only four weeks after first opening the bottle, to prevent infections. Discard the opened bottle with any remaining solution after that time.

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 Eye Drops contain

The active substance is timolol. One ml of Timolol 0.25% w/v Eye Drops solution contains 2.5 mg of timolol (as 3.4mg of timolol maleate). One ml of Timolol 0.5% w/v Eye Drops Solution contains 5 mg of timolol (as 6.8mg of timolol maleate).

The other ingredients are disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, sodium chloride, benzalkonium chloride, sodium hydroxide (E524) (0.08% w/v in timolol 0.25% w/v eye drops, solution and 0.1% w/v in timolol 0.5% w/v eye drops, solution) and water for injections.

What Timolol Eye Drops looks like and contents of the pack

Timolol is a clear, colourless to light yellow, solution that is used as an eye drop.

Timolol Eye Drops are available in a 5 ml natural plastic (low density polyethylene) bottle, containing 5 ml of timolol eye drop solution, fitted with a natural plastic (low density polyethylene) plug and a white plastic (high density polyethylene) screw cap with a tamper-evident seal, contained within a cardboard carton.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, U.K.

Manufacturer:

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, U.K.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Timolol 0.25% w/v Eye Drops, Solution	29831/0353
Timolol 0.5% w/v Eye Drops, Solution	29831/0354

This is a service provided by the Royal National Institute of Blind People.

For the Republic of Ireland or Malta please call +44 1978 669272.

These medicinal products are authorised in the following Member States in the EEA, under the following names:

Cyprus - Timolol Wockhardt 0.25% w/v Eye Drops, Solution; Timolol Wockhardt 0.5% w/v Eye Drops, Solution

Malta - Timolol 0.25% w/v Eye Drops, Solution; Timolol 0.5% w/v Eye Drops, Solution

Republic of Ireland - Timolol 0.25% w/v Eye Drops, Solution; Timolol 0.5% w/v Eye Drops, Solution

United Kingdom - Timolol 0.25% w/v Eye Drops, Solution; Timolol 0.5% w/v Eye Drops, Solution

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