

Package leaflet: Information for the user

Dorzolamide PharmaSwiss 20 mg/ml, eye drops solution

Dorzolamide hydrochloride

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

1. What Dorzolamide PharmaSwiss is and what it is used for

Dorzolamide PharmaSwiss 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).

Dorzolamide PharmaSwiss eye drops solution is a sterile solution that does not contain a preservative.

2. What you need to know before you use Dorzolamide PharmaSwiss

Do not use Dorzolamide PharmaSwiss

- 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.

If you are not sure whether you should use this medicine, contact your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using Dorzolamide PharmaSwiss

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 Dorzolamide PharmaSwiss is causing an allergic reaction (for example, skin rash, severe skin reaction or itching) stop using this medicines and contact your doctor immediately.

If you have a history of contact hypersensitivity to silver, you should not use this product.

If you wear contact lenses, you should consult your doctor before Dorzolamide PharmaSwiss.

Children and adolescents

Dorzolamide (preserved formulation) 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 dorzolamide (preserved formulation), the effects of Dorzolamide (preserved formulation) 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 Dorzolamide PharmaSwiss

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 using 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

You should not use this medicine during breast-feeding. 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 Dorzolamide PharmaSwiss, 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.

3. How to use Dorzolamide PharmaSwiss

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

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

Do not change the dose of the drug without consulting your doctor.

Do not allow the tip of the multi dose 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 of the multi-dose container, wash your hands before using this medicine and keep the tip of the multi-dose 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 container.

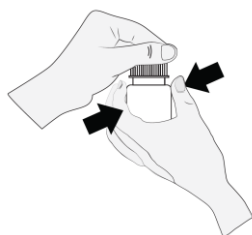
Instructions for use:

Before instillation of the eye drops:

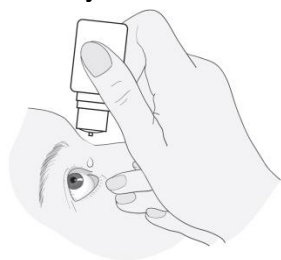
- Wash your hands before opening the bottle.
- Do not use this medicine if you notice that the tamper-proof seal on the bottle neck is broken before you first use it.
- When using for the first time, before delivering a drop to the eye, you should first of all practise using the dropper bottle by squeezing it slowly to deliver one drop into the air, away from the eye.
- When you are confident that you can deliver one drop at a time, choose the position that you find most comfortable for the instillation of the drops (you can sit down, lie on your back, or stand in front of a mirror).

Instillation:

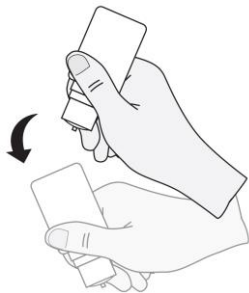
1. Hold the bottle directly below the cap and turn the cap to open the bottle. Do not touch anything with the tip of the bottle to avoid contamination of the solution.



2. Tilt your head back and hold the bottle above your eye.



3. Pull the lower eyelid down slightly to form a pocket between your eyelid and eye as shown and look up. Squeeze the bottle gently in the middle and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.
4. Put one drop in the affected eye(s) as directed by your doctor. Blink a few times so that the drop spreads over the eye. If you are not sure how to administer your medicine, ask your doctor, pharmacist or nurse.
5. 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.
6. Repeat the instructions 2. – 5. to deliver a drop into the other eye also, if your doctor has instructed you to do this. Sometimes only one eye needs to be treated and your doctor will advise if this applies to you and which eye needs treatment.



7. After use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops.
8. After you have used all doses there will be some Dorzolamide PharmaSwiss left in the bottle. You should not be concerned since an extra amount of Dorzolamide PharmaSwiss has been added and you will get the full amount of Dorzolamide PharmaSwiss that your doctor has prescribed. Do not attempt to use the excess medicine remaining in the bottle after you have completed the course of treatment.

Do not use the eye drops for longer than 28 days after first opening the bottle.

If you use more Dorzolamide PharmaSwiss 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 PharmaSwiss

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 the forgotten dose.

If you stop using Dorzolamide PharmaSwiss

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 dorzolamide preservative free either during clinical trials or during post-marketing experience:

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

- Burning and stinging of the eyes.

Common (may affect up to 1 in 10 people)

- 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
- Fatigue.

Uncommon (may affect up to 1 in 100 people)

- Inflammation of the iris.

Rare (may affect 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)
- 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

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:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance

Website: <http://www.hpra.ie>

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

5. How to store Dorzolamide PharmaSwiss

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

Store below 30 °C.

After first opening, the product may be stored for a maximum of 28 days.

Do not use Dorzolamide PharmaSwiss after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month. Make sure the container is properly closed.

Do not use this medicine if you notice that the seal is broken the first time you use the container.

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 further information

What Dorzolamide PharmaSwiss contains

- The active substance is dorzolamide.
- Each ml contains 20 mg of dorzolamide (as dorzolamide hydrochloride).
- The other ingredients are hydroxyethyl cellulose, mannitol (E421), sodium citrate dihydrate, sodium hydroxide (E524), and water for injections.

What Dorzolamide PharmaSwiss looks like and contents of the pack

Dorzolamide PharmaSwiss eye drops solution is presented as a 5 ml clear, colorless aqueous, slightly viscous solution, in white opaque 11 ml LDPE bottle and white Novelia nozzle (HDPE and silicone) with a white HDPE cap.

Pack sizes: 1, 3 or 4 bottles in cardbox

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer**Marketing Authorization Holder:**

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3013 Lake Drive
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Manufacturer:

EXCELVISION
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