

## Package Leaflet: Information for the patient

### Dorzolamide/Timolol Mylan 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 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.

#### **What is in this leaflet:**

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

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

Dorzolamide/Timolol Mylan is a combination of 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”.

Dorzolamide/Timolol Mylan is used to lower raised pressure within the eye in the treatment of glaucoma when beta-blocker eye drops used alone are not adequate.

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

##### **Do not use Dorzolamide/Timolol Mylan**

- if you are allergic to dorzolamide, timolol, beta-blockers or any of the other ingredients of this medicine (listed in section 6).
- if you have or have had respiratory problems such as asthma or severe chronic obstructive pulmonary disease (COPD, severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- if you have certain heart problems, including certain heart rhythm disturbances producing an abnormally slow heart rate or severe heart failure.
- if you have severe kidney problems, or a prior history of kidney stones
- if you have excess acid in your blood, caused by a build-up of chloride in the blood (hyperchloraemic acidosis).

If you think any of these apply to you, do not use Dorzolamide/Timolol Mylan until you have consulted your doctor.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Dorzolamide/Timolol Mylan, if you have now or have had in the past:

- coronary heart disease (heart disease caused by poor blood flow in the blood vessels of the heart), Prinzmetal's angina (chest pains while resting), heart failure, low blood pressure

- other heart problems including some types of heart rhythm disturbances such as slow heart rate or severe heart failure.
- any other lung or breathing problems
- poor blood circulation such as Raynaud's disease or Raynaud's syndrome
- diabetes or hypoglycaemia (low blood sugar), as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms
- if you now have or have had liver problems, if you have muscle weakness or have been diagnosed as having myasthenia gravis.

### **During treatment**

If you have a history of heart disease your doctor may wish to monitor your heart rate and other signs of this disease while you are using Dorzolamide/Timolol Mylan.

If you develop conjunctivitis (redness and irritation of the eye(s)), swelling of the eye or eyelids, skin rash, or itching in and around the eye contact your doctor immediately. Such symptoms may be due to an allergic reaction or may be a side-effect of Dorzolamide/Timolol Mylan (see section 4 "Possible Side Effects").

Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, develop other reactions or worsening of symptoms.

If you wear soft contact lenses, it is important that your lenses are removed before using your eye drops and not put back into your eyes until 15 minutes after using your eye drops as the preservative benzalkonium chloride may possibly discolour the contact lenses.

Tell your doctor before you have an operation that you are using Dorzolamide/Timolol Mylan, as there may be a sudden fall in blood-pressure associated with the anaesthetic and timolol may change the effects of some medicines used during anaesthesia.

### **Children and adolescents**

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

### **Elderly patients**

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

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

Dorzolamide/Timolol Mylan 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 or might take any other medicines, including medicines obtained without a prescription. This is particularly important if any of the following apply to you:

- you are taking antihypertensive medicines which are used to lower high blood pressure such as guanethidine or clonidine or medicines to treat heart disease such as calcium channel blockers and  $\beta$ -blockers or digoxin
- you are taking medicines to treat a disturbed or uneven heartbeat such as amiodarone, quinidine (used to treat heart conditions and some types of malaria) or digoxin (used to treat heart conditions)
- you are using another eye drops that contains a  $\beta$ -blocker such as timolol
- you are taking another carbonic anhydrase inhibitor such as acetazolamide. You may be taking this type of medicine by mouth, as eye drops, or by some other method
- you are taking monoamine oxidase inhibitors (MAOIs) or selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine and paroxetine, both of which are used to treat depression or another illness
- you are taking a parasympathomimetic medicine such as bethanechol which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which are sometimes used to help restore normal movements through the bowel

- you are taking narcotics such as morphine used to treat moderate to severe pain or if you are taking large doses of aspirin. Although there is no evidence that dorzolamide hydrochloride interacts with aspirin, some other medicines which are related to dorzolamide hydrochloride and which are taken by mouth, have been known to interact with aspirin
- you are taking medicines to treat diabetes or high blood sugar
- you are taking adrenaline (epinephrine).

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

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.

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

Do not use Dorzolamide/Timolol Mylan 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**

Dorzolamide/Timolol Mylan may cause side effects such as blurred vision in some patients. Do not drive or use any tools or machines until the signs have cleared.

### **Dorzolamide/Timolol Mylan contains the preservative benzalkonium chloride.**

- Benzalkonium chloride may cause eye irritation
- Benzalkonium chloride is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before re-insertion.

## **3. How to use Dorzolamide/Timolol Mylan**

Always use Dorzolamide/Timolol Mylan exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The appropriate dose and duration of treatment will be established by your doctor.

The recommended dose is one drop in the affected eye(s) two times a day, for example in the morning and in the evening.

If you use Dorzolamide/Timolol Mylan with any other eye drops, leave at least 10 minutes between putting in Dorzolamide/Timolol Mylan and the other medicine.

Do not change the dosage of this medicine without consulting your doctor. If you must stop treatment, contact your doctor immediately.

