PACKAGE LEAFLET: INFORMATION FOR THE USER

Dorzostill 20 mg/ml, oogdruppels, oplossing
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 <NATIONALLY COMPLETED NAME> IS AND WHAT IT IS USED FOR

<Nationally completed name> is an ophthalmic product (eye drops) containing dorzolamide, which belongs to the group of medicinal products called carbonic anhydrase inhibitors.

The eye drops are used for the reduction of increased pressure in the eye and to treat glaucoma. The drops can be used either alone or with other eye drops which lower pressure in the eye (so-called beta-blockers).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE <NATIONALLY COMPLETED NAME>

Do not use <Nationally completed name>
- if you are allergic to dorzolamide or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney problems
- if you have a disturbance in the pH (acid/alkali balance) of your blood

Warnings and precautions <Nationally completed name>
Talk to your doctor or pharmacist before taking <Nationally completed name> if:
- you have or have had liver problems in the past
- if you have or have had in the past kidney stones
- you have been told you have a corneal defect
- you have had any allergies to any medicines
- you have had, or are about to have eye surgery
- you have suffered an eye injury or have an eye infection
- you wear contact lenses (see section 'Important information about some of the ingredients of <Nationally completed name> below).

You should 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 surface layer of the eye or eyelids.

Stop using <Nationally completed name> and contact your doctor immediately if you suspect that <Nationally completed name> 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
Dorzolamide has been shown to have the same effects in elderly patients as in younger.

Other medicines and <Nationally completed name>
Please tell your doctor if you have recently used, are using or plan to use any other medicines, including other eye drops or medicines obtained without a prescription, particularly if you are taking large doses of painkillers containing salicylic acid (e.g. aspirin). Although there is no evidence that <Nationally completed name> interacts with painkillers containing salicylic acid , some other medicines which are related to <Nationally completed name> and which are taken by mouth, have been known to interact with painkillers containing salicylic acid .

You should also tell your doctor if you are taking another carbonic anhydrase inhibitor such as acetazolamide or a sulfa drug.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.
If you are pregnant or likely to be pregnant, you should not use <Nationally completed name>.
These eye drops should not be used while breast-feeding.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. Possible side effects of <Nationally completed name> such as dizziness and visual disturbances may affect your ability to drive or operate machinery. If you experience such side-effects, you should not drive or operate machinery.

<Nationally completed name> contains the preservative benzalkonium chloride

This medicine contains 0.0022 mg of benzalkonium chloride in each drop which is equivalent to 0.075 mg/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 <Nationally completed name>

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

Dosage and frequency of administration

When <Nationally completed name> is used alone, the usual dose is one drop in the affected eye(s) three times a day, for example in the morning, in the afternoon and in the evening.

If your doctor has recommended you use <Nationally completed name> with a beta-blocker eye drop to lower eye pressure, then the usual dose is one drop of <Nationally completed name> in the affected eye(s) two times a day, for example in the morning and in the evening.

If you are using <Nationally completed name> with another eye drop, the drops should be instilled at least 10 minutes apart. Alternatively if you are going to use <Nationally completed name> to replace another eye drop medicine, used to lower eye pressure, you should stop using the other medicine after taking the proper dosing on one day, and start <Nationally completed name> on the next day.

Do not change the dosage of the drug without consulting your doctor and ask your doctor or pharmacist explain anything that you do not understand. If you must stop the treatment, contact your doctor immediately.

Instructions for use
<Nationally completed name> is intended for ocular use.

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.

Always wash your hands before putting in your eye drops.

1. To open the bottle unscrew the cap.

2. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.
3. Squeeze lightly the upturned dropper bottle until a single drop is dispensed into the eye. Do not touch the eye, eye lid or anything else with the dropper tip.. 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.
4. Repeat steps 2 & 3 with the other eye if instructed to do so by your doctor.

Replace the cap immediately after use by screwing down until it is firmly touching the bottle. Do not over-tighten the cap.

