

Timolol maleate

Timabak

5mg/mL (0.50%) Ophthalmic Solution (Drops)

Beta-Adrenoceptor Blocker

FOR EXTERNAL USE ONLY

Formulation:

Each mL contains: Timolol (as maleate) 5mg/mL

Read all of this leaflet carefully before you start using this medicine

- 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 any of the side effects get serious or if you notice any side effect not listed in this leaflet, talk to your doctor or pharmacist

What is in this leaflet

1. What is Timolol maleate (TIMABAK) 0.50%, eye drops solution and what is used for
2. What should you know before using Timolol maleate (TIMABAK) 0.50%, eye drops solution
3. How to use 0.50%, eye drops solution
4. Possible side effects
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1. WHAT IS Timolol maleate (TIMABAK) 0.50%, eye drops solution AND WHAT IS USED FOR?

It is a beta-blocker used by eye drops route.

This medicine is prescribed for the treatment of certain types of eye disease involving intraocular hypertension e.g., glaucoma and intraocular hypertension

2. WHAT SHOULD YOU KNOW BEFORE USING Timolol maleate (TIMABAK) 0.50%, eye drops solution

Never use Timolol maleate (TIMABAK) 0.50%, eye drops solution in the following cases:

- Allergy to one of the components of the eye drops solution
- Cardiac insufficiency not controlled by medication (heart function failure not controlled by the treatment)
- Cardiogenic shock (shock of cardiac origin)
- Prinzmetal's angina (type of angina attack)
- Sinus dysfunction of the heart (including sino-auricular block)
- Bradycardia (pulse less than 45-50 beats per minute) slowed rate rhythm)
- Cardiac conduction disorders (second- and third-degree atrioventricular block)
- Raynaud's disease and peripheral circulatory disturbances (symmetrical circulatory disturbances in the fingers with numbness and peripheral arterial disturbances),
- Untreated phaeochromocytoma (excessive hormone production causing severe arterial hypertension),
- Hypotension,
- Treatment with floctafenine
- Treatment with sultopride (medicine used mostly to psychiatric therapy),
- Asthma and chronic pulmonary and bronchial disease with obstruction (except on doctor's advice)

This medicine should generally not be taken in combination with amiodarone, certain calcium antagonists (Bepiridil, verapamil, diltiazem) and beta-blockers used to treat heart failure.

Take special care when using Timolol maleate (TIMABAK) 0.50%, eye drops solution

DO NOT STOP TREATMENT SUDDENLY WITHOUT YOUR DOCTOR'S ADVICE

DO NOT INJECT, DO NOT SWALLOW.

Periodontic ophthalmological examination should be performed while undergoing this treatment, in particular, to check for drug resistance (loss of drug efficacy during long-term treatment)

Before using this medicine tell your doctor of any current or previous occurrence of the following medical conditions:

- Coronary heart disease (symptoms may include pain or tightness in the chest, shortness of breath or choking), heart failure or drop in blood pressure (hypotension),
- Heart rhythm disorders such as slow pulse,
- Respiratory problems asthma chronic pulmonary or bronchial disease with obstruction
- Poor blood circulation (such as Raynaud's syndrome or disease)
- Diabetes-as timolol may mask the signs and symptoms
- Phaeochromocytoma – this will require careful monitoring of your arterial pressure
- Psoriasis (skin disorder)

- Contact lens wearers: Avoid wearing contact lenses during the treatment due to reduction in lachrymal secretion, linked to beta-blockers in general
- If you have to undergo surgery, tell your doctor that you are using TIMABAK as timolol may modify the effects of certain drugs used during anesthesia
- Paediatric population
- Eye drops solutions containing Timolol must always be used with caution with young patients. Timolol must be used with extreme caution with newborns, infants and young children. If the patients develop symptoms such as coughing, wheezing, abnormal breathing or abnormal pauses in breathing (apnea), the use of this product should be discontinued immediately. Contact your doctor as soon as possible. A portable apnea monitor may also be useful
- Timolol has been studied in infants and young children aged from 12 days to 5 days presenting with increased pressure in one or both eyes or who have been diagnosed with glaucoma. See your doctor for more information.