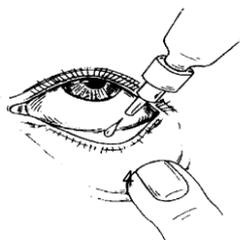
Do not allow the tip of the container to touch your eye or areas around your eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from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

In order to secure correct dosage - the dropper tip should not be enlarged.

### **Instructions for use:**

It is recommended that you wash your hands before putting in your eye drops.

It may be easier to apply your eye drops in front of a mirror.



1. Before using the medicine for the first time, be sure that the tamper-proof seal on the bottle neck is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.
2. Take off the cap of the bottle.
3. Tilt your head back and gently pull your lower eyelid down to form a small pocket between your eyelid and your eye.
4. Invert the bottle, and squeeze it until a single drop is dispensed into the eye as directed by your doctor. **DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP.**
5. Repeat steps 3 & 4 with the other eye if instructed to do so by your doctor.
6. Put the cap back on and close the bottle straight after you have used it.



After using Dorzolamide/Timolol Mylan, press a finger into the corner of your eye, by the nose (seen in the picture above) for 2 minutes. This helps to stop dorzolamide/timolol getting into the rest of the body.

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

It is important to keep to the dose your doctor has prescribed. If you put too many drops in your eye or swallow any of the contents of the bottle, you may feel unwell, for example you may have a headache or become tired, light-headed or dizzy, have difficulty breathing, shortness of breath, or feel that your heart rate has slowed. If you feel any of the above effects you should seek medical attention immediately.

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

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

If you miss a dose, apply 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 use a double dose to make up for forgotten dose.

**If you stop taking Dorzolamide/Timolol Mylan**

If you want to stop using this medicine talk to your doctor first.

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.

Like other medicines applied into eyes, dorzolamide/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.

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 Mylan without speaking to your doctor.

**Stop using Dorzolamide/Timolol Mylan and contact your doctor or go to the nearest hospital emergency department at once if you experience any of the following:**

**Common** (may affect up to 1 in 10 people)

- swelling, watering or redness of the eyes with eye pain and blurred vision, possibly with sensitivity to light or a feeling that something is in the eye (keratitis).

**Uncommon** (may affect up to 1 in 100 people)

- inflammation of the iris (coloured part of the eye) causing redness of the eyes, eye pain and sensitivity to light (iridocyclitis)

**Rare** (may affect up to 1 in 1,000 people)

- serious allergic reactions including rash, hives, itching, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing.
- stroke or reduced blood supply to the brain (you may collapse, or notice numbness or weakness in the arms or legs, difficulty swallowing, slurred, mixed up or loss of speech).
- heart failure, or 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 (known as “heart block”) which changes the rhythm of your heartbeat and may cause fainting, dizziness, tiredness, shortness of breath and chest pain.
- heart attack (you may notice sudden chest pain which may spread to the neck/jaw or arm, with a shortness of breath and a clammy feeling).
- build-up of fluid under the retina, following filtration surgery for glaucoma, which may cause visual disturbances
- serious problems with the lungs or with breathing (which may cause bluish coloration of the lips or fingernails, confusion, loss of consciousness, fainting, fatigue, irregular heart rate, rapid breathing or shortness of breath)
- systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs) with signs such as joint pain (similar to rheumatoid arthritis), fever, change in blood count and skin rash
- serious skin reactions causing widespread painful redness of the skin, large blisters, skin peeling off in sheets, bleeding of the lips, eyes, genitals or mouth accompanied by fever (Stevens-Johnson syndrome, toxic epidermal necrolysis)

**Other possible side effects seen with dorzolamide and timolol used in combination**

**Very common** (may affect more than 1 in 10 people)

- burning and stinging of the eyes
- unusual taste

**Common** (may affect up to 1 in 10 people)

- damage to the surface of the eye(s), causing eye pain, redness in and around the eye(s), feeling of having something in the eye (corneal erosion)
- sinusitis (feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing pain, fever, stuffy nose and loss of the sense of smell)
- blurred vision, itching, watery or red eyes

**Uncommon** (may affect up to 1 in 100 people)

- kidney stones (often marked by a sudden onset of excruciating, cramping pain in their low back and/or side, groin, or abdomen).

