

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dorzon Eye drops, solution 2% 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Dorzon is and what it is used for

Dorzon 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 Dorzon

Do not use Dorzon

- 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, or nurse before using Dorzon

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 Dorzon 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

Dorzon 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 Dorzon, 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 Dorzon 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 this medicine.

Pregnancy

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

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 Dorzon, 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.

Dorzon contains benzalkonium chloride

Dorzon contains the preservative benzalkonium chloride. This preservative may be deposited in soft contact lenses and may possibly discolour the lenses. If you wear contact lenses, you should consult your doctor before using this medicine.

3. How to use Dorzon

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

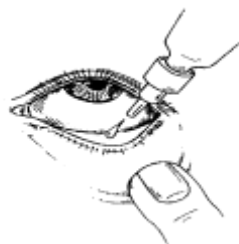
The appropriate dosage and duration of treatment will be established by your doctor.

When Dorzon 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 Dorzon with a beta-blocker eye drop to lower eye pressure, then the usual dose is one drop of Dorzon in the affected eye(s) two times a day, for example in the morning and in the evening.

If you use Dorzon 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, 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 use:



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 3 & 4 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.

If you use more Dorzon 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 Dorzon

It is important to take Dorzon 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 use a double dose to make up for forgotten doses.

If you stop using Dorzon

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 Dorzon 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 user 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).

Reporting of side effects

If you get any side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Pharmaceutical Services

Ministry of Health

CY-1475 Nicosia

Fax: + 357 22608649

Website: www.moh.gov.cy/phs

By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store Dorzon

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

Do not use Dorzon 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.

This medicinal product does not require any special storage conditions.

Dorzon 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Dorzon contains

- The active substance is dorzolamide.
- Each ml contains 22.3 mg of dorzolamide hydrochloride equivalent to 20 mg of dorzolamide. The other ingredients are Mannitol, Hydroxy Ethyl Cellulose, Benzalkonium Chloride (as a preservative), Sodium Citrate, Sodium Hydroxide for pH adjustment and Water for injection.

What Dorzon looks like and contents of the pack

Dorzon is a colourless, clear, slightly viscous eye drop solution in a plastic bottle. Each pack contains 1 plastic bottle with a screw-cap. Each bottle is about half full and contains 5 millilitres of solution. This is enough for 4 weeks' usage.

Pack sizes:

1 x 5 ml (single 5 ml container)

Marketing Authorisation Holder and Manufacturer

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