



Timolol Maleate 0.5 % Preservative free in COMOD Timo-COMOD eye drops

Active substance: Timolol maleate I.P.

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. 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 serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Timo-COMOD 0.5 % is and what it is used for
2. Before you use Timo-COMOD 0.5 %
3. How to use Timo-COMOD 0.5 %
4. Possible side effects
5. How to store Timo-COMOD 0.5 %
6. Further information

1. What Timo-COMOD 0.5 % is and what it is used for

Timo-COMOD 0.5 % is used in diseases of the eye in which the intraocular pressure should be lowered.

Timo-COMOD 0.5 % is used for the therapy of

- elevated intraocular pressure (ocular hypertension)
- chronic open-angle glaucoma
- aphakic glaucoma
- congenital glaucoma, if other therapeutic regimens are not sufficient.

2. Before you use Timo-COMOD 0.5 %

Contraindications

Do not use Timo-COMOD 0.5 % if you are hypersensitive to timolol maleate or one of the other ingredients or if you suffer from one of the following diseases:

- bronchial hyperreactivity
- existing or formerly diagnosed bronchial asthma
- chronic obstructive pulmonary diseases (long lasting disorders with bronchial asthma or bronchitis)
- sinus bradycardia (decelerated heartbeat)
- second and third degree atrio-ventricular block
- overt cardiac failure (heart failure which is not treated with medicines)
- cardiogenic shock
- severe allergic rhinitis (nasal mucosa)
- nutritional disorders involving the cornea

Warnings and precautions

Before you use this medicine, 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
- disturbances of heart rate such as slow heart beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation 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

Tell your doctor before you have an operation that you are using Timo-COMOD 0.5% as timolol may change effects of some medicines used during anaesthesia.

Paediatric population:

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 should be stopped immediately. Contact your doctor as soon as possible. A portable apnoea monitor may also be helpful. Timo-COMOD 0.5 % 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.

Interaction with other medicinal products and other forms of interaction

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 case of concomitant application of adrenaline-containing eye drops (other medicine for lowering the intraocular pressure) they may cause mydriasis (widening of the pupil).

Timolol's pharmacologic action of reducing intraocular pressure is enhanced by adrenaline- or pilocarpine-containing eye drops (other medicines for lowering the intraocular pressure).

In case of concomitant systemic use of beta-blockers (medicines for the treatment of increased blood pressure and disorders of coronary blood vessels) they may lead to a mutual increase in each drug's pharmacologic activity in the eye (lowering of pressure) as well as in the heart- and vascular system.

If Timo-COMOD 0.5 % is used concomitantly with medicines for the lowering of increased blood pressure or for the treatment of heart diseases (e.g. calcium antagonists, reserpine-containing products or beta-receptor blockers), hypotension and significant bradycardia may occur as side effects more often.

Interactions can occur with quinidine (used to treat heart conditions and some types of malaria), antidepressants known as fluoxetine and paroxetine.

Note: If you use concomitant eye drops/ointments, you should wait about 15 minutes between the application of the different medicines. Eye ointments should always be applied at last.

Pregnancy and breast-feeding

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

No well-controlled studies with Timo-COMOD 0.5 % in pregnant and breast-feeding women exist. Therefore, Timo-COMOD 0.5 % should only be used after a careful benefit-risk-assessment has been made by the doctor.

Driving and using machines

This medicinal product may cause blurred vision and impair reaction capability after application even with proper use. Thus, it may influence the ability to drive, use machines or work without secure hold. This is especially relevant in combination with alcohol.

3. How to use Timo-COMOD 0.5 %

Always use Timo-COMOD 0.5 % exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

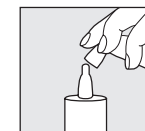
Posology

If not otherwise instructed by your physician, the usual dose is:

At the beginning of the therapy apply 1 drop twice daily into the affected eye. If the intraocular pressure is syntonised on the desired value under regular control, the physician may set the dose to 1 drop per day.

Method of administration

For ocular use.



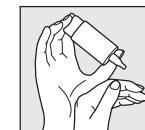
Picture 1

Remove the cap before use (see picture 1). Before the first application please invert the Timo-COMOD 0.5 % bottle with its tip pointing down and press on the base of the bottle until the first drop is ejected from the nozzle. Now the bottle is ready for further use.



Picture 2

Hold the bottle with your first two fingers on the base of the bottle and thumb on the shoulder of the bottle and invert the bottle with its tip pointing down (see picture 2).



Picture 3

Support the hand holding the COMOD® bottle with the other hand as shown in picture 3.

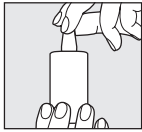


Picture 4

With your head leaning back slightly, pull down your lower eyelid and press firmly on the base of the bottle. This activates the valve mechanism to dispense one drop (see picture 4).

The design of the COMOD® valve system ensures that the size and speed of each drop are the same regardless of the pressure applied to the base of the bottle. Slowly close your eyes to allow the fluid to spread evenly over the eye surface.





Picture 5

Replace the cap immediately after use (see picture 5). Please ensure that the dropper tip is dry. When applying the eye drops, please avoid any contact between the tip of the bottle and your eye or your skin.

Usually, the treatment with Timo-COMOD 0.5 % is a long-term treatment. A treatment withdrawal or a change of dosing should only be done if recommended by your doctor.

Please consult your doctor if you have the impression that the effect of Timo-COMOD 0.5 % is too strong or too weak.