**Rare** (may affect up to 1 in 1,000 people)

- runny or stuffed nose
- itchy rash caused by a substance that comes into contact with your skin (contact dermatitis) shortness of breath or wheezing

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

- depression
- trouble sleeping, nightmares
- dizziness
- weakness/tiredness
- tingling or numbness of the hands or feet
- ringing noises in your ear
- headache
- irregular heartbeat
- chest pain
- palpitations (a quicker and/or irregular heartbeat)
- slow heartbeat
- fluid retention (oedema)
- low blood pressure
- fainting
- swelling or coldness of your hands and feet and reduced circulation in your arms and legs
- nose bleeds
- cough
- feeling sick (nausea)
- dry mouth
- indigestion
- hair loss
- skin rash with white, silvery coloured appearance (psoriasiform rash) or worsening of skin disease with thickened patches of red skin, often with silvery scales (psoriasis)
- curving of the penis, which may cause pain during erection (Peyronie's disease)
- eye irritation or swelling, dry eyes, double vision, eyelid crusting or irritation

**The following side effects have been seen in addition, or more frequently with dorzolamide, timolol or other ophthalmic beta-blockers when used on their own:**

**Common** (may affect up to 1 in 10 people)

- Headache
- decreased corneal sensitivity (you may not notice getting something in the eye and not feel any pain)
- eye pain, dry eyes
- eyelid swelling/inflammation
- feeling sick (nausea)
- tiredness or unusual weakness

**Uncommon** (may affect up to 1 in 100 people)

- Depression
- dizziness
- slow heart beat
- shortness of breath
- indigestion
- fainting

**Rare** (may affect up to 1 in 1,000 people)

- insomnia (difficulty sleeping), nightmares
- memory loss
- tingling or numbness of the hands or feet
- increase in signs and symptoms in people who already have myasthenia gravis (disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in arms and legs)

- ringing noises in your ear
- irregular heartbeat
- chest pain
- palpitations (a quicker and/or irregular heartbeat)
- low blood pressure
- 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)
- cough, throat irritation
- diarrhoea
- dry mouth
- hair loss or thinning
- skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of skin disease with thickened patches of red skin, often with silvery scales (psoriasis)
- curving of the penis, which may cause pain during erection (Peyronie's disease)
- decreased sex drive
- temporary shortsightedness, which should resolve when treatment is stopped
- low pressure in the eye
- double vision
- drooping eyelid (ptosis)
- nose bleeds
- fluid retention (oedema)

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

- low blood glucose levels which can be seen in a blood test (hypoglycaemia)
- abdominal pain, vomiting
- itching (pruritus)
- aching muscles, muscle tenderness or weakness, not caused by exercise (myalgia)
- sexual problems such as inability to get or maintain an erection

### **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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Dorzolamide/Timolol Mylan**

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

Do not use this medicine after the expiry date which is stated on the bottle label and the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light and moisture.

Dorzolamide/Timolol Mylan should be used within 28 days after the bottle is first opened. Therefore, you must throw away the bottle 4 weeks after you first opened it, even if some solution is left. To help you remember, write down the date that you opened it in the space on the carton.

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

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

### What Dorzolamide/Timolol Mylan contains

- The active substances are Dorzolamide and Timolol. Each ml contains 20 mg dorzolamide (as dorzolamide hydrochloride) and 5 mg timolol (as timolol maleate).
- The other ingredients are mannitol, hydroxy ethyl cellulose, benzalkonium chloride (as a preservative) (see section 2 “Dorzolamide/Timolol Mylan contains the preservative benzalkonium chloride”), sodium citrate, sodium hydroxide and water for injections.

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

Your medicine is in the form of a sterile, clear, slightly viscous, colourless aqueous eye drop solution.

Dorzolamide/Timolol Mylan is presented in a white opaque medium density polyethylene bottle with a sealed low density polyethylene dropper tip and a high density polyethylene cap with tamper proof seal, containing 5 ml of the ophthalmic solution.

Pack sizes: 1, 3 or 6 bottles of 5ml each.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories  
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

### Manufacturer

Pharmathen S.A.  
6 Dervenakion str., 15351 Pallini, Attiki, Greece.

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

Austria	Dorzolamid + Timolol Arcana 20 mg/ml + 5 mg/ml - Augentropfen
Belgium	TensocMylan 20 mg/ml + 5 mg/ml oogdruppels, oplossing
Bulgaria	Dorzotimologen eye drops 2%/0,5%
Czech Republic	Dorzogen Combi
Germany	Dorzolamid dura plus 20 mg/ml + 5 mg/ml Augentropfen
Denmark	Tirzopt
Greece	Dorzolamide + Timolol / Generics eye drop solution 20mg/mL + 5mg/mL
Spain	Dorzolamida Timolol Mylan 20 mg/ml + 5 mg/ml, colirio en solución
France	Dorzolamide/Timolol Mylan 20 mg/ml + 5 mg/ml, collyre en solution
Ireland	Dorzolamide/Timolol Mylan 20 mg/ml + 5 mg/ml eye drops, solution
Iceland	Tirzopt
Italy	Dorzolamide e timololo Mylan Generics
The Netherlands	Dorzolamide/Timolol Mylan 20/5 mg/ml, oogdruppels, oplossing
Norway	Tirzodol
Portugal	Timolol + Dorzolamida Mylan
Romania	Gloptic 20 mg/5 mg/ml picături oftalmice, soluție
Slovenia	Zortam 20 mg/5 mg v 1 ml kapljice za oko, raztopina
Slovakia	Dorzogen Combi
United Kingdom	Dorzolamide/Timolol 20 mg/ml + 5 mg/ml eye drops solution

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