The dispenser tip is designed to provide a pre-measured drop; therefore, do not enlarge the hole of the dispenser tip. After you have used all doses, there will be some <Nationally completed name> left in the bottle. You should not be concerned since an extra amount of <Nationally completed name> has been added and you will get the full amount of <Nationally completed name> that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

If you use more <Nationally completed name> than you should
If you put too many drops in your eye or swallow any of the contents, you should contact your doctor immediately. Symptoms include sleepiness in case you have swallowed <Nationally completed name> and nausea, dizziness, headache, tiredness, fatigue, abnormal dreams and difficulty in swallowing after application of too many drops in the eyes.

If you forget to use <Nationally completed name>

It is important to take <Nationally completed name> 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.

If you stop using <Nationally completed name>
If you must stop treatment, contact your doctor immediately.

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.
The potential side effects of <Nationally completed name> may include:

Very common: (may affect more than 1 in 10 people)
Effects on the eye(s): burning and stinging

Common: (may affect up to 1 in 10 people) *Effects on the eye(s):* sensitivity to light and pain in the eye resulting from inflammation of the front part of the eye (keratitis), inflammation of the conjunctiva, effects on the surface of the eye, watering or itching of the eye(s), inflammation or irritation of the eyelid(s) and/or skin around the eye(s), blurred vision.

Effects on other parts of the body: headache, nausea, tiredness, bitter taste in the mouth after application of the eye drops.

Uncommon: (may affect up to 1 in 100 people)
Effects on the eye(s): inflammation of the coloured part of the eye

Rare: (may affect up to 1 in 1,000 people)
Effects on the eye(s): irritation and redness of the eye(s), eye pain, swelling of the surface layer of the eye(s), crusting of the eyelid(s), temporary short-sightedness (which stops when the medicine is discontinued), choroidal detachment which may be accompanied by visual changes/disturbances (following eye surgery).

Effects on other parts of the body: dizziness, numbness/tingling sensation, nose bleed, dry mouth, throat irritation, severe skin reactions, allergic reactions including rash, hives, itching, possible swelling of the lips, eyes and mouth, shortness of breath and kidney stones.

Not known (frequency cannot be estimated from the available data):
Effects on the eye(s): foreign body sensation in eye (feeling that there is something in your eye).
Effects on other parts of the body: shortness of breath, forceful heartbeat that may be rapid or irregular (palpitations), i*ncreased heart rate, increased blood pressure.*

Please tell your doctor (or pharmacist) promptly about these or any other unusual symptoms, particularly if you experience any visual changes/disturbances when using <Nationally completed name> after eye surgery.

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

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 the national

reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE <Nationally completed name>

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

Do not use <Nationally completed name> after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

Do not use <Nationally completed name> later than 30 days after first opening. Open a new bottle after 30 days even if there is some <Nationally completed name> left in the old bottle.

Store the unopened bottle below 30°C. Store the bottle after first opening below 25°C. Always keep the bottle in the outer carton 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 protect the environment.>

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What <Nationally completed name> contains
- The active substance is dorzolamide. Each ml contains 20.0 mg dorzolamide (as 22.3 mg dorzolamide hydrochloride).
- The other ingredients are: hydroxyethylcellulose, mannitol, sodium citrate, sodium hydroxide/hydrochloride acid (for pH adjustment), benzalkonium chloride (preservative) and purified water.

What <Nationally completed name> looks like and contents of the pack
<Nationally completed name> is clear or slightly opalescent, colourless, isotonic, buffered, slightly viscous aqueous eye drop solution free from visible particles. It is available in sterile bottles with a dropper and cap made of plastic. Each bottle contains 5 ml solution.

The bottles are packed in cartons of 1 x 5 ml (single bottle) or 3 x 5 ml (pack containing 3 bottles) or 6x 5ml (pack containing 6 bottles). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Bruschettini s.r.l.
Via Isonzo, 6
16 147 Genova
Italië

In het register ingeschreven onder:
RVG 109493

This medicinal product is authorised in the Member States of the EEA under the following names:
Danemark / Dorzostill 20 mg/ml øjendråber, opløsning
Italy / Dorzostill 2% collirio, soluzione
Netherlands / Dorzostill 20 mg/ml oogdruppels, oplossing
Poland / Dorzostill 20 mg/ml krople do oczu, roztwór

Deze bijsluiter is voor het laatst goedgekeurd in december 2023.