

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**DORZOLAMIDE / TIMOLOL**  
**20 mg/ml + 5 mg/ml eye drops, solution**  
(dorzolamide/timolol)

**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.
- This medicine has been prescribed for you. 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.

**What is in this leaflet:**

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

**1. WHAT DORZOLAMIDE / TIMOLOL IS AND WHAT IT IS USED FOR**

Dorzolamide / Timolol contains two medicines: dorzolamide and timolol.

- Dorzolamide belongs to a group of medicines called “carbonic anhydrase inhibitors”.
- Timolol belongs to a group of medicines called “beta blockers”.

These medicines lower the pressure in the eye in different ways.

Dorzolamide / Timolol is prescribed to lower raised pressure in the eye in the treatment of glaucoma when beta-blocker eye drop medicine used alone is not adequate.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE DORZOLAMIDE / TIMOLOL**

**Do not use Dorzolamide / Timolol**

- if you are allergic (hypersensitive) to dorzolamide hydrochloride, timolol maleate or any of the other ingredients of Dorzolamide / Timolol (listed in section 6).
- if you have now or had in the past respiratory problems, such as asthma or severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- if you have a slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats)
- if you have severe kidney disease or problems, or a prior history of kidney stones
- if you have excess acidity of the blood caused by a build up of chloride in the blood (hyperchloremic acidosis).

If you are not sure whether you should use Dorzolamide / Timolol, contact your doctor or pharmacist.

## **Warnings and precautions**

Tell your doctor about any of the following medical or eye problems 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

Also tell your doctor:

- before you have an operation that you are using Dorzolamide / Timolol as timolol may change effects of some medicines used during anaesthesia
- if you have muscle weakness or have been diagnosed as having myasthenia gravis
- if you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately
- if you develop an eye infection, receive an eye injury, have eye surgery, or develop a reaction including new or worsening symptoms.

When Dorzolamide / Timolol is instilled into the eye it may affect the entire body.

## **Children and adolescents**

There is limited experience with Dorzolamide / Timolol in infants and children.

## **Use in elderly**

In studies with Dorzolamide / Timolol, the effects of Dorzolamide / Timolol were similar in both elderly and younger patients.

## **Use in patients with liver impairment**

Tell your doctor about any liver problems you now have or have suffered from in the past.

## **Other medicines and Dorzolamide / Timolol**

Dorzolamide / 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 medicines obtained without a prescription.

This is particularly important if you are:

- taking medicine to lower blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers or digoxin)
- taking medicines to treat a disturbed or irregular heartbeat such as calcium channel blockers, beta-blockers or digoxin
- using another eyedrop that contains a beta-blocker
- taking another carbonic anhydrase inhibitor such as acetazolamide
- taking monoamine oxidase inhibitors (MAOIs) which are used to treat depression

- taking a parasympathomimetic medicine which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which is sometimes used to help restore normal movements through the bowel.
- taking narcotics such as morphine used to treat moderate to severe pain
- taking medicines to treat diabetes
- taking antidepressant known as fluoxetine and paroxetine
- taking a sulfa medicine
- taking quinidine (used to treat heart conditions and some types of malaria).

### **Pregnancy, breast-feeding and fertility**

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

#### Use in pregnancy

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

#### Use in breast-feeding

Do not use Dorzolamide / 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**

No studies on the effects on the ability to drive or use machines have been performed. There are side effects associated with Dorzolamide / Timolol, such as blurred vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until you feel well or your vision is clear.

### **Dorzolamide / Timolol contains benzalkonium chloride**

This medicine contains 0.003 mg benzalkonium chloride in each drop which is equivalent to 0.075 mg/ml.

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.

## **3. HOW TO USE DORZOLAMIDE / TIMOLOL**

Always use Dorzolamide / Timolol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The appropriate dosage and duration of treatment will be established by your doctor.

The recommended dose is one drop in the affected eye(s) in the morning and in the evening.

If you are using Dorzolamide / Timolol with another eye drop, the drops should be instilled at least 10 minutes apart.

Do not change the dose of the drug without consulting 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 infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, wash your hands before using this medicine and keep the tip of the container away from contact with any surface. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

### **Instructions for use**

Always wash your hands before applying eye drops.

**Apply your eye drops in the following way:**

1. Remove protective cap.
2. Tilt your head back and look at the ceiling.
3. Gently pull the lower eyelid down until there is a small pocket.
4. Squeeze the upturned dropper bottle to release a drop into your eye.
5. Whilst keeping the affected eye closed, press your finger against the inner corner of the closed eye (the side where the eye meets the nose) and hold for about 2 minutes. This helps to stop the medicine from getting into the rest of the body.

Avoid touching the dropper tip against your eye or anything else.

Replace and tighten the cap straight after use.

**If you use more Dorzolamide / Timolol than you should**

If you put too many drops in your eye or swallow any of the contents of the container, among other effects, you may become light-headed, have difficulty breathing, or feel that your heart rate has slowed. Contact your doctor immediately.

