

Package leaflet: Information for the user

## **Dorzolamide 20 mg/ml and Timolol 5 mg/ml**

### **Eye Drops, Solution**

**(Dorzolamide hydrochloride / 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.
- 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. See section 4.
- Your medicine, Dorzolamide 20 mg/ml and Timolol 5 mg/ml Eye Drops, Solution will be referred to as Dorzolamide/Timolol 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**

These eye drops contain 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 to dorzolamide hydrochloride, timolol maleate or any of the other ingredients of Dorzolamide/Timolol (listed in section 6).
- if you have now or have 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 heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats).
- if you have severe kidney diseases or problems, or a prior history of kidney stones.
- if you have excess acidity of the blood caused by a buildup of chloride in the blood (hyperchloraemic acidosis).

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

### **Warnings and precautions**

Talk to your doctor before using Dorzolamide/Timolol.

Before you use Dorzolamide/Timolol please tell your doctor about any 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.

- allergies or allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing.

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

Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, or develop a reaction including new or worsening symptoms.

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.

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

If you wear soft contact lenses, you should consult your doctor before using Dorzolamide/Timolol.

### **Use in children**

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. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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 eye drop 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 quinidine (used to treat heart conditions and some types of malaria).
- taking antidepressants known as fluoxetine and paroxetine.
- taking a sulfa medicine.

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

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

#### **Use in pregnancy**

Do not use Dorzolamide/Timolol if you are pregnant or intend to become 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**

Dorzolamide and Timolol contains 0.075mg/ml (0.002mg per drop) 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.

### **3. How to use dorzolamide/timolol**

Always use Dorzolamide/Timolol exactly as your doctor has told you. 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 Dorzolamide/Timolol 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**

- 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.
- Dorzolamide/Timolol is supplied in a plastic bottle with an insert cap assembly, with a tamper proof dust cover. When using the bottle for the first time, snap off the dust cover by turning it clockwise to break the seal.
- Unscrew the inner cap.



- Tilt your head back and look at the ceiling.
- Pull the lower eyelid gently downwards to form a pocket between your eyelid and eye.



- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye. **DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP.**
- Keep the affected eye closed and press your fingertip against the inside corner of the closed eye and hold for 2 minutes. This helps to stop Dorzolamide/Timolol getting into the rest of the body



- Repeat for the other eye if instructed to do so by your doctor.
- Recap the bottle after every use, tighten the inner cap on the nozzle

### **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 use a double dose to make up for a 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.

**If the effects are serious or you develop allergic reactions including hives or itchy rash, localized and generalized rash, itchiness, swelling of the face, lips, tongue, limbs and/or throat which may cause difficulty in breathing or swallowing, severe sudden life-threatening allergic reaction, you should stop Dorzolamide/Timolol and talk to your doctor immediately.**

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

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

The following side effects have been reported with Dorzolamide/Timolol or one of its components either during clinical trials or during post-marketing experience:

##### **Very Common:**

Burning and stinging of the eyes, unusual taste.

##### **Common:**



Headache, signs and symptoms of eye irritation (e.g. itching and tearing), blurred vision, decreased corneal sensitivity (not realizing of getting something in the eye and not feeling pain), dry eyes, corneal erosion (damage to the front layer of the eyeball), sinusitis (a feeling of tension or fullness in the nose), feeling sick, also called nausea, weakness/tiredness and fatigue. Redness in and around the eye(s), swelling and/or irritation in and around the eye(s), feeling of having something in the eye.

### **Uncommon:**

Depression, dizziness, fainting, inflammation of the iris, visual disturbances including refractive changes (in some cases due to withdrawal of medication to treat excessive contraction of the pupil of the eye), slow heart rate, difficulty in breathing (dyspnoea), indigestion, and kidney stones (often marked by a sudden onset of excruciating, cramping pain in their low back and/or side, groin, or abdomen).

### **Rare:**

Allergic type reactions such as rash, hives, itching, in rare cases possible swelling of lips, eyes and mouth, wheezing, or severe skin reactions (Stevens Johnsons syndrome, toxic epidermal necrolysis), difficulty sleeping (insomnia), nightmares, memory loss, stroke, cerebral ischaemia (reduced blood supply to the brain), increases in signs and symptoms of myasthenia gravis (muscle disorder), tingling or numbness of the hands or feet, drooping of the eyelids (making the eye stay half closed), temporary short-sightedness (transient myopia) which may resolve when treatment is stopped, double vision, detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, eye pain, eyelid crusting, swelling of the cornea (with symptoms of visual disturbances), low pressure in the eye, ringing noises in your ear, chest pain, palpitations (a quicker and/or irregular heartbeat), 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), heart attack, low blood pressure, Raynaud's phenomenon, swelling or coldness of hands and feet and reduces circulation in your arms and legs, claudication (cramps in leg and/or leg pain when walking), shortness of breath, feeling out of breath, runny or stuffed nose, nose bleed, constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough, throat irritation, dry

mouth, diarrhoea, contact dermatitis, hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs), Peyronie's disease (which may cause a curvature of the penis), decreased libido.

Like other medicines applied into your eyes, timolol is absorbed into the blood. This may cause 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, hallucination, foreign body sensation in eye (feeling that there is something in your eye), increased heart rate and increased blood pressure.

**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 Yellow Card Scheme 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 Dorzolamide/Timolol out of the sight and reach of children.

Do not store above 25°C. Keep the bottle in the outer carton in order to protect from light. Use the solution within 28 days after opening the bottle.

Do not use Dorzolamide/Timolol after the expiry date which is stated on the bottle and on the carton the bottle is packed in. The expiry date refers to the last day of that month.

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 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 22.26 mg of Dorzolamide Hydrochloride equivalent to 20 mg Dorzolamide and 6.83 mg of Timolol Maleate equivalent to 5 mg Timolol.
- The other ingredients are Hydroxyethyl cellulose, Mannitol, Sodium Citrate, Sodium Hydroxide and Water for Injections.

Benzalkonium Chloride is added as a Preservative.

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

One bottle of Dorzolamide/Timolol contains 5 ml solution.

It is a clear, colourless slightly viscous solution filled in 5 ml labeled LDPE bottle with insert cap assembly comprising of a dark blue coloured screw cap over a LDPE nozzle with tamper-evident LDPE dust-cover sealing the bottle cap.

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

Marketing Authorisation Holder:

FDC Pharma

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