

**Package leaflet:  
Information for the user**

  
**eydelto**

**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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**Important information about the administration of this product**

Eydelto Eye Drops are contained within a novel multi-dose eye drop bottle, which allows for the solution not to contain any preservatives. Due to the design of the container, administration with these eye drops is not the same as standard eye drop bottles.

- Prior to first use, practice using the drops away from the eye. Slowly squeeze the bottle to deliver one drop in the air to get used to the pressure and time required to deliver one drop.
- Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard, or more than one drop may come out.
- 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.
- If more than one type of eye drop is used, leave at least 10 minutes between administration of each eye drop solution.

Please read the full instructions on the correct use of this product in **Section 3** of the leaflet ("How to use Eydelto"), before using these eye drops.

**What is in this leaflet**

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

**1. What Eydelto is and what it is used for**

Eydelto 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 (for example beta-blockers).

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

**2. What you need to know before you use Eydelto**

**Do not use Eydelto:**

- 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**

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 this medicine is causing an allergic reaction (for example, skin rash, severe skin reaction or itching) stop its use and contact your doctor immediately.

If you have a history of contact hypersensitivity to silver, you should not use this product as dispensed drops may contain traces of silver from the container closure.

If you wear contact lenses, you should consult your doctor before using Eydelto.

**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 Eydelto**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor about all medicines (including eye drops) that you are using or plan to use, including those obtained without a prescription, particularly another carbonic anhydrase inhibitor such as acetazolamide, or a sulfa medicine such as sulfamethoxazole (medicines used to prevent the growth of bacteria).

**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.

**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 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.

**3. How to use Eydelto**

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 Eydelto 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 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 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).

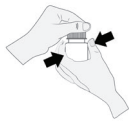
**Instillation:**

1. Hold the bottle directly below the cap and turn the cap to open the bottle.

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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. 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.



5. Repeat the instructions 2. – 4. 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.

6. After each 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.



7. At the end of the 28-day in-use shelf life of the medicine, there will be some Eydolto left in the bottle. 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 Eydolto 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 Eydolto

It is important to use this medicine 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 use a double dose to make up for a forgotten dose.

#### If you stop using Eydolto

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, 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 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 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
- Localised 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 the Yellow Card Scheme (website: [www.mhra.gov.uk/yellowcard](http://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 Eydolto

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 Eydolto contains

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

##### What Eydolto looks like and contents of the pack

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

Pack sizes: 1 or 3 bottles in a cardboard box

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder:

Aspire Pharma Ltd  
Unit 4, Rotherbrook Court  
Bedford Road, Petersfield  
Hampshire, GU32 3QG  
United Kingdom

##### Manufacturer:

Pharmathen S.A.,  
6 Dervenakion  
15351 Pallini Attiki  
Greece  
and  
EXCELVISION  
27 st. La Lombardière,  
ZI La Lombardière,  
ANNONAY 07100  
France

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