

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Dorzolamide 20 mg/ml eye drops, solution** dorzolamide

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

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

Dorzolamide belongs to a group of medicines called "carbonic anhydrase inhibitors".

This medicine is prescribed to lower raised pressure in the eye and to treat glaucoma. This medicine can be used alone or in addition to other medicines which lower the pressure in the eye (so-called beta-blockers).

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

##### **Do not use Dorzolamide**

- if you are allergic to dorzolamide hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have severe kidney impairment or problems or a prior history of kidney stones.

##### **Warnings and Precautions**

Talk to your doctor or pharmacist before using Dorzolamide

- if you have or have had liver problems in the past
- if you have been told you have a corneal defect
- if you have had, or are about to have eye surgery
- if you have suffered an eye injury or have an eye infection
- if you have had an allergic reaction including conjunctivitis or eyelid reaction
- if you have a prior history of kidney stones
- if you are taking another carbonic anhydrase inhibitor
- if you wear contact lenses (see the section 'Dorzolamide contains benzalkonium chloride').

Tell your doctor or pharmacist about any medical problems you have now or have had in the past, including eye problems and eye surgeries, and about any allergies to any medications.

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 is causing an allergic reaction (for example, skin rash, severe skin reaction or itching), stop using this medicine and contact your doctor immediately.

### **Use in children**

Dorzolamide has been studied in infants and children less than 6 years of age who have raised pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

### **Use in elderly**

In studies with Dorzolamide, the effects of this medicine 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**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines (including eye drops).

This is particularly important if you are taking another carbonic anhydrase inhibitor such as acetazolamide, or a sulfa drug.

### **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.

#### **Use in pregnancy**

You should not use this medicine during pregnancy. Tell your doctor if you are pregnant or intend to become pregnant.

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

If treatment with this medicine is required, breast-feeding is not recommended. Tell your doctor if you are breast-feeding or intend to breast-feed.

### **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, such as dizziness and 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 contains benzalkonium chloride**

Dorzolamide contains the preservative benzalkonium chloride.

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**

Always use this medicine 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.

When Dorzolamide is used alone, the recommended dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.

If your doctor has recommended you use Dorzolamide with a beta-blocker eye drop to lower eye pressure then the recommended dose is one drop of Dorzolamide in the affected eye(s) in the morning and in the evening.

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

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, 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 proper 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 medication 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 2 & 3 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.
7. The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.
8. After you have used all doses, there will be some medicine left in the bottle. You should not be concerned since the extra amount of medicine has been added and you will get the full amount of medicine that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

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

If you put too many drops in your eye or swallow any of the contents of the container, you should contact your doctor immediately.

### **If you forget to use Dorzolamide**

It is important to use Dorzolamide 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 a forgotten dose.

#### **If you stop using Dorzolamide**

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, this medicine can cause side effects, although not everybody gets them.

Serious side effects (Rare: may affect up to 1 in 1,000 people)

If you develop allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, you should stop using this medicine and seek immediate medical advice.

A severe inflammatory eruption of the skin and mucous membranes, usually occurring after an infection, with malignancy, or as an allergic reaction to drugs or other substances. Blistering of the skin, mouth, eyes and genitals (this may indicate Stevens-Johnson syndrome or Toxic epidermal necrolysis). If you get any of the above stop using this medicine and seek immediate medical advice.

The following side effects have been reported with dorzolamide either during clinical trials or during post-marketing experience:

Very common side effects: (affects more than 1 user in 10)

Burning and stinging of the eyes

Common side effects: (affects 1 to 10 users in 100)

Disease of the cornea with sore eye and blurred vision (superficial punctate keratitis), discharge with itching of the eyes (conjunctivitis), irritation/inflammation of the eyelid, blurred vision, headache, nausea, bitter taste, fatigue, and watering or itching of the eye(s).

Uncommon side effects: (affects 1 to 10 users in 1,000)

Inflammation of the iris.

Rare side effects: (affects 1 to 10 user in 10,000)

Tingling or numbness of the hands or feet, temporary short sightedness which may resolve when treatment is stopped, development of fluid under the retina (choroidal detachment, following filtration surgery), eye pain, eyelid crusting, low pressure in the eye, swelling of the cornea (with symptoms of visual disturbances), eye irritation including redness, kidney stones, dizziness, nose bleed, throat irritation, dry mouth, localized skin rash (contact dermatitis),

Not Known: (frequency cannot be estimated from the available data)

foreign body sensation in eye (feeling that there is something in your eye)

#### **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 national reporting system listed in Yellow Card Scheme Website: [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**

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.

Keep the bottle in the outer carton in order to protect from light. Store below 30°C.

Dorzolamide 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 you no longer use. These measures will help protect the environment.

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

### **What Dorzolamide contains**

- The active substance is dorzolamide. Each ml contains 20 mg dorzolamide (as dorzolamide hydrochloride).
- The other ingredients are Mannitol, Hydroxyethyl Cellulose, Benzalkonium Chloride (as a preservative), Sodium Citrate, Sodium Hydroxide for pH adjustment and Water for injection.

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

Dorzolamide is a sterile, isotonic, buffered, colourless, slightly viscous solution in a white opaque medium density polyethylene bottle with a sealed dropper tip and a two-piece cap assembly. Each bottle contains 5 mL of the eye drop solution.

Dorzolamide is available in packs containing 1 bottle, 3 bottles or 6 bottles.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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### **Manufacturer**

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**This leaflet was last revised in 01/2019.**