If you use more Timo-COMOD 0.5 % as you should do,

symptoms of overdose like disorders with the heart, circulation, respiratory system or brain function may occur. If severe disorders occur, check with your doctor immediately.

If overdosage occurs, the following measures should be considered:

- Administration of activated charcoal, if the preparation has been taken orally. Studies have shown that timolol maleate cannot be removed by haemodialysis.
- Symptomatic bradycardia: Atropine sulphate, 0.25 to 2 mg intravenously, should be used to induce vagal blockade. If bradycardia persists, intravenous isoprenaline hydrochloride should be administered cautiously. In refractory cases, the use of a cardiac pacemaker should be considered.
- Hypotension: A sympathomimetic agent such as dopamine, dobutamine or noradrenaline should be given. In refractory cases, the use of glucagon has been useful.
- Bronchospasm: Isoprenaline hydrochloride should be given. Concomitant therapy with aminophylline may be considered.
- Acute cardiac failure: Conventional therapy with digitalis, diuretics and oxygen should be instituted immediately. In refractory cases, the use of intravenous aminophylline is recommended.

This may be followed, if necessary, by glucagon, which has been found useful.

Heart blocks: Isoprenaline hydrochloride or a pacemaker should be used.

If you forget to use Timo-COMOD 0.5 %,

make up for the application as soon as possible and continue to use Timo-COMOD 0.5 % with the same dosage and time intervals as described above or as advised by your doctor.

If you stop using Timo-COMOD 0.5 %,

note that an elevated intraocular pressure can exist over a long period of time without any disorders realised by the patient. Nevertheless, the eye may suffer permanent damages. Therefore, a regular treatment is important for the protection of vision.

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

4. Possible side effects

Like any medicinal product Timo-COMOD 0.5 % can cause side effects, although not everybody gets them.

For the assessment of side effects the following frequencies of occurrence are defined:

Very common: more than 1 of 10 treated patients

Common: 1 to 10 of 100 treated patients

Uncommon: 1 to 10 of 1,000 treated patients

Rare: 1 to 10 of 10,000 treated patients
Very rare: less than 1 of 10,000 treated patients, including single cases
Unknown: frequency not assessable on the basis of available data

While using medicinal products for ocular use not only side effects concerning the eyes, but also systemic side effects concerning other parts of the body are possible. In the treatment with Timo-COMOD 0.5 % the same side effects as in systemic treatment with this active substance (beta-receptor blocking agent) are possible.

Possible side effects:

Immune system disorders

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, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction

Investigations

Low blood glucose levels

Psychiatric disorders

Difficulty sleeping (insomnia), depression, nightmares, memory loss

Nervous system disorders

Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations, and headache

Eye disorders

Irritations of the eyes, (e.g. burning, stinging, itching, tearing, redness), 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, conjunctivitis, blepharitis, keratitis, and dry eye sensation, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed) are possible. Very rarely, diplopia and ptosis have been reported.

Cardiac disorders

Especially in patients suffering from cardiac diseases, cardiovascular disorders as side effects may occur such as bradycardia, arrhythmia, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build-up), hypotension, palpitations, atrioventricular block, chest pain, heart attack and heart failure. Apart from that, cerebral ischemia can occur. Very rarely, cardiac arrest was reported.

Vascular disorders

Raynaud's phenomenon, cold hands and feet

Respiratory, thoracic and mediastinal disorders

Timo-COMOD 0.5 % can increase airway resistance. Especially in patients suffering from broncho-spastic diseases (bronchospasms), respiratory insufficiency, difficulty breathing, cough may occur.

Gastrointestinal disorders

Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain and vomiting

Skin and subcutaneous tissue disorders

Hypersensitivity reactions were observed, such as local or general exanthems, urticaria and in individual cases loss of hair, worsening of psoriasis, localized and generalized rash

Reproductive system and breast disorders

Sexual dysfunction, decreased libido

General disorders and administration site conditions

Weakness/tiredness, muscle pain not caused by exercise, sickness

Warning: If irritation persists or increases, discontinue the use and consult the physician.

Advice: During treatment with timolol eye drops signs of hypoglycaemia may be masked. After finishing the treatment the effect of timolol can prolong several days. If the treatment with Timo-COMOD 0.5 % eye drops lasted for a longer period of time, the pressure lowering effect may last furthermore for 2-4 weeks. Beta-receptor blocking agents may lower the intraocular pressure in both eyes, even if only one eye was treated. Timo-COMOD 0.5 % eye drops is not suitable for patients who have an elevated pressure at night.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Incompatibilities

Not applicable.

5. How to store Timo-COMOD 0.5 %

Shelf life as packaged for sale: 3 years

Keep out of the reach and sight of children.

Do not use Timo-COMOD 0.5 % after the expiry date which is stated on the label and the carton.

Do not store above 25 °C.

Reference to stability after first use:

You can use Timo-COMOD 0.5 % for 12 weeks after first opening.

6. Further information

What Timo-COMOD 0.5 % contains:

The active substance is timolol maleate I.P. equivalent to 5 mg timolol. The other ingredients are sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, water for injections.

Note: Timo-COMOD 0.5 % is preservative-free.

Nature and contents of the pack

Timo-COMOD 0.5 % are clear, colourless eye drops. 10 ml of the preparation are filled in a multidose container with an airless pump system.

Each pack contains 1 dropping bottle.

Imported & Marketed in India by:

URSAPHARM India Pvt. Ltd.

PLOT NO A-I, FIEE, BASEMENT, OKHLA INDL. AREA PHASE II, NEW DELHI-110020.

Import license no.:

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