Using or taking other medicines

If your doctor has prescribed you another eye drops solution you must instill this solution 15 minutes before using Timolol maleate (TIMABAK) 0.50% eye drops

Timolol maleate (TIMABAK) 0.50% eye drops solution can affect or be affected by other medicines that you are using or taking particularly other eye drops solutions for the treatment of glaucoma.

Tell your doctor of any medicines that you are taking or plan to taking or plan to take for hypotension heart problems or diabetes, quinidine (used to treat heart rhythm disorders and certain types of malaria), or antidepressants such as fluoxetine and paroxetine

Tell your doctor or pharmacist if you are taking or have recently taken another medicine, including a medicine available without prescription.

Pregnancy and Lactation

Do not use Timolol maleate (TIMABAK) 0.50% eye drops solution if you are pregnant unless your doctor consider it necessary.

Do not use Timolol maleate (TIMABAK) 0.50% eye drops solution if breastfeeding. Timolol may pass into your breast milk.

Ask you doctor for advice before taking any medicine during breastfeeding

Athletes

The attention of sports professionals is drawn to the fact that this medicinal product contains an active ingredient which can induce a positive reaction in anti-doping tests.

Driving vehicles and operating machines

You may have temporary blurred eyesight after ocular administration of the product. Wait until your vision returns to normal before driving vehicles or operating machines. Timolol maleate (Timabak) may also cause other side effects (dizziness, fatigue) liable to affect your ability to drive or operate machines, if no doubt, seek you doctor's advice.

3. HOW TO USE Timolol maleate (TIMABAK) 0.50%, eye drops solution

Follow your doctor's instructions very carefully when using Timolol maleate (TIMABAK) 0.50%, eye drops solution. If in doubt ask your doctor or pharmacist.

As guideline, the usual dosage is 1 drop in the affected eye, twice daily (morning and evening)

Premature babies, newborns and infants: the use of this eye drops solution is not recommended.

Method of Administration

Only one single drop of Timolol must be instilled at each administration.

After instillation, keep the eyes closed as long as possible (i.e. 3 to 5 minutes) and press down continuously on the corner of the eye closest to the nose to prevent the drop of Timolol diffusing throughout the body.

Means of administration

Eye drops route. This medicine is intended to be used in the eye

DO NOT INJECT, DO NOT SWALLOW

- Wash your hands carefully before instilling the drops
- Avoid touching eye or eyelids with the tip
- Look upwards and pull the lower lid of the eye down slightly and instill 1 drop
- After using Timolol maleate (TIMABAK) 0.50%, eye drops solution press your finger on the corner of your eye next to your nose for 2 minutes. This helps to prevent timolol diffusing into the rest of your body
- Put the cap back on the bottle after use

Frequency of administration

Apply twice daily (morning and evening) or as prescribed by the physician Your ophthalmologist will advise on the time of day to apply

Duration of treatment

Follow your doctor's prescription

Use in children

Dosage

A full medical examination will have to be carried out before using Timolol maleate (TIMABAK) 0.50%, eye drops solution. Your doctor will take great care in assessing the risks and benefits outweigh the risks. It is recommended to use the smallest possible concentration available of the

active ingredient once daily.

Concerning 'use in children', the concentration of 0.1% of active ingredient may be sufficient to control the internal eye pressure. If this dosage does not provide sufficient control the internal eye pressure, it may be necessary to instill the drops twice daily at 12 hours interval. Patients particularly newborns, must be closely monitored for one to two hours after the first administration, any side effects must be monitored very carefully up to surgery.

Duration of treatment

In infants and young children, Timolol maleate (TIMABAK) 0.50%, eye drops solution will be prescribed as part of a transitional treatment.

If you have used too much Timolol maleate (TIMABAK) 0.50%, eye drops solution:

If you have instilled too many drops or accidentally swallowed the contents of the bottle, you may, in addition to other side effects, feel empty-headed, have difficulty breathing or feel your pulse rate slow down. In this case CONTACT YOUR DOCTOR IMMEDIATELY

If you forgot to take Timolol maleate (TIMABAK) 0.50%, eye drops solution:

Take Timolol maleate (TIMABAK) 0.50%, eye drops solution as prescribed by your doctor

Do not take a double dose to compensate for the dose you forgot to take. Instill the forgotten dose as soon as possible. However, if it is nearly time to take the next dose; do not instill the forgotten dose.