**If you forget to use Dorzolamide / Timolol**

It is important to use Dorzolamide / Timolol as prescribed by your doctor.

If you miss a dose, use it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten dose.

**If you stop using Dorzolamide / 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, Dorzolamide / 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 Dorzolamide / Timolol without speaking to your doctor.

**Serious side effects**

If you develop 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 or itchy rash, localized and generalized rash, itchiness or a severe sudden life-threatening allergic reaction, you should stop using Dorzolamide / Timolol and seek medical advice immediately.

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects more than 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Not known (frequency cannot be estimated from the available data)

The following adverse reactions have been reported with dorzolamide / timolol eye drops or one of its components either during clinical trials or during post-marketing experience:

Very common

Burning and stinging of the eyes, taste perversion.

Common

Redness in and around the eye(s), watering or itching of the eye(s), corneal erosion (damage to the front layer of the eyeball), swelling and/or irritation in and around the eye(s), feeling of having something in the

eye, decreased corneal sensitivity (not realising of getting something in the eye and not feeling pain), eye pain, dry eyes, blurred vision, headache, sinusitis (feeling of tension or fullness in the nose), weakness/tiredness, and fatigue.

#### Uncommon

Dizziness, depression, inflammation of the iris, visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases), slow heartbeat, fainting, difficulty breathing (dyspnoea), indigestion, and kidney stones.

#### Rare

Systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs), tingling or numbness of the hands or feet, trouble sleeping, nightmares, memory loss, an increase in signs and symptoms of myasthenia gravis (muscle disorder), decreased sex drive, stroke, temporary shortsightedness which may resolve when treatment is stopped, detachment of the layer below the retina that contains blood vessels following from filtration surgery which may cause visual disturbances, drooping of the eyelids, double vision, eyelid crusting, swelling of the cornea (with symptoms of visual disturbances), low pressure in the eye, ringing noises in your ear, low blood pressure, changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of feet and legs due to fluid build up), oedema (fluid build up), cerebral ischaemia (reduced blood supply to the brain), chest pain, forceful heartbeat that may be rapid or irregular (palpitations), heart attack, Raynaud's phenomenon, swelling or coldness of your hands and feet and reduced circulation in your arms and legs, leg cramps and/or leg pain when walking (claudication), shortness of breath, impaired lung function, runny or stuffed nose, nose bleed, constriction of the airways in the lungs, cough, throat irritation, dry mouth, diarrhoea, contact dermatitis, hair loss, skin rash with white silvery coloured appearance (psoriasiform rash), Peyronie's disease (which may cause a curvature of the penis), allergic type reactions such as rash, hives, itching, in rare cases possible swelling of the lips, eyes and mouth, wheezing, or severe skin reactions (Steven Johnson syndrome, toxic epidermal necrolysis).

Like other medicines applied into eyes, timolol maleate is absorbed into the blood. This may cause similar side effects as seen with 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 additional side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

#### Not known

Low blood glucose levels, heart failure, a type of heart rhythm disorder, abdominal pain, vomiting, muscle pain not caused by exercise, sexual dysfunction, shortness of breath, foreign body sensation in eye (feeling that there is something in your eye), hallucinations, increased heart rate, increased blood pressure.

### **Reporting of side effects**

If you get any side effects talk your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE DORZOLAMIDE / TIMOLOL**

Keep out of the reach and sight of children.

Do not use this medicine after the date shown by the six digits following EX (or EXP) on the container and on the carton. The first two digits indicate the month; the last four digits indicate the year. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Keep the bottle in the outer carton in order to protect from light.

Discard Dorzolamide / Timolol 28 days after first opening.

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 Dorzolamide / Timolol contains**

- The active substances are dorzolamide and timolol.
- Each ml contains 20 mg of dorzolamide (as 22.3 mg dorzolamide hydrochloride) and 5 mg of timolol (as 6.84 mg timolol maleate).
- The other ingredients are hydroxyethyl cellulose, mannitol, sodium citrate, sodium hydroxide, hydrochloric acid and water for injections. Benzalkonium chloride is added as a preservative.

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

Dorzolamide / Timolol is a clear, colourless to nearly colourless slightly viscous solution.

Pack sizes:

1 x 5 ml (single 5-ml containers)

3 x 5 ml (three 5-ml containers)

6 x 5 ml (six 5-ml containers)

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Macarthy's Laboratories Ltd T/A  
Martindale Pharma, Bampton  
Road Harold Hill, Romford, Essex,  
RM38UG. United Kingdom

### **Manufacturer**

Tubilux Pharma S.p.A.  
Via Costarica 20/22  
00071 Pomezia (RM)  
ITALY

**This medicinal product is authorised in the Member States of the EEA under the following names**

### **UK**

Dorzolamide / Timolol 20 mg/ml + 5 mg/ml eye drops solution

### **ITALY**

Betaclar 20 mg/ml + 5 mg/ml collirio, soluzione

**This leaflet was last revised in January 2023**