

## **Package leaflet: Information for the patient**

### **AUROTIM**

**Timolol Eye drops 0.5% w/v**

**Timolol (as 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, please 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. See section 4.
- Your medicine, Timolol Eye Drops will be referred to as Timolol in this leaflet.

### **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. Contents of the pack and other information

### **1. What Timolol is and what it is used for**

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

### **2. What you need to know before you use Timolol**

#### **Do not use Timolol if:**

- you are allergic (hypersensitive) to timolol ,beta-blockers or any other ingredient of this medicine (see section 6: Content of the pack and other information).
- 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).
- you have a slow heart beat, heart problems, heart failure or disorders of heart rhythm (irregular heart beats).“Cardiogenic shock” – a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and lightheadedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness.

If you are not sure whether you should use Timolol talk to your doctor or pharmacist.

### **Warnings and precautions**

Talk to 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
- you wear soft contact lenses (see section Timolol contains benzalkonium chloride and phosphates).

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

If your eye becomes irritated or any new eye problems come on, talk to your doctor straight away. Eye problems could include redness of the eye or swelling of the eyelids (see Section 4: Possible side effects).

If you suspect that Timolol is causing an allergic reaction or hypersensitivity (for example, skin rash, or redness and itching of the eye), stop using Timolol and contact your doctor immediately.

Tell your doctor if:

- you get an eye infection
- you injure your eye or have an operation on it
- your eye problems get worse or you get any new symptoms.

**Children and adolescents** There is only limited data available on the use of timolol in infants and children. For example, in one small clinical study, timolol, the active ingredient in Timolol eye drops, has been studied in infants and children aged 12 days to 5 years, who have elevated pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

Timolol 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.

### **Other medicines and Timolol**

Timolol 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 other eye drops or medicines obtained without a prescription.

It is important to tell your doctor before using Timolol if you are taking one or more of the following medicines:

- a calcium antagonist (e.g. nifedipine, verapamil or diltiazem) often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud's syndrome
- digoxin, a medicine 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
- medicines called pressor amines (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 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.

### **Pregnancy and breast-feeding**

Ask your doctor for advice before taking any medicine.

### **Use in pregnancy**

Do not use Timolol if you are pregnant unless your doctor considers it necessary.

### **Use in breast-feeding**

Do not use Timolol if you are breast-feeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

### **Driving and using machines**

There are possible side effects associated with Timolol, such as dizziness, tiredness and changes in your eyesight, such as blurred vision, drooping of the upper eyelid (making the eye stay half closed), double vision which may affect your ability to drive and/or operate machinery. Do not drive and/or operate machinery until you feel well and your vision is clear.

### **Timolol contains benzalkonium chloride and phosphates**

This medicine contains 0.10 mg/ml benzalkonium chloride as a preservative. 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.

This medicine contains the following phosphates

- disodium phosphate
- sodium dihydrogen phosphate dihydrate

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

## **3. How to use Timolol**

Always use Timolol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The doctor will decide how many drops you should take each day and how long you should use them.

The usual dose is one drop in the affected eye(s) twice each day:

- one in the morning.
- one in the evening.

Do not change your usual dose without talking to your doctor.

Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infection leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from contact with any surface.

### **Use in children and adolescents**

A detailed medical examination should precede the use of Timolol. Your doctor will carefully evaluate the risks and benefits when considering treatment with Timolol. 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 the 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 to form a pocket between your eyelid and your eye.
- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye.
- After using Timolol, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop timolol getting into the rest of the body.
- Repeat the above steps for the other eye if necessary.
- Replace and tighten the cap immediately after use.

### Method of administration:

Follow the "Instructions for Use" above when administering the eye drops. After instillation keep the eyes closed for as long as possible (e.g. 3 – 5 minutes) and apply pressure to the corner of the eye closest to the nose to prevent the eye drops spreading throughout the body.

### Duration of treatment:

Your doctor or your child's doctor will decide for how long the eye drops will be needed.

### **If you use more Timolol than you should**

If you put too many drops in your eye or swallow any of the drops, you may:

- have a headache
- feel dizzy or light-headed
- have difficulty in breathing
- chest pain
- feel that your heart rate has slowed down.

If this happens, contact your doctor immediately.

### **If you forget to use Timolol**

It is important to take Timolol as prescribed by your doctor.

- If you miss the dose, use the drops as soon as possible.
- If it is almost time for the next dose, skip the missed dose and take the next dose at the usual time.
- Do not take a double dose to make up for the forgotten dose.

### **If you stop using Timolol**

If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this product, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, Timolol 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 Timolol without speaking to your doctor.

Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with intravenous and/or oral 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

- If you develop allergic reactions including swelling beneath the skin that can occur in areas such as the face, limbs and can obstruct the airway which may cause difficulty in swallowing or breathing, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction, stop taking your eye drops and seek medical attention immediately.
- Low blood glucose levels.
- Difficulty in sleeping (insomnia), depression, nightmares, memory loss, hallucination.
- 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), double vision, sensitivity to light, discharge from the eye, pain in the eye.
- If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.
- Ringing sound in the ears.
- 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 failure, heart attack.
- Low blood pressure, Raynaud's phenomenon, cold hands and feet. limping because there is a reduced blood supply to your legs.
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty in breathing, shortness of breath, wheezing, cough.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Fainting, stroke, reduced blood supply to the brain, increased signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like tingling or pins and needles, and headache.
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash, itching.
- Sexual dysfunction, decreased sex drive, decreased libido In men a condition which affects your penis called Peyronie's disease. The signs may be abnormal curve, pain or hardening of the tissue of your penis.
- Muscle weakness/tiredness, muscle pain not caused by exercise.
- A condition called lupus (systemic lupus erythematosus).

If any of the side effects get serious, or if you notice any side effects not mentioned in this leaflet, please inform 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. You can also report side effects directly via the CDSCO, India. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Timolol**

Keep this medicine out of sight and reach of children.

- Do not store at a temperature above 25<sup>0</sup>C.
- Store the bottle in the outer carton in order to protect it from light.
- **Discard the bottle 30 days after opening, even if there is solution remaining.**

Do not use Timolol after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month. Make sure the container is properly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What Timolol contains**

The active ingredient is timolol maleate, where 5mg/ml timolol is equivalent to 6.8mg/ml of timolol maleate

This product also contains sodium dihydrogen ortho phosphate dihydrate, disodium Hydrogen orthophosphate, benzalkonium chloride (as preservative) 1% w/v, Purified water.

#### **What Timolol looks like and contents of the pack**

One bottle of timolol contains 5 ml solution .Your medicine is a clear colourless solution.

#### **Marketing Authorisation Holder and Manufacturer**

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