

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, a sulphonamide-related compound, as the active ingredient.

Dorzolamide is an ophthalmic carbonic anhydrase inhibitor which reduces high pressure in the eye.

It is indicated in the treatment of elevated intra-ocular pressure in conditions such as ocular hypertension and glaucoma (open-angle glaucoma, pseudo-exfoliative glaucoma). Dorzolamide can be used alone or in addition to other medicines which lower the pressure in the eye (so-called beta-blockers).

2. 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 problems.

Warnings and precautions

Talk to your doctor before taking Dorzolamide

- if you have or have had liver problems in the past
- if you have been told you have a corneal defect
- if you have had any allergies to any medicines

- if you have had, or are about to have eye surgery
- if you have suffered an eye injury or have an eye infection
- if you have a prior history of kidney stones
- if you are taking orally another carbonic anhydrase inhibitor
- if you wear contact lenses (see the section 'Dorzolamide contains the preservative benzalkonium chloride ').

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 Dorzolamide and contact your doctor immediately if you suspect that Dorzolamide is causing an allergic reaction (for example, skin rash, severe skin reactions with blistering of the skin which may affect the mouth, eyes or genitals, itching, inflammation of the eye).

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.

In particular you should tell your doctor if you are taking another carbonic anhydrase inhibitor such as acetazolamide. You may be taking this type of medicine by mouth, as eye drops, or by some other method.

Pregnancy, breast-feeding and fertility

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.

Dorzolamide should not be used during pregnancy unless your doctor still recommends it.

Dorzolamide should not be used while breast-feeding.

Driving and using machines

Dorzolamide may cause dizziness and visual disturbances in some patients. Do not drive or use any tools or machines until the symptoms have cleared.

Dorzolamide contains the preservative benzalkonium chloride.

Benzalkonium chloride may cause eye irritation.

Benzalkonium chloride is known to discolour soft contact lenses.

Avoid contact with soft contact lenses.

Remove contact lenses prior to application and wait until 15 minutes before reinsertion.

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

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

If you use Dorzolamide with another eye drop, leave at least 10 minutes between putting in Dorzolamide and the other medicine. Alternatively if you are going to use Dorzolamide 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 Dorzolamide on the next day.

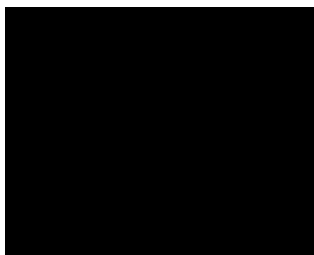
Do not change the dosage of the drug without consulting your doctor. If you must stop treatment, contact your doctor immediately.

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.

Instructions for proper 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.
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 Dorzolamide than you should

If you put too many drops in your eye or swallow any of the contents, you should contact your doctor immediately.

If you forget to use Dorzolamide

It is important to use Dorzolamide as prescribed by your doctor.

If you miss a dose, apply 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

Dorzolamide should be used every day to work properly. If you must stop treatment, contact your doctor immediately.

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. Symptoms of allergic reactions include the following;

- swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- severe skin reactions with blistering of the skin which may affect the mouth, eyes and genitals
- hives.

The following side effects may be seen with Dorzolamide.

Very common side effects (may affect more than 1 in 10 people)

- burning and stinging

Common side effects (may affect up to 1 in 10 people)

- disease of the cornea with sore eye and blurred vision (superficial punctate keratitis), inflammation or swelling of the surface layer of the eye(s) and possible inflammation of the eyelid(s) and/or skin around the eye(s), watering or itching of the eye(s), blurred vision, effects on the surface of the eye
- nausea, bitter taste
- asthenia/fatigue
- headache

Uncommon side effects (may affect up to 1 in 100 people)

- inflammation of the middle layer of the eye.

Rare side effects (may affect up to 1 in 1,000 people)

- swelling of the surface layer of the eye(s), choroidal detachment which may be accompanied by visual changes/disturbances (following eye surgery), ocular hypotony, redness of the eye(s), eye pain, crusting of the eyelid(s), temporary shortsightedness (which stops when the medicine is discontinued).
- throat irritation, dry mouth
- hypersensitivity: signs and symptoms of local reactions (palpebral reactions) and systemic allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, hives and itching, rash, shortness of breath and more rarely bronchospasm (contraction of the smooth muscle in the bronchi)
- dizziness, numbness/tingling sensation
- formation of urinary calculi
- bleeding from the nose

- severe skin reactions, skin inflammation

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)

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 676497; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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.

Do not throw away and medicines via wastewater or household waste. Ask your pharmacist how to throw away dispose of 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 20 mg dorzolamide (as dorzolamide hydrochloride).
- 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 Dorzolamide looks like and contents of the pack

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

Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork T45 K857, Ireland

Manufacturer

Pharmathen S.A., 6 Dervenakion str., 15351 Pallini, Attiki, Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom	Dorzolamide 2% Eyedrops
Ireland	Dorzolamide 20 mg / ml Eye Drops, Solution

This leaflet was last approved in December 2019.