

Package leaflet: Information for the user

Eyreida 0.3mg/ml eye drops, solution Bimatoprost

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.

Important information about the administration of this product

Eyreida Eye Drops are contained within a novel multidose 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 5 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 Eyreida”), before using these eye drops.

What is in this leaflet

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

1. What Eyreida is and what it is used for

Eyreida is an anti-glaucoma preparation. It belongs to a group of medicines called prostamides.

Eyreida is used to reduce high pressure in the eye in adults. This medicine may be used on its own or with other drops called beta-blockers which also reduce pressure.

Your eye contains a clear, watery liquid that feeds the inside of the eye. Liquid is constantly being drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up. This medicine works by increasing the amount of liquid that is drained. This reduces the pressure inside the eye. If the high pressure is not reduced, it could lead to a disease called glaucoma and eventually damage your sight.

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

2. What you need to know before you use Eyreida

Do not use Bimatoprost:

- if you are allergic to bimatoprost or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Eyreida.

Please tell your doctor or pharmacist, if:

- You have any breathing problems
- You have liver or kidney problems
- You have had a cataract surgery in the past
- You have or have had low blood pressure or low heart rate
- You have had a viral infection or inflammation of the eye

Eyreida may cause your eyelashes to darken and grow, and cause the skin around the eyelid to darken too. The colour of your iris may also go darker over time. These changes may be permanent. The change may be more noticeable if you are only treating one eye.

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

Children and adolescents

Eyreida has not been tested in children under the age of 18 and therefore should not be used by patients under 18 years.

Other medicines and Eyreida

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

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.

Bimatoprost may get into breast milk so you should not breast-feed while you are taking this medicine

Driving and using machines

Your sight may become blurred for a short time just after using Eyreida. You should not drive or use machines until your sight is clear again.

3. How to use Eyreida

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

The recommended dose is one drop, in the evening, once daily in each eye that needs treatment. Eyreida should only be applied to the eye.

If you use Eyreida with another eye medicine, wait at least 5 minutes between using Eyreida and the other eye medicine. Use any eye ointment or eye gel last.

Do not use more than once a day as the effectiveness of treatment may be reduced.

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.

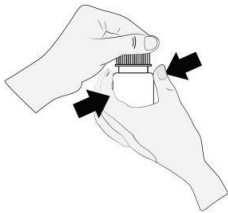
Instructions for use

Before instillation of the eye drops:

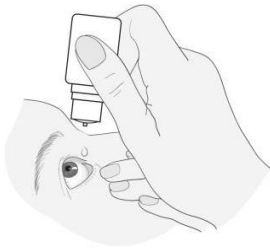
- Wash your hands before opening the bottle.
- Do not use this medicine if you notice that the tamper-proof seal on the bottle neck is broken before you first use it.
- At the first use, after cap removal, without positioning the eyedropper above the eye, slowly squeeze the bottle to deliver one drop in the air to get used to the pressure and time required to deliver one drop. In case of difficulties of delivering one drop at a time, this step might be repeated.
- 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.



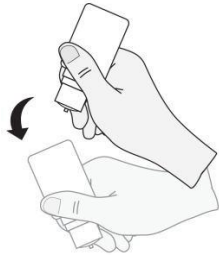
3. Pull the lower eyelid down and look up. Squeeze the bottle gently in the middle and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.

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



4. Blink a few times so that the drop spreads over the eye.

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 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. After you have used all doses there will be some Eyreida left in the bottle. You should not be concerned since an extra amount of Eyreida has been added and you will get the full amount of Eyreida 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.

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

If you use more Eyreida than you should:

If you use more of this medicine than you should, it is unlikely to cause you any serious harm. Put your next dose in at the usual time. If you are worried, talk to your doctor or pharmacist

If you forget to use Eyreida:

If you forget to use this medicine, use a single drop as soon as you remember, and then go back to your regular routine. Do not take a double dose to make up for a forgotten dose.

If you stop using Eyreida:

Eyreida should be used every day to work properly. If you stop using Bimatoprost 0.3mg/ml eye drops solution the pressure inside your eye may go up, therefore talk to your doctor before stopping this treatment.

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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Very common: may affect more than 1 in 10 people

- Slight redness of the eye

Common: may affect up to 1 in 10 people

- Small breaks in the surface of the eye, with or without inflammation
- Irritation of the eye
- Itchy eyes

- Eye pain
- Dry eyes
- A feeling that something is in your eye
- Longer eyelashes
- Darker skin colour around the eye
- Red eyelids

Uncommon: may affect up to 1 in 100 people

- Tired eyes
- Sensitivity to light
- Darker iris colour
- Itchy and swollen eyelids
- Tears
- Swelling of the see-through layer which covers the surface of the eye
- Blurred vision
- Headaches
- Hair growth around the eye

Not known: frequency cannot be estimated from the available data

- Asthma
- Worsening of asthma
- Worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- Shortness of breath
- Symptoms of allergic reaction (swelling, redness of the eye and rash of the skin)
- Ocular discomfort
- Skin discoloration (periocular)

In addition to the side effects for Eyreida, the following side effects have been seen with the preserved multi-dose formulation of Bimatoprost 0.3 mg/ml and may occur in patients taking Eyreida:

- Dizziness
- Burning sensation in the eye
- An allergic reaction in the eye
- Inflamed eyelids
- Difficulty in seeing clearly
- Sticky eyes
- Worsening vision
- Darker eyelashes
- Retinal bleeding
- Inflammation within the eye
- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Iris inflammation
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- Eyes appear sunken
- Increased blood pressure
- Nausea
- Skin redness around the eye
- Weakness
- An increase in blood-test results that show how your liver is working

Other side effects reported with eye drops containing phosphates

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; 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 Eyreida

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

This medicine does not require any special storage conditions.

You can use Eyreida for 28 days after first opening the bottle.

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

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 Eyreida contains

- The active substance is Bimatoprost.
- The other ingredients are: sodium chloride, disodium hydrogen phosphate heptahydrate, citric acid monohydrate, sodium hydroxide or hydrochloric acid (for pH adjustment), water for injection.

What Eyreida looks like and contents of the pack

Eyreida eye drops, solution is presented as a clear, colorless aqueous solution in a white opaque 5 ml LDPE bottle and white Novelia nozzle (HDPE and silicone) with a blue tip and sealed 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

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