

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dorzolamide 20mg/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 is a sterile eye drop solution. Dorzolamide 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

Do not use Dorzolamide:

- if you are allergic to dorzolamide 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 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.

Contact your doctor immediately if you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids.

Stop using Dorzolamide and contact your doctor immediately if you suspect that Dorzolamide is causing an allergic reaction (for example, skin rash, severe skin reaction or itching).

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.

Elderly

In studies with dorzolamide, the effects of this medicine were similar in both elderly and younger patients.

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 sulphamide.

Pregnancy and breast-feeding

Pregnancy

You should not use this medicine during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 this medicine, 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 the preservative benzalkonium chloride

This medicine contains 0.075mg benzalkonium chloride in each ml of solution.

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 dose 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.

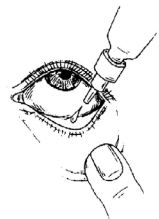
Do not allow the tip of the container to touch your eye or areas around your eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from contact with any surface. If you think your medicine may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

Instructions for 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 medicine 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. Turn the bottle upside down 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.**



- Repeat steps 3 & 4 with the other eye if instructed to do so by your doctor.
- Put the cap back on and close the bottle straight after you have used it.

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 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

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, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Stop using this medicine and seek immediate medical advice, if you develop

- allergic reactions including hives, swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing
- discharge with itching of the eyes (conjunctivitis) irritation/inflammation of the eyelid
- severe skin reactions, such as blistering and peeling of the skin (Stevens-Johnson syndrome and Toxic epidermal necrolysis)

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

Very common (affects more than 1 in 10 people)

- burning and stinging of the eyes

Common (affects up to 1 in 10 people)

- disease of the cornea with sore eye and blurred vision (superficial punctate keratitis), blurred vision
- nausea, bitter taste
- fatigue
- headache

Uncommon (affects up to 1 in 100 people)

- inflammation of the iris

Rare (affects 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
- localized skin rash (contact dermatitis)

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)

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 (website: 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 and the bottle.

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 22.3mg of dorzolamide hydrochloride equivalent to 20mg of dorzolamide.
- The other ingredients are Mannitol (E421), Hydroxyethyl Cellulose, Benzalkonium Chloride solution 50% (as a preservative), Sodium Citrate, Sodium Hydroxide for pH adjustment and Water for injections.

What Dorzolamide looks like and contents of the pack

Dorzolamide is a sterile, isotonic, buffered, colourless, clear, slightly viscous, aqueous solution in a white opaque medium density polyethylene bottle with a sealed dropper tip and a two-piece cap assembly. Each bottle contains 5ml 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 and Manufacturer**Marketing Authorisation Holder**

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

Manufacturer

Pharmathen S.A.
6 Dervenakion str.,
153 51 Pallini Attiki,
Greece
or
Famar S.A.
63 Agiou Dimitriou Street,
174 56 Alimos
Greece

This leaflet was last revised in 01/2020

1010122/P8-1