Effects that may appear on discontinuing treatment with Timolol maleate (TIMABAK) 0.50%, eye drops solution:

If you interrupt your treatment without your doctor's advice

4. Possible side effect

Like any medicine, Timolol maleate (TIMABAK) 0.50%, eye drops solution is liable to have side effects, however they do not occur systematically in everyone.

Provided there are no serious side effects, you can usually continue to use the eye drops solution. If you have any concerns, talk to a doctor or a pharmacist. Do not discontinue of Timolol maleate (TIMABAK) 0.50%, eye drops solution without seeking your doctor's advice.

As with other eye care medicines, timolol passes into the blood. This can have side effects similar to those observed with beta-blocker agents that are administered intravenously and/or orally. The frequency of occurrence of side effects after topical eye drops administration is less than that observed when the medicines are taken orally or injected. This listed side effects are those observed in the class of beta-blockers used to treat ocular pathologies.

- Generalised allergic reactions particularly swelling under the skin (that can occur in areas such as the face, arms or legs and which may obstruct the airways leading to difficulties in breathing in swallowing, hives (or itching) localized or generalized skin eruptions, itching, sudden onset and serious allergic reaction that may cause a life-threatening risk.
- Drop in blood sugar level (hypoglycemia)
- Sleep disorders (insomnia), depression, nightmare, loss of memory
- Loss of consciousness, strokes, decreased of blood flow to the brain, increase in signs and symptoms of myasthenia gravis (muscular disorder), dizziness, unusual sensations (such as tingling), and headaches.
- Signs and symptoms of ocular irritation (such as burning sensation, stinging, watery eyes, redness), inflammation of the eyelid, conjunctival redness, conjunctivitis, inflammation of the cornea blurred vision and detachment of the sub-retinal layer containing blood vessels following filtration surgery that may cause visual disorders, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the upper layer of the eyeball) , upper eyelid sagging (leaving the eye half-closed), double vision, visual disorders including changes in the refraction index (sometimes due to discontinued treatment with myopic drops)
- Slow pulse, chest pain, palpitations, oedema (accumulation of fluids) changes in heart rhythm and rate congestive heart failure (heart disease characterized by shortness of breath or swelling of the feet and legs due to accumulation of fluids) a certain type of heart rhythm disorder, heart attack, heart failure.
- Hypotension, Raynaud's phenomenon, cold hands and feet and cloudification (cramps in the feet and/or pain in the legs when walking)
- Constriction of the pulmonary airways (mainly in patients already suffering a pathology) breathing difficulties, coughing
- Taste disorders, nausea, indigestion, diarrhea, dry mouth, abdominal pain, vomiting
- Hair loss, skin eruptions with a silvery white appearance (psoriasis-like outbreaks) or worsening of psoriasis, skin eruptions
- Muscular pain not due to exercise, systemic lupus erythematosus
- Sexual disorders, loss of libido, impotence
- Weakness/muscular fatigue
- Positive results during tests for anti-nuclear antibodies

If you notice any side effects not listed in this notice, or if certain side effects become serious, please tell your doctor or pharmacist

5. HOW TO USE TIMOLOL MALEATE (TIMABAK) 0.50%, eye drops solution

Keep out of reach and sight of children

Do not use Timolol maleate (TIMABAK) 0.50% eye drops solution

after expiry date refers to the last day of the month.

Store at temperatures not exceeding 25°C

At first-time opening of the bottle, the eye drops solution can be kept for up to 8 weeks.

Do not use Timolol maleate (TIMABAK) 0.50% eye drops solution if you notice visible signs of damage or deterioration

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of any unused medicines. Doing this helps to protect the environment.

6. FURTHER INFORMATION

What is Timolol maleate (TIMABAK) 0.50% eye drops solution contains:

Active Ingredients

	0.50%
Timolol	0.500g
In the form of timolol maleate For 100 mL of solution	0.685g

Other components:

Disodium phosphate dodecahydrate, sodium dihydrogen, phosphate dihydrate, water for injections

What is Timolol maleate (TIMABAK) 0.50% eye drops solution how is the external box presented

This medicine is an eye drops solution is dispensed in 5ml or 10ml bottles

Caution:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

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