

Package leaflet: Information for the user

Dorzolamide + Timolol 20 mg/ml + 5 mg/ml eye drops, solution dorzolamide/timolol

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

1. What Dorzolamide + Timolol is and what it is used for

Dorzolamide + Timolol contains two medicines: dorzolamide and timolol.

- Dorzolamide belongs to a group of medicines called “carbonic anhydrase inhibitors”.
- Timolol belongs to a group of medicines called “beta-blockers.”

These medicines lower pressure in the eye in different ways.

Dorzolamide + Timolol is prescribed to lower raised pressure in the eye in the treatment of glaucoma when beta-blocker eyedrop medicine used alone is not adequate.

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

2. What you need to know before you use Dorzolamide + Timolol

Do not use Dorzolamide + Timolol

- if you are allergic to dorzolamide, timolol or any of the other ingredients of this medicine (listed in section 6);
- if you have now or had in the past respiratory problems, such as asthma or severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough);
- if you have a slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats);
- if you have severe kidney disease or problems, or a prior history of kidney stones;
- if you have excess acidity of the blood caused by a buildup of chloride in the blood (hyperchloraemic acidosis).

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

Warnings and precautions

Talk to your doctor before using Dorzolamide + Timolol

Tell your doctor about any medical or eye problems you have now or have had in the past, such as:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness, or choking), heart failure, low blood pressure;
- disturbances of heart rate such as slow heart beat;
- breathing problems, asthma or chronic obstructive pulmonary disease;
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome);
- diabetes, as timolol may mask signs and symptoms of low blood sugar;
- overactivity of the thyroid gland, as timolol may mask signs and symptoms.

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

Tell your doctor before you have an operation that you are using Dorzolamide + Timolol, as timolol may change effects of some medicines used during anaesthesia.

Also tell your doctor about any allergies or anaphylactic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing. Tell your doctor if you have muscle weakness or have been diagnosed as having myasthenia gravis.

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 + Timolol is causing an allergic reaction or hypersensitivity (for example, skin rash, severe skin reaction, or redness and itching of the eye), stop using this medicine and contact your doctor immediately.

Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, or develop a reaction including new or worsening symptoms.

When Dorzolamide + Timolol is instilled into the eye, it may affect the entire body. Dorzolamide + Timolol has not been studied in patients wearing contact lenses. If you wear soft contact lenses, you should consult your doctor before using this medicine.

Children

There is limited experience with Dorzolamide + Timolol (preserved formulation) in infants and children.

Elderly

In studies with Dorzolamide + Timolol (preserved formulation), the effects of Dorzolamide + Timolol (preserved formulation) were similar in both elderly and younger patients.

Use in patients with liver impairment

Tell your doctor about any liver problems you have now or have suffered from in the past.

Other medicines and Dorzolamide + Timolol

Dorzolamide + Timolol can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes. Tell

your doctor or pharmacist if you are using, have recently used or might use any other medicines.

This is particularly important if you are:

- taking medicine to lower blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers or digoxin);
- taking medicines to treat a disturbed or irregular heartbeat such as calcium channel blockers, beta-blockers or digoxin;
- using another eye drop that contains a beta-blocker;
- taking another carbonic anhydrase inhibitor such as acetazolamide;
- taking monoamine oxidase inhibitors (MAOIs);
- taking a parasympathomimetic medicine which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which is sometimes used to help restore normal movements through the bowel;
- taking narcotics such as morphine used to treat moderate to severe pain;
- taking medicines to treat diabetes;
- taking antidepressants known as fluoxetine and paroxetine;
- taking a sulfa medicine;
- taking quinidine (used to treat heart conditions and some types of malaria).

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 using this medicine.

Use in pregnancy

You should not use Dorzolamide + Timolol if you are pregnant unless your doctor considers it necessary.

Use in breast-feeding

You should not use Dorzolamide + Timolol if you are breast-feeding. Timolol may get into your milk.

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 + Timolol, such as 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 + Timolol

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.

The recommended dose is one drop in the affected eye(s) in the morning and in the evening. If you are using Dorzolamide + Timolol with another eye drop, the drops should be instilled at least 10 minutes apart.

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

If you have difficulty administering your eye drops, seek the assistance of a family member or carer.

Do not allow the tip of the multi dose container to touch the eye or areas around the eye. It could cause injury to your eye. The eye drops solution 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, keep the tip of the multi-dose container away from contact with any surface.

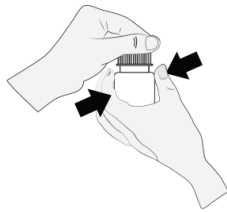
Instructions for use

Before instillation of the eye drops:

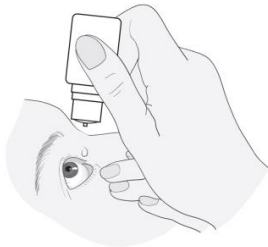
- Wash your hands before opening the bottle.
- Do not use this medicine if you notice that the tamper-proof seal on the bottle neck is broken before you first use it.
- When using for the first time, before delivering a drop to the eye, you should first of all practise using the dropper bottle by squeezing 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 backwards and hold the bottle above your eye.

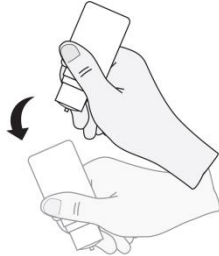


3. Pull the lower eyelid down and look up. Squeeze the bottle gently in the middle and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.

If you are not sure how to administer your medicine, ask your doctor, pharmacist or nurse.



