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Forthcoming version

Package leaflet: Information for the patient

TIMOSOL 0.5 %, eye drops solution

Timolol as timolol maleate

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 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TIMOSOL is and what it is used for
2. What you need to know before you use TIMOSOL
3. How to use TIMOSOL
4. Possible side effects
5. How to store TIMOSOL
6. Contents of the pack and other information

1. What TIMOSOL is and what it is used for

The eye contains a liquid that is produced inside the eye. This liquid is then drained in the blood stream, which maintains a necessary pressure for the eye. If the liquid cannot evacuate, the pressure inside the eye increases.

TIMOSOL belongs to the family of beta blocking agents. It acts by decreasing the pressure inside the eye. This medicine is used to reduce the elevated pressure inside the eye (intraocular hypertension).

2. What you need to know before you use TIMOSOL

Do not use TIMOSOL:

- If you are allergic to the active substance (timolol), to beta blocking agents or any of the other ingredients of this medicine (listed in section 6).
- If you currently suffer or if you have previously suffered from respiratory problems as asthma, severe chronic obstructive bronchitis (severe lung disease that can cause wheeze, respiratory disorders et/or persisting cough).
- If you have a slow cardiac rhythm (sinus bradycardia), a heart sinus dysfunction (sinus disease, sinoatrial bloc), cardiac conduction disorders (2nd and 3rd degree atrioventricular bloc).

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- If you have confirmed cardiac failure, or have a shock of cardiac origin (cardiogenic shock).
- If you have an excessive production of hormone that cause severe arterial hypertension (untreated pheochromocytoma).
- If you have a cornea malformation (corneal dystrophy).
- In case of treatment with floctafenine (used to treat pain) or sultopride (used mostly in psychiatry).

Warnings and precautions

Talk to your doctor or pharmacist before using TIMOSOL.

Before using this medicine, warn that you currently suffer or previously suffered from:

- Coronary diseases (symptoms might be pain in the chest or chest oppression, breathlessness or stuffiness), cardiac failure or decrease arterial blood pressure,
- Cardiac rhythm disorders, as slow pulse,
- Respiratory disorders, asthma or chronic bronchial or lung diseases, with congestion,
- Poor blood circulation (as Raynaud disease or syndrome),
- Diabetes, as timolol might cover signs and symptoms of hypoglycaemia,
- Thyroidal hyperactivity, as timolol can cover the signs and symptoms,
- If you wear contact lenses. Wearing contact lenses required specific monitoring because of the risk of decrease of tear secretion and of related corneal hypoesthesia, generally, to beta blocking agents,
- If you have an eye infection
- If you have an eye injury.
- If you have to go through surgery, tell you doctor that you use TIMOSOL because timolol can modify the effect of certain medicines used for anaesthesia.

Children

Timolol was studied in infants and children aged 12 days to 5 years whose eye(s) was increased or to whom a glaucoma was diagnosed. In new-born, infants and children, timolol should be used with extreme precaution. For more information, talk to your doctor.

Other medicines and TIMOSOL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

TIMOSOL can influence or be influenced by other medicines that you used, notably other eye drops for the treatment of glaucoma.

Tell your doctor if you take or intend to take other medicines for hypotension, medicines for the heart or for the treatment of diabetes, quinidine (used for heart rhythm disorders and certain types of malaria), antidepressants called fluoxetine and paroxetine.

Tell your doctor or pharmacist if you take, have recently taken or might take any medicines, notably floctafenine or sulpride.

Pregnancy and breast-feeding

Do not use TIMOSOL is you are pregnant, except if your doctor considers it necessary.

Do not use TIMOSOL if you are breast-feeding. Timolol might pass into your milk.

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If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may experience transient blurred vision after the administration of TIMOSOL. Wait until you recover your normal vision before driving vehicles or using machines. TIMOSOL may also cause other undesirable effects (dizziness, tiredness) likely to affect your ability to drive or use machines. In case of any doubt, ask your doctor.

TIMOSOL contains benzalkonium chloride

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.

Sportsmen (athletes)

The active substances (timolol) may cause a positive test in anti-doping control.

3. How to use TIMOSOL

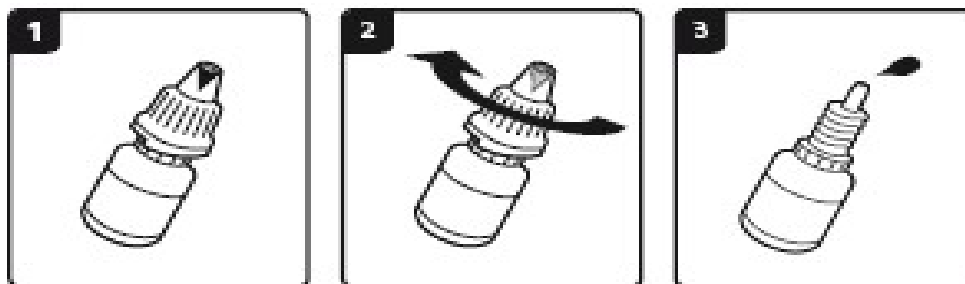
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Posology

The recommended dose is 1 drop in the eye, twice a day (1 drop in the morning and 1 in the evening).

