

PACKAGE LEAFLET: INFORMATION FOR THE USER

TIMALEN

0.5% eye drops

TIMOLOL (AS TIMOLOL MALEATE)

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 • 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 TIMALEN is and what it is used for
2. Before you take TIMALEN
3. How to take TIMALEN
4. Possible side effects
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1. WHAT TIMALEN IS AND WHAT IS IT USED FOR

The active ingredient TIMALEN belongs to a group of medicines called beta-blockers. TIMALEN is used to treat raised pressure of eye (intraocular pressure) which occurs in various conditions including glaucoma and ocular hypertension.

2. BEFORE YOU TAKE TIMALEN

Do not use if you:

- are allergic (hypersensitive) to TIMALEN maleate or beta-blockers or to any other ingredient of this medicine 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).
- if you have a slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats)

Take special care with TIMALEN

Before you use TIMALEN please 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
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes as TIMALEN may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as TIMALEN may mask signs and symptoms

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

Paediatric population:

TIMALEN eye drop solution should generally be used with caution in young patients. In newborns, infants and younger children TIMALEN 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.

TIMALEN 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.

Using other medicines

TIMALEN 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 a prescription. In particular:

- a calcium antagonist (e.g. verapamil or diltiazem) often used to treat high blood pressure, angina, or an abnormal heartbeat
- digoxin, often used to treat heart failure or an abnormal heartbeat
- medicines known as a catecholamine-depleting agents (e.g. rauwolfia alkaloids/reserpine) used to treat high blood pressure
- a pressor amine (e.g. adrenaline) used to treat severe allergic reaction
- clonidine to treat high blood pressure
- quinidine, a medicine used to treat heart conditions and some types of malaria
- other beta-blockers (e.g. other preparations of TIMALEN both oral and/or ocular), which belong to the same group of medicines
- antidepressants known as fluoxetine and paroxetine.

Pregnancy and breast-feeding

Do not use TIMALEN if you are pregnant unless your doctor considers it necessary. Do not use TIMALEN if you are breast-feeding. TIMALEN may get into your milk.

Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines

No effects on ability to drive and use machines have been reported. However do not drive or operate machines if you experience any visual disturbance after using the product. Wait until this clears before driving or using machines.

Important information about some of the ingredients of TIMALEN Eye Drops

The eye drops contain benzalkonium chloride as preservative which may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses before using the eye drops and wait at least 15 minutes before reinserting. The preservative is known to discolour soft contact lenses.

3. HOW TO TAKE TIMALEN

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

The usual starting dose is one drop of 0.25% eye drops into each affected eye(s) twice daily, approximately 12 hours apart. Your doctor will change your treatment as necessary. If you are using in combination with another eye drop medicine, wait 5-15 minutes before applying the second eye drop.

Posology:

Paediatric population:

A detailed medical examination should precede the use of TIMALEN. Your doctor will carefully evaluate the risks and benefits when considering treatment with TIMALEN. 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.

Instructions for use:

(please also refer to pictograms at the end of the leaflet)

- First wash your hands
- Avoid touching the eye (or any other surface) with the tip of the bottle
- If you wear soft contact lenses, they should be removed before using the eye drops and wait at least 15 minutes before reinserting
- These drops are supplied as a sealed bottle with a spiked cap. When using the
- bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle
- Tilt your head back and look at the ceiling
- Pull the lower eyelid gently downwards
- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye
- After using TIMALEN, press a finger into the corner of your eye, by the nose for 3 - 5
- minutes. This helps to stop TIMALEN getting into the rest of the body.
- Repeat for the other eye if necessary
- Replace and tighten the cap immediately after use.

Duration of treatment:

For a transient treatment in the paediatric population.

Be careful not to touch the tip of the bottle on your eye or on any other surface.

Ocular solutions if handled wrongly can become contaminated by common bacteria and cause eye infections. If you do develop any other eye condition whilst using this product, see your doctor immediately.

Keep using your medicine until your doctor tells you to stop.

If you use more TIMALEN than you should

If you accidentally use too much, **contact your doctor or go to the nearest hospital casualty department immediately.**

Overdose:

There is no experience of an overdosage with TIMALEN which is unlikely when given as eye drops. The signs of overdosage include slow heart rate, drop of blood pressure, breathing difficulties, and heart attack.

If you forget to use TIMALEN

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal schedule dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TIMALEN 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 TIMALEN without speaking to your doctor.**

If you experience a rare (these may affect between 1 in 1,000 and 1 in 10,000 patients) but serious allergic reaction (difficulty breathing, closing of the throat, swelling of the lips, tongue, or face or hives) to TIMALEN, stop using the medication and contact your doctor immediately.

Like other medicines applied into eyes, TIMALEN 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, itchiness, severe sudden life-threatening allergic reaction.

- Low blood glucose levels
- Difficulty sleeping (insomnia), depression, nightmares, memory loss
- 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), conjunctivitis, 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 block, heart failure, heart attack, 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, nasal congestion, cough.
- Taste disturbances, loss of appetite, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting
- fainting, stroke, reduced blood supply to the brain, increased signs and symptoms of myasthenia gravis (weakness, drooping eyelids, double vision, muscle disorder),
- dizziness, unusual sensations (like pins and needles), and headache.
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Muscle pain not caused by exercise.
- Sexual dysfunction, decreased libido.
- Muscle weakness, tiredness.
- Depression, anxiety or psychiatric disturbances

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TIMALEN

Keep all medicines out of the sight and reach of children. Do not store at a temperature above 25°C.
Protect from light.

Discard the bottle 28 days after opening, even if there is solution remaining.

Do not use TIMALEN after the expiry date which is stated on the bottle and on the carton the bottle is packed in.