



# Dorzolamide 20mg/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 eye drops are and what they are used for
2. What you need to know before you use Dorzolamide eye drops
3. How to use Dorzolamide eye drops
4. Possible side effects
5. How to store Dorzolamide eye drops
6. Contents of the pack and other information

## 1 What Dorzolamide eye drops are and what they are used for

Dorzolamide eye drops contains the active substance 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.

It 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 eye drops

### Do not use Dorzolamide eye drops

- 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 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 eye drops.

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 medicines.

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 eye drops are 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 eye drops.

### Patients with liver problems

Tell your doctor about any liver problems you have now or have suffered from in the past.

### Use in children

Dorzolamide hydrochloride (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 (preserved formulation), the effects of this medicine were similar in both elderly and younger patients.

### Other medicines and Dorzolamide eye drops

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 medicine.

### 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 hydrochloride, 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 eye drops contains phosphates

This medicine contains 0.0144mg phosphates in each single-dose container which is equivalent to 0.072mg/ml. 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 eye drops

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 eye drops in the affected eye(s) in the morning and in the evening.

If you are using Dorzolamide eye drops with another eye drop, the drops should be instilled at least 10 minutes apart. Do not change the dose of the medicine 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.

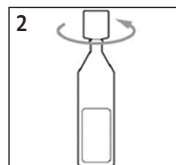
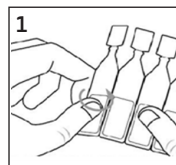
### Instructions for use

Ocular use only: this medicine is eye drops to be used in the eye.

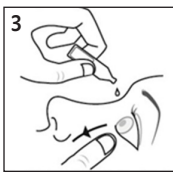
The solution from one individual single-dose container of Dorzolamide eye drops is to be used immediately after opening for administration to the affected eye(s). Since sterility cannot be maintained after the individual single-dose container is opened, a new container must be opened prior to each use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

### Every time you use Dorzolamide eye drops

1. Wash your hands.
2. Open the package and remove a container from the sachet. Break off one single-dose container from the strip (see picture 1).
3. Put the remaining strip back in the sachet.
4. Twist and pull cap to separate from the body of the container (see picture 2).
5. Hold the container between your thumb and index finger. Note that the tip of the container must not show more than 5 mm above the edge of your index finger.

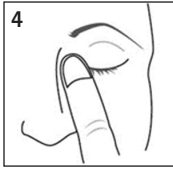


6. Tilt your head backwards or lie down. Pull the lower eyelid downwards with the index finger, until there is a 'pocket' between eyelid and eye. Position the tip of the container very closely to your eye. Look up. **Do not allow any part of the container to touch your eye or any area around your eye.** Gently squeeze the container to let one drop fall into the space between the lid and the eye (see picture 3).



Do not blink while applying the drop to your eye. Each single dose container contains enough solution for both eyes.

7. 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 (see picture 4).
8. Wipe off any excess solution from the skin around the eye.



#### If you use more Dorzolamide eye drops 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 eye drops

It is important to take this medicine 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 eye drops

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, talk to 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 20mg/ml eye drops either during clinical trials or during post-marketing experience:

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

- burning and stinging of the eyes.

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

- disease of the cornea with sore eye and blurred vision (superficial punctuate keratitis),
- discharge with itching of the eyes (conjunctivitis),
- irritation/inflammation of the eyelid,
- blurred vision,
- headache,
- nausea (feeling sick),
- bitter taste,
- fatigue (tiredness).

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

- inflammation of the iris.

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

- 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,
- localised 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:** (frequency 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,
- 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 eye drops

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 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.

Keep the container in the sachet in order to protect from light.

After first opening of the sachet, keep the single-dose containers in the sachet for up to 30 days.

After opening of the single-dose container: use immediately and throw away the single-dose container after 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 eye drops contains

- The active substance is dorzolamide. Each ml contains 22.26mg of dorzolamide hydrochloride equivalent to 20mg of dorzolamide. Each drop contains approximately 1.03mg of dorzolamide hydrochloride equivalent to 0.93mg of dorzolamide.
- The other ingredients are mannitol (E421), sodium citrate (E331), hydroxyethylcellulose (E1525), sodium hydroxide (E524) (for pH-adjustment), hydrochloric acid (E507) (for pH adjustment) and water for injections.

#### What Dorzolamide eye drops looks like and contents of the pack

Dorzolamide eye drops is a clear, colourless to slightly yellow, slightly viscous solution, free of visible particles.

Single-dose containers (LDPE) filled with 0.2ml solution.

The containers are presented in polyethylene terephthalate/ aluminium/polyethylene sachets of 5, 10 or 15 single-dose containers.

Packages of 10, 20, 30, 60, 90, 100 or 120 single-dose containers.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder

Aspire Pharma Limited  
Unit 4, Rotherbrook Court  
Bedford Road, Petersfield  
Hampshire, GU32 3QG  
United Kingdom

##### Manufacturer

Uni-pharma Kleon Tsetis Pharmaceutical Laboratories S.A.  
14th km National Road 1  
Building B  
145 64 Kifisia  
Greece

This leaflet was last revised in 01/2026.

**ASPIRE**<sup>®</sup>  
P H A R M A

<b>Artwork for:</b>	Aspire Pharma Limited
<b>Product name:</b>	Dorzolamide 20mg/ml eye drops, solution in SDC
<b>Size:</b>	0.2ml
<b>PL/PA no:</b>	PL35533/0298
<b>Type:</b>	Leaflet
<b>Artwork dimensions:</b>	160mm x 300mm
<b>Reason for request:</b>	Initial submission - RFI - small text amends
<b>Version no:</b>	2.1
<b>Date of revision:</b>	13.1.26
<b>Colours:</b>	As swatches
<b>Font(s):</b>	Strada Pro
<b>A/W software:</b>	Indesign CC