4. Blink a few times so that the drop spreads over the eye.
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 + Timolol left in the bottle. You should not be concerned since an extra amount of Dorzolamide + Timolol has been added and you will get the full amount of Dorzolamide + Timolol 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 + Timolol than you should

If you put too many drops in your eye or swallow any of the contents of the container, among other effects, you may become light-headed, have difficulty breathing, or feel that your heart rate has slowed. Contact your doctor immediately.

If you forget to use Dorzolamide + Timolol

It is important to take Dorzolamide + Timolol as prescribed by your doctor.

If you miss a dose, use 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 + Timolol

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. You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Dorzolamide + Timolol without speaking to your doctor.

Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction.

The following adverse reactions have been reported with Dorzolamide + Timolol or one of its components 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
- Unusual taste .

Common (may affect up to 1 in 10 people)

- Redness in and around the eye(s)
- Watering or itching of the eye(s)
- Corneal erosion (damage to the front layer of the eyeball), swelling and/or irritation in and around the eye(s)
- Feeling of having something in the eye
- Decreased corneal sensitivity (not realizing of getting something in the eye and not feeling pain)
- Eye pain
- Dry eyes
- Blurred vision
- Headache
- Sinusitis (feeling of tension or fullness to the nose)
- Nausea
- Weakness/tiredness and fatigue

Uncommon (may affect up to 1 in 100 people)

- Dizziness
- Depression
- Inflammation of the iris
- Visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases)
- Slow heartbeat
- Fainting
- Difficulty breathing (dyspnoea)
- Indigestion
- Kidney stones

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

- Systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs)
- Tingling or numbness of the hands or feet
- Insomnia
- Nightmares
- Memory loss
- An increase in signs and symptoms of myasthenia gravis (muscle disorder)
- Decreased sex drive
- Stroke
- Temporary short sightedness which may resolve when treatment is stopped

- Detachment of the layer below the retina that contains blood vessels following from filtration surgery which may cause visual disturbances
- Drooping of the eyelids (making the eye stay half closed)
- Double vision
- Eyelid crusting
- Swelling of the cornea (with symptoms of visual disturbances)
- Low pressure in the eye
- Ringing noises in your ear
- Low blood pressure
- Changes in the rhythm or speed of the heartbeat
- Congestive heart failure (heart disease with shortness of breath and swelling of feet and legs due to fluid buildup)
- Oedema (fluid buildup)
- Cerebral ischaemia (reduced blood supply to the brain)
- Chest pain,
- Palpitations (a quicker and/or irregular heartbeat)
- Heart attack
- Raynaud's phenomenon, swelling or coldness of your hands and feet and reduced circulation in your arms and legs
- Leg cramps and/or leg pain when walking (claudication)
- Shortness of breath
- Impaired lung function
- Runny or stuffed nose
- Nose bleed
- Constriction of the airways in the lungs
- Cough
- Throat irritation
- Dry mouth
- Diarrhoea
- Contact dermatitis
- Hair loss
- Skin rash with white silvery coloured appearance (psoriasiform rash)
- Peyronie's disease (which may cause a curvature of the penis)
- Allergic type reactions such as rash, hives, itching, in rare cases possible swelling of the lips, eyes and mouth, wheezing, or severe skin reactions (Stevens Johnsons syndrome, toxic epidermal necrolysis).

Not known (frequency cannot be estimated from the available data):

- Forceful heartbeat that may be rapid or irregular (palpitations).
- Increased heart rate
- Increased blood pressure.

Like other medicines applied into your eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with oral beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed additional side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

Not known (frequency cannot be estimated from the available data)

- Low blood glucose levels

- Heart failure
- A type of heart rhythm disorder
- Abdominal pain
- Vomiting
- Muscle pain not caused by exercise
- Sexual dysfunction
- Hallucination

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>

5. How to store Dorzolamide + Timolol

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 this medicine 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.

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 Dorzolamide + Timolol contains

- The active substances are dorzolamide and timolol. Each ml contains 20 mg of dorzolamide (as dorzolamide hydrochloride) and 5 mg of timolol (as 6.83 mg timolol maleate).
- The other ingredients are hydroxyethyl cellulose, mannitol (E421), sodium citrate dihydrate, sodium hydroxide (E524), and water for injections.

What Dorzolamide + Timolol looks like and contents of the pack

Dorzolamide + Timolol eye drops solution is presented as a 5 ml clear, colourless 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:

Bausch + Lomb Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin 24
Ireland

Manufacturer:

EXCELVISION
27 st. La Lombardière, ZI La Lombardière,
ANNONAY 07100
France

And

PHARMATHEN S.A.
Dervenakion 6
Pallini Attikis 15351
Greece

This medicinal product is authorized in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Bulgaria: Oftidorix PF 20 mg/ml + 5 mg/ml капки за очи, разтвор
Denmark: Vizidor Duo
United Kingdom (Northern Ireland): Vizidor Duo
Ireland: Dorzolamide + Timolol PharmaSwiss 20 mg/ml + 5 mg/ml Eye Drops, Solution
Croatia: Oftidorix PF 20 mg/ml + 5 mg/ml kapi za oko, otopina
Poland: Vizidor Duo
Germany: Vizidor Duo 20 mg/ml + 5 mg/ml Augentropfen, Lösung
Hungary: Dozopticum Duo 20 mg/ml + 5 mg/ml oldatos szemcsepp
Austria: Vizidor Duo 20 mg/ml + 5 mg/ml Augentropfen
Latvia: Vizidorix 20 mg/ 5 mg/ ml acu pilieni, šķīdums
Lithuania: Dorzolamide/Timolol Bausch 20 mg/5 mg/ml akių lašai (tirpalas)
Estonia: Vizidor Duo
Slovakia: Vizidor Duo 20 mg/ml + 5 mg/ml
Greece: Vizidor Duo
Czech Republic: Vizidor Duo

This leaflet was last revised in April 2023.