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P2890T

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dorzolamide 20mg/ml eye drops, solution

Read all of this leaflet carefully before you start taking 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 take 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 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 take Dorzolamide

Do not take Dorzolamide if
- you are allergic (hypersensitive) to dorzolamide hydrochloride or any of the other ingredients of this medicine (listed in Section 6).
- you have severe kidney impairment or problems, or a prior history of kidney stones.

Warnings and precautions
Talk to your doctor or pharmacist before taking your medicine if:
- you have now or have had in the past, including eye problems and eye surgeries, and about any allergies to any medications.
- you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids.
- you suspect that this medicine is causing an allergic reaction (for example, skin rash, severe skin reaction or itching) and stop its use.
- any liver problems you now have or have suffered from in the past.
- if you wear contact lenses (see the section Dorzolamide contains the preservative benzalkonium chloride).

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.

Other medicines and Dorzolamide
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those obtained without a prescription, particularly 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 for advice before taking this medicine.

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 Benzalkonium Chloride
This medicine contains approximately 0.002mg benzalkonium chloride in each drop which is equivalent to 0.075mg/ml.

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

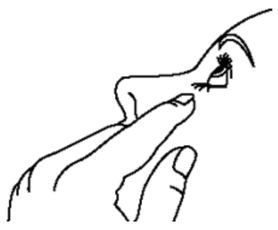
If your doctor has recommended you use this medicine with a beta-blocker eye drop to lower eye pressure, then the dose is one drop of Dorzolamide in the affected eye(s) in the morning and in the evening.

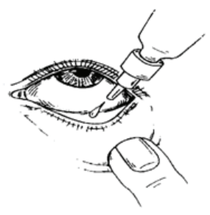
If you are using this medicine with another eye drop, the drops should be instilled at least 10 minutes apart.

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 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. Then break the seal.
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 and 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.

37 mm

Pharma code

190 mm

585 mm

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If you use more Dorzolamide than you should
If you put too many drops in your eye or the contents of the container are swallowed, you should contact your doctor immediately.

If you forget to use Dorzolamide
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 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, Dorzolamide 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: (more than 1 user in 10)
Burning and stinging of the eyes.

Common side effects: (1 to 10 users in 100)
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, bitter taste, and fatigue.

Uncommon side effects: (1 to 10 users in 1,000)
Inflammation of the iris.

Rare side effects: (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), 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.

If any of the side effects get serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

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 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 carton and label after 'EXP'. The expiry date refers to the last day of that month.

Shelf-life after first opening: 28 days.

This medicinal product does not require any special temperature storage conditions.
Keep the bottle in the outer carton in order to protect from light.

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 to 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 corresponding to 20mg of dorzolamide.
- The other ingredients are hydroxyethylcellulose, mannitol, sodium citrate, sodium hydroxide and water for injections. Benzalkonium chloride is added as a preservative.

What Dorzolamide looks like and contents of the pack
Dorzolamide 20mg/ml eye drops, solution is a slightly opalescent, colourless to nearly colourless, slightly viscous solution filled in gamma sterilized low density polyethylene (LDPE) bottle with translucent LDPE nozzle and white high density polyethylene (HDPE) cap with a tamper evident ring, that has to be broken upon first time use.

Pack sizes:
1 x 5ml (single 5ml container)
3 x 5ml (three 5ml containers)
6 x 5ml (six 5ml containers)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Crescent Pharma Ltd., Key House,
Sarum Hill, Basingstoke, RG21 8SR, UK.

Manufacturer:
PHARM, a.s.
Jarková 269/17
Šarišské Michaľany 082 22
Slovak RepublicIMUNA

Wessling Hungary Kft.
1047 Budapest, Fóti út 56.
Hungary

This leaflet was last revised in March 2026.

P2890T

G2DDCLL01AESWU

585 mm

37 mm

Pharma code

190 mm

Product:	Dorzolamide 20mg/ml eye drops, solution
Item Code:	P2890T
Size:	190 x 585 mm
Min. Point size:	12pt
O. Artwork	03/06/24
Proof No.	5
Amendment Date	31/03/26

Colours Used	
	Process Black
	Keyline - does not print