

## **Package leaflet: information for the user**

### **Dorzolamide Preservative-Free 20 mg/ml eye drops, solution in single-dose container 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 Preservative-Free 20 mg/ml eye drops, solution is and what it is used for
2. What you need to know before you use Dorzolamide Preservative-Free 20 mg/ml eye drops, solution
3. How to use Dorzolamide Preservative-Free 20 mg/ml eye drops, solution
4. Possible side effects
5. How to store Dorzolamide Preservative-Free 20 mg/ml eye drops, solution
6. Contents of the pack and other information

#### **1. What Dorzolamide Preservative-Free 20 mg/ml eye drops, solution is and what it is used for**

Dorzolamide Preservative-Free 20 mg/ml eye drops, solution contains dorzolamide which 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 Preservative-Free 20 mg/ml eye drops, solution**

##### **Do not use Dorzolamide Preservative-Free 20 mg/ml eye drops, solution**

- 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.
  - if you have too much acidity in your blood (a condition called hyperchloraemic acidosis).
- If you are not sure whether you should use this medicine, contact your doctor or pharmacist.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using Dorzolamide Preservative-Free 20 mg/ml eye drops, solution.

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 Preservative-Free 20 mg/ml eye drops, solution is causing an allergic reaction (for example, skin rash, severe skin reaction, or itching), stop using this medicine and contact your doctor immediately.

If you wear contact lenses, you should consult your doctor before using Dorzolamide Preservative-Free 20 mg/ml eye drops, solution.

### **Use in children**

Dorzolamide eye drops, solution (preserved formulation) 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 eye drops, solution (preserved formulation), 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 Preservative-Free 20 mg/ml eye drops, solution**

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 sulpha 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 any medicine.

### **Pregnancy**

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

### **Breast-feeding**

You should not use this medicine during breast-feeding. 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 Preservative-Free 20 mg/ml eye drops, solution, 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.

This medicinal product contains phosphate buffers

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

## **3. How to use Dorzolamide Preservative-Free 20 mg/ml eye drops, solution**

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 this medicine 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 this medicine with a beta-blocker eye drop to lower eye pressure, then the recommended dose is one drop of Dorzolamide Preservative-Free 20 mg/ml eye drops, solution in the affected eye(s) in the morning and in the evening.

If you are using Dorzolamide Preservative-Free 20 mg/ml eye drops, solution with another eye drop, the drops should be instilled at least 10 minutes apart.

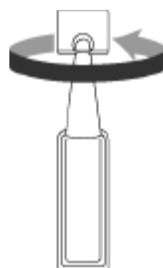
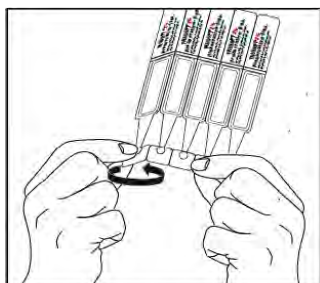
Do not change the dose of the drug without consulting your doctor.

Do not allow the tip of the single-dose 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 single-dose container, wash your hands before using this medicine and keep the tip of the single-dose container away from contact with any surface.

### **Instructions for use:**

The solution from one individual single-dose container of Dorzolamide Preservative-Free 20 mg/ml eye drops, solution is to be used immediately after opening for administration to the affected eye(s). Since sterility cannot be maintained after the individual single-dose container is opened, a new container must be opened prior to each use and must be discarded immediately after administration. Each single-dose container contains enough solution for both eyes.

1. Open the foil sachet which contains the individual single dose containers.
2. First wash your hands then break off one single-dose container from the strip and twist open the top of the single-dose container as shown.



3. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and eye as shown.



4. Put one drop in the affected eye(s) as directed by your doctor.

5. Close your eye and press the inner corner of the eye with your finger for about two minutes. This helps to stop the medicine from getting into the rest of the body.
6. After putting the drop into the eye, throw away the used single-dose container even if there is solution remaining to avoid contamination of the preservative free solution.
7. Store the remaining single-dose containers in the sachet; the remaining single-dose containers must be used within 15 days after opening of the sachet. ***Write down the date of first opening on the sachet.*** If there are any containers left 15 days after opening the sachet they should be safely thrown away and a fresh sachet opened. It is important to continue to use the eye drops as prescribed by your doctor.

**If you use more Dorzolamide Preservative-Free 20 mg/ml eye drops, solution 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 Preservative-Free 20 mg/ml eye drops, solution**

It is important to take this medicine as prescribed by your doctor. If you miss a dose, take 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 Preservative-Free 20 mg/ml eye drops, solution**

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.

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.

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, and fatigue.

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

Inflammation of the iris.

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

Tingling or numbness of the hands or feet, temporary shortsightedness 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), severe skin reactions, allergic type reactions such as rash, hives, itching, in rare cases possible swelling of the lips, eyes and mouth, shortness of breath, and more rarely wheezing.

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

Shortness of breath, foreign body sensation in eye (feeling that there is something in your eye), forceful heartbeat that may be rapid or irregular (palpitations), Increased heart rate, Increased blood pressure and abnormal sensitivity of the eyes to light.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Preservative-Free 20 mg/ml eye drops, solution**

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

Do not use the unopened sachets of this medicine after the expiry date which is stated by the six digits following EX (or EXP) on the outer carton and foil package. 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.

Expiry date on each single-dose container which is stated by the four digits following EXP, the first two digits indicate the month; the last two digits indicate the year. The expiry date refers to the last day of that month.

Do not store above 30°C.

You can use Dorzolamide Preservative-Free 20 mg/ml eye drops, solution 15 days after first opening the sachet.

Discard any unused single-dose containers after that time.

Discard the opened single-dose container with any remaining solution immediately after first use.

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 Preservative-Free 20 mg/ml eye drops, solution contains**

- The active substance is dorzolamide.
- Each ml contains dorzolamide hydrochloride equivalent to 20 mg of dorzolamide.
- The other ingredients are hydroxyethyl cellulose, mannitol, sodium citrate, sodium hydroxide and water for injections

### **What Dorzolamide Preservative-Free 20 mg/ml eye drops, solution looks like and contents of the pack**

Dorzolamide Preservative-Free 20 mg/ml eye drops, solution in single-dose container is available in 0.2 ml in low density polyethylene single dose container in an aluminium sachet.

Pack sizes:

10 x 0.2 ml (1 sachet with 10 single dose containers)

15 x 0.2 ml (1 sachet with 15 single dose containers)

30 x 0.2 ml (2 sachets with 15 single dose containers or 3 sachets with 10 single dose containers)

50 x 0.2 ml (5 sachets with 10 single dose containers)

60 x 0.2 ml (4 sachets with 15 single dose containers or 6 sachets with 10 single dose containers)

90 x 0.2 ml (6 sachets with 15 single dose containers or 9 sachets with 10 single dose containers)

120 x 0.2 ml (8 sachets with 15 single dose containers or 12 sachets with 10 single dose containers)

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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