Method of administration

This medicine is for ophthalmic use only. **DO NOT SWALLOW, DO NOT INJECT.**



While using this eye drops solution, please respect the following steps

1. Wash your hands prior to instillation
2. Avoid touching your eye or eyelid with the tip of the bottle.
3. Squeeze one drops inside the lower lid while looking upwards and close your eye for a few seconds

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4. Press a finger into the corner of your eye by the nose for about 30 seconds or close your eyes for 2 minutes. This helps to stop timolol getting into the rest of your body to reduce the occurrence of side effects
5. Put the cap back on the bottle after use

Duration of treatment

Respect the duration of treatment indicated by your doctor.

If you use more TIMOSOL than you should

There is no data existing on overdose with TIMOSOL in human.

The most usual effects observed during an overdose with medicines of the same family as TIMOSOL (beta blocking agents) are: slowed cardiac rhythm (symptomatic bradycardia), decreased in arterial blood pressure (hypotension), difficulty breathing (bronchospasm) and a heart disease (acute heart failure).

If you have used too much TIMOSOL, tell your doctor or pharmacist immediately.

If you forget to use TIMOSOL

Do not take a double dose to make up for a forgotten dose. Take your treatment as soon as possible, without modifying the quantity of the number of drops to be administered.

If you have any further questions on the use of this medicine, 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 keep using the eye drops, unless the effects are serious. If this worries you, tell your doctor or pharmacist. Do not stop using TIMOSOL without consulting your doctor.

As the other medicines intended to be used in the eyes, timolol passes into the blood stream. This can bring side effects similar to those observed with intravenously and/or orally administered beta blocking agents. The frequency of the side effects after topical ophthalmic administration is smaller than the orally or injection administration. The side effects listed below are those observed in the class of beta blocking agents, used to treat ophthalmologic pathologies.

- Disseminated lupus erythematosus, generalised allergic reactions, notably swelling under the skin (that can occur in areas like the face and limbs and that can block the respiratory ways, causing difficulty breathing or swallowing, urticarial (or itching), localised or generalised skin rash, itching, sudden and serious allergic reaction that can threaten the vital prognostic.
- Decrease of the blood sugar level.
- Sleeping disturbances (insomnia), depression, nightmares, memory loss.
- Loss of consciousness, stroke, decrease in the blood supply to the brain, increase of the signs of myasthenia gravis (muscular disorder), dizziness, unusual sensation (as tingling), headaches.

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- Signs and symptoms of eye irritation (for example, burning sensation, tingling, itching, tearing, reddening), conjunctival reddening, conjunctivitis, decrease of corneal sensitivity, eyelid inflammation, blurred vision and detachment of the layer under the retina that contains the blood vessels following a filtrating surgery that can cause visual disorders, decreased sensitivity of the cornea, dry eyes, corneal erosion (damage at the upper layer of the eye globe), upper eyelid collapse (half-closed eye), double vision.
- Slow pulse, chest pain, palpitation, oedema (fluid accumulation), change in the rhythm or speed of the heartbeat, congestive heart failure (chronic disease characterised by breathlessness, feet and legs swelling caused by fluid accumulation), a certain type of heart rhythm disorder, stroke, heart failure.
- Hypotension, Raynaud phenomenon, cold hands and feet.
- Respiratory ways constriction at the level of the lungs (predominantly in patients already suffering from a disease), respiratory difficulties, cough.
- Taste perversion, nausea, indigestion, diarrhoea, dry mouth, abdominal pains, vomiting.
- Hair loss, skin rash with white-silver aspect (psoriasiform eruptions) or worsening of a psoriasis, skin rash.
- Muscle pain not related to an effort.
- Sexual disorders (as impotence) libido decreased.
- Muscle weakness/tiredness.
- Blood test: positive results when testing antinuclear antibodies.

In very rare cases, some patients with serious damage of the transparent part located at the front of the eye (cornea) have developed opaque stains on the cornea because of the accumulation of calcium during the treatment.

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. You can also report side effects directly via the national reporting system.

5. How to store TIMOSOL

Keep this medicine out of the sight and of reach children.

Do not use TIMOSOL after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30 °C. Keep the bottle in the outer pack in order to protect from light. Do not use the eye drops for more than 30 days after first opening.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

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What TIMOSOL contains

- The active substance is timolol maleate.
- The other ingredients are disodium orthophosphate dihydrate, benzalkonium chloride solution, sodium dihydrogen phosphate dihydrate, disodium edetate, sodium chloride, water for injections

What TIMOSOL looks like and contents of the pack

This medicine is an eye drops, solution available in bottle containing 5 ml of clear solution.

Marketing Authorisation Holder and Manufacturer

TIMOSOL[®] is a registered trademark of Exphar s.a., Zoning Industriel Nivelles Sud, Zone II, Avenue Thomas Edison 105, 1402 Thines, Belgium

Manufactured by: Ahlcon Parenterals (India) Ltd, SP 918, Phase III; Bhiwadi (Raj.), India.

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