

## PATIENT INFORMATION

### Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution For topical ophthalmic use (door-ZOHL-uh-mide/TIE-moh-loh)

#### What is Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution?

Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution is a prescription eyedrop solution that contains two medicines, dorzolamide hydrochloride called an ophthalmic carbonic anhydrase inhibitor and timolol maleate called a beta-blocker.

Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution is used to lower high pressure in the eye in people with open-angle glaucoma or ocular hypertension when beta-blocking medicine alone does not work to control the eye pressure. It is not known if Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution is safe and effective in children 2 years of age and younger.

#### Do not use Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution if you:

- have or have had asthma.
- have chronic obstructive pulmonary disease (COPD) which includes emphysema, chronic bronchitis or both.
- have heart problems including a slow heartbeat, heart block, heart failure, or your heart muscle suddenly becomes weak due to a severe heart attack or other heart problem that caused heart damage (cardiogenic shock).
- are allergic to any of the ingredients in Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution. See the end of this Patient Information leaflet for a complete list of ingredients in Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.

#### Before using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution, tell your healthcare provider about all your medical conditions, including if you:

- have or have had allergies to sulfa drugs
- have a history of anaphylactic reactions to allergens
- have atopy (genetic disposition to develop allergic reactions)
- have or have had muscle weakness or myasthenia gravis
- have diabetes
- have thyroid disease
- have or have had kidney or liver problems
- plan to have any type of surgery
- wear contact lenses
- are using any other eye drops
- have an eye infection or eye trauma
- are pregnant or plan to become pregnant. It is not known if Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution. You and your healthcare provider will decide if you should use Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution passes into breastmilk. Talk to your healthcare provider about the best way to feed your baby while using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.

#### Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution may affect the way medicines work, and other medicines may affect how Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution works. Do not start a new medicine without first talking to your healthcare provider.

Ask your healthcare provider or pharmacist for a list of medicines you are using, if you are not sure. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

#### How should I use Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution?

- See the complete Instructions for Use at the end of this Patient Information leaflet for detailed instructions about the right way to use Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.
- Use Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution exactly as your healthcare provider tells you.
- Use 1 drop of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution in the affected eye or both eyes if needed, 2 times each day, 1 drop in the morning and 1 drop in the evening.
- If you are using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution with another eyedrop, **wait at least 5 minutes** before or after using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.
- If you have eye surgery or have any problems with your eye such as trauma or an infection, talk to your healthcare provider about continuing to use the bottle (multidose) that contains Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.
- Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution contains a preservative called benzalkonium chloride. The preservative may be absorbed by soft contact lenses. If you wear contact lenses, remove them before using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution. The lenses can be placed back into your eyes 15 minutes after using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.
- **Do not** touch your eye or eyelid with the dropper tip. Eye medicines, not handled the right way, can become contaminated by bacteria that can cause eye infections. Serious damage to the eye and followed by loss of vision may happen from using contaminated eye medicines. **If you think your Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution medicine may be contaminated, or if you develop an eye infection, contact your healthcare provider right away about continuing to use your bottle of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.**

- If you use too much Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution you may have dizziness, headaches, shortness of breath, slow heartbeats, or problems breathing. If you have any of these symptoms call your healthcare provider or go to the nearest hospital emergency room right away.

#### What are the possible side effects of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution?

Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution may cause serious side effects, including:

- **severe breathing problems.** These breathing problems can happen in people who have asthma, chronic obstructive pulmonary disease, or heart failure and can cause death. Tell your healthcare provider right away if you have breathing problems while using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.
- **heart failure.** This can happen in people who already have heart failure and in people who have never had heart failure before. Tell your healthcare provider right away if you get any of these symptoms of heart failure while taking Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution:
  - shortness of breath
  - irregular heartbeat (palpitations)
  - swelling of your ankles or feet
  - sudden weight gain
- **serious sulfa (sulfonamide) reactions.** Serious reactions including death can happen in people who are allergic to sulfonamide medicines like one of the medicines in Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution. Other serious reactions can include:
  - severe skin reactions
  - liver problems
  - blood problems

#### Stop using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution and call your healthcare provider or get emergency help right away if you get any of these symptoms of an allergic reaction:

- swelling of your face, lips, mouth, or tongue
- wheezing
- skin rash, redness, or swelling
- fast heartbeat or pounding in your chest
- trouble breathing
- severe itching
- dizziness or fainting
- sweating

