

PACKAGE LEAFLET: Information for the patient

TIMOLOL

Eye drops solution – 0.5%

(Timolol maleate)

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 symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

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. Other information

1. WHAT TIMOLOL IS AND WHAT IT IS USED FOR

Timolol is a non-selective beta-blocker. When applied to the eye, timolol reduces normal and increased intra-ocular pressure. Reduction of the intra-ocular pressure is related to the reduction of the synthesis of aqueous humour in the ciliary body. Unlike myotic drugs, timolol does not affect pupil size.

Timolol eye drops are indicated in the reduction of raised intra-ocular pressure in various conditions such as in patients with ocular hypertension, patients with chronic open-angle glaucoma, including aphakic patients, in several patients with secondary glaucoma. It is also

indicated as adjunct treatment in children with glaucoma that is not adequately treated by other antiglaucoma drugs.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TIMOLOL

Do not use Timolol if:

- you are sensitive (allergic) to the adrenergic beta-blockers (such as timolol) or to any of the excipients of this medicine, because allergic reactions, including anaphylaxis, may occur;
- you have bronchial asthma or bronchospasm or history of obstructive airway disease;
- you have chronic obstructive bronchopneumonia;
- you have sinus bradycardia or sick sinus syndrome;
- you have atrioventricular (A-V) block of second- or third-degree;
- you have a severely decompensated heart;
- you have cardiogenic shock;
- you have pheochromocytoma (apart from specific use with alpha-blockers);
- you have hypotension;
- you have metabolic acidosis;
- you have Prinzmetal angina;
- you have severe peripheral arterial disease.

Take special care with Timolol

Talk to your doctor or pharmacist before using Timolol.

Timolol eye drops should be cautiously used in patients who are also using other adrenergic beta-blockers or calcium channel blockers, because systemic effects may occur.

Patients who use oral adrenergic beta-blockers and are prescribed timolol eye drops, should be monitored for the possibility of additive effects occurring in the intra-ocular pressure and other general effects of this drug category.

When timolol eye drops are used for reduction of increased intra-ocular pressure in narrow-angle glaucoma, it is necessary that they are used in combination with a myotic drug and not used alone.

Use of timolol eye drops in pregnancy is not recommended. If strictly necessary, the therapeutic benefits for the mother should be weighed against the possible risks for the child.

Use of timolol eye drops during breast-feeding is not recommended.

If a strict control of intra-ocular pressure is needed, then timolol eye drops may be combined with myotics, adrenaline and carbonic anhydrase inhibitors (systemically acting, not locally).

Timolol, eye drops, may mask the symptoms of hyperthyroidism and hypoglycaemia.

Timolol, eye drops, should be used with caution in patients with heart problems (such as first-degree atrioventricular block, coronary artery disease, heart failure, or low blood pressure) and in heart patients with heart rate problems (such as slow and irregular heartbeat).

Timolol should be used with caution in problems related to poor blood circulation (such as Raynaud's syndrome).

Timolol should be used with caution in myasthenia gravis and psoriasis.

Timolol should be used with caution in patients with corneal disease.

Soft contact lenses should be removed prior to application of timolol eye drops (see “Important information for some of the ingredients of Timolol”).

Use of timolol eye drops may produce positive results in anti-doping tests.

Tell your doctor before surgery that you are using Timolol eye drops because it may change the way some medicines work during anesthesia.

Children

Use in children requires extreme caution and in each case it should be justified by the doctor.

Other medicines and Timolol

Contact your doctor or pharmacist if you are taking / using, have recently taken / used other medicines, including medicines without prescription. Inform your doctor about your treatment with Timolol if any other medicine is prescribed to you during treatment. Clinically important medication interactions are observed after systemic absorption of timolol.

It is **particularly important** that your doctor is aware that you are treated with:

- anesthetics, anxiolytics and hypnotics;
- antihypertensives (the antihypertensive effect is potentiated);
- alfa-blockers (enhanced hypotensive effect); also, increased risk of first-dose hypotension with post-synaptic alpha-blockers such as prazosin;

- antiarrhythmics (increased risk of myocardial depression, bradycardia and atrioventricular block);
- calcium-channel blockers and cardiac glycosides (increased risk of bradycardia and atrioventricular block);
- 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);
- antidepressants known as fluoxetine and paroxetine;
- sympathomimetics (severe hypertension and bradycardia may occur if used with adrenaline, noradrenaline or dobutamine);
- xanthine alkaloids (decreased therapeutic effect);
- fingolimod (possible increased risk of bradycardia);
- moxislyte (possible severe postural hypotension).

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using this medicine.

Safety of the use of this medicine during pregnancy and breast-feeding is not yet confirmed, therefore, its use during pregnancy and breast-feeding should be avoided (Category C).

If strictly necessary, the therapeutic benefits for the mother should be weighed against the possible risks for the child.