- **increased allergic reactions.** People who have a genetic history of developing allergies (atopy) or who have a history of severe anaphylactic reactions from different allergens may have increased allergic reactions while taking beta-blockers, like one of the medicines in Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution. Your usual dose of epinephrine used to treat your anaphylactic reactions may not work as well. **Stop using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution and call your healthcare provider or get emergency help right away if you get any of these symptoms of an allergic reaction:**

- swelling of your face, lips, mouth, or tongue
- wheezing
- skin rash, redness, or swelling
- fast heartbeat or pounding in your chest
- trouble breathing
- severe itching
- dizziness or fainting
- sweating
- **worsening muscle weakness.** Muscle weakness symptoms including double vision or drooping eyelids can happen while using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution. Muscle weakness can get worse in people who already have problems with muscle weakness like myasthenia gravis.
- **swelling of eye.** Some people with low counts of certain types of cells in the eye have developed corneal edema when using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution. Call your healthcare provider if you have swelling in your eyes.

#### The most common side effects of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution include:

- eye burning
- eye redness
- eye tearing
- a bitter, sour, or unusual taste after putting in your eyedrops
- eye stinging
- blurred vision
- eye itching

These are not all the possible side effects of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA1088

#### How should I store Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution?

- Store at 68° to 77°F (20° to 25°C).
- Protect from light.
- **Do not use** Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution after the expiration date on the bottle.

#### Keep Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution and all medicine out of the reach of children.

#### General information about the safe and effective use of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution for a condition for which it was not prescribed. Do not give Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution that is written for health professionals.

#### What are the ingredients in Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution?

**Active ingredients:** dorzolamide hydrochloride and timolol maleate

**Inactive ingredients:** hydroxyethylcellulose, mannitol, sodium citrate dihydrate, sodium hydroxide, water for injection, and benzalkonium chloride added as a preservative.

This Patient Package Information has been approved by the U.S. Food and Drug Administration

#### INSTRUCTION FOR USE

### Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution For topical ophthalmic use (door-ZOHL-uh-mide/TIE-moh-loh)

Read this Instructions for Use before you start using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

#### Important Information:

- **Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution is for use in the eye.**
- If you are using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution with another eyedrop, **wait at least 5 minutes** before or after using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.
- If you wear contact lenses, remove them before using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution. The lenses can be placed back into your eyes **15 minutes after** using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.
- **Do not** touch your eye or eyelid with the dropper tip. Eye medicines, not handled the right way, can become contaminated by bacteria that can cause eye infections. Serious damage to the eye and followed by loss of vision may happen from using contaminated eye medicines. **If you think your Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution medicine may be contaminated, or if you develop an eye infection, contact your healthcare provider right away about continuing to use your bottle of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.**
- Wash your hands before each use to make sure you do not infect your eyes while using Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.
- Before using the eyedrops for the first time, be sure the Safety Seal around the cap is not broken. If the Safety Seal is broken, call your pharmacist to get a new bottle of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution.

#### Step 1. Tear off the Safety Seal.

**Step 2.** To open the Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution bottle, unscrew the cap by turning counterclockwise.

**Step 3.** Tilt your head back. Gently pull your lower eyelid downwards to form a pocket between your eyelid and your eye, look up (See Figure A).

**Step 4.** Turn the Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution bottle upside down.

**Step 5.** Place the dropper tip of the Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution bottle close to your eye but be careful **not** to touch your eye with it. Gently press the Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution bottle lightly with your thumb or index finger until 1 drop of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution falls into your eye (See Figure B).

**Step 6.** Repeat Steps 4 and 5 with the other eye if instructed to do so by your healthcare provider.

**Step 7.** Replace the cap by turning until it is firmly touching the bottle. **Do not** overtighten the cap.

**Step 8.** If you use contact lenses, **wait at least 15 minutes** before placing them back into your eyes.

- The dropper tip is made to give a single drop of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution. **Do not** enlarge the hole of the dropper tip.
- After you have used all of your doses of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution, there will be some Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution left in the bottle.
- There is an extra amount of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution that has been added to the bottle. You will get the full amount of Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution that your doctor prescribed.
- **Do not** try to remove the extra Dorzolamide Hydrochloride and Timolol Maleate Ophthalmic Solution medicine from the bottle.

This Instructions for Use has been approved by the U.S. Food and Drug Administration

**AKORN**

Manufactured by: Akorn Operating Company LLC, Lake Forest, IL 60045  
Marketed by: GSMS Incorporated, Camarillo, CA 93012

Made in Switzerland  
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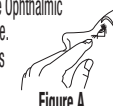


Figure A

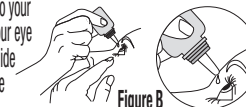


Figure B