Driving and using machines

Because Timolol is an eye drops solution (applied to the eye), it should not be used when driving or using machines. Also, care should be taken during treatment, because Timolol may cause side effects such as blurred vision and vision disturbances. Avoid driving and using machines.

Important information for some of the excipients of Timolol

Timolol eye drops, solution 0.5% contains 0.1 mg benzalkonium chloride in 1 ml solution, which may 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. 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.

3. HOW TO USE TIMOLOL

Your doctor will inform you about the dose of timolol that you should use and when to use it. It is important to strictly follow the doctor's advice and to never change the dose yourself, regardless of how you feel.

Ask your doctor or pharmacist if you are not sure about the dose that you should use and when you should use it.

Dosage:

1 drop of solution, twice daily into the affected eye.

Administration method of Timolol eye drops, solution is as follows:

- Wash your hands thoroughly
- Do not touch the dropper tip
- Look upward
- Pull down the lower eyelid to make a pouch
- Place the dropper as close as possible to the pouch, but do not let the dropper touch it
- Instill the appropriate number of drops to the pouch
- Close your eye for about 2 minutes
- The excess solution coming out of the eye may be wiped with a sterile gauze.

When administered, eye drops may cause a burning sensation, which does not last for more than several minutes. Otherwise, consult your doctor or pharmacist.

If you use more Timolol than you should

If you use more Timolol than you should or if the children have used this medicine by mistake, please contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on actions that should be taken.

Side effects due to timolol eye drops solution overdose are rare.

However, side effects that may occur because of timolol overdose (these high doses may pass through the nasolacrimal canal) include systemic absorption of timolol that may be associated with systemic effects of beta-blockers such as: confusion, cardiac insufficiency, breathing difficulty, bradycardia, hypotension, alopecia.

If you forget to use Timolol

If you forget to use one dose of Timolol, use it as soon as possible. If it is almost time for your next dose, use it and skip the missed dose. Do not use a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are dose-related and disappear when the dose is reduced or treatment is interrupted.

Timolol eye drops are generally well tolerated. Side effects such as pain (of the eyes), visual disturbances may occur and rare cases of mild irritation of the eye have been observed.

As with other locally used ophthalmic preparations, the active ingredient (timolol) may be absorbed into the blood. The same undesirable effects occurring with systemic adrenergic beta-blockers may appear during their local use. These effects are:

- Uncommon side effects: headache, bradycardia, dyspnea, fatigue.
- Rare side effects: dizziness, sleep disturbances (including nightmares), heart failure, hypotension, bronchospasm, paresthesia, coldness of the extremities, exacerbation of Raynaud phenomenon, rashes, exacerbation of psoriasis, alopecia (reversible), gastrointestinal disturbances.
- Frequency not known: thrombocytopenia, hyperglycemia, hypoglycaemia.

Other side effects include: systemic lupus erythematosus (immune system disease that can cause inflammation of internal organs); allergic reactions such as rash, hives, skin itching, in rare cases possible swelling of the lips, eyes, and mouth; chest pain; a certain type of cardiac arrhythmia (AV block); palpitations (a fast and/or irregular heartbeat); changes in rhythm or speed of the

heartbeat; cardiac arrest; edema (fluid retention); itching; depression; increase in signs and symptoms of myasthenia gravis (muscle disease); cerebral ischemia (decreased blood flow to the brain); double vision; drooping of the eyelids (causing the eyes to remain half closed); detachment of the layer under the retina that contains blood vessels, after filtration surgery, possibly with visual disturbances; signs and symptoms of ocular irritation (e.g. burning, stinging, itching, tearing, redness); blurred vision, corneal erosion (damage to the top layer of the eyeball); swelling and/or irritation of the eyes and surrounding areas, feeling something in the eye, decreased corneal sensitivity (inability to feel when something enters the eye, not feeling pain), dry eyes; cough; taste disturbance; nausea; indigestion; diarrhea; dry mouth; abdominal pain; vomiting; muscle pain not caused by exercise; sexual dysfunction; decreased sex drive; asthenia.

In very rare cases, some patients with severe damage to the transparent layer of the front part of the eye (the cornea) have developed opaque areas on the cornea due to calcium accumulation during treatment.

Talk to your doctor or pharmacist if you notice side effects not mentioned above.

5. HOW TO STORE TIMOLOL

Keep this medicine in a dry, cool place at a temperature below 25°C!

Protect from light!

Do not freeze!

Do not use Timolol after the expiry date!

Keep this medicine in a safe place out of the sight and reach of children! This medicine may harm them.

6. OTHER INFORMATION

What Timolol 0.5% eye drops, solution contains

The **active substance** is timolol maleate.

1 ml solution contains 6.8 mg timolol maleate equivalent to 5 mg timolol (0.5%).

The **excipients** are: benzalkonium chloride, sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dihydrate, sodium hydroxide (may be added for pH adjustment), water for

injection.

Content of the pack

Box with 1 plastic vial of 5 ml.

Marketing Authorization Holder (MAH) and Manufacturer:

PROFARMA Sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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