

Package leaflet: Information for the user**Bimatoprost 0.3mg/ml eye drops, solution in single-dose container**

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.

What is in this leaflet

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

1. What Bimatoprost is and what it is used for

Bimatoprost 0.3mg/ml eye drops, solution in single-dose container is an anti-glaucoma preparation. It belongs to a group of medicines called prostamides.

This medicine is used to reduce high pressure in the eye. 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.

This medicine does not contain a preservative.

2. What you need to know before you use Bimatoprost**Do not use this medicine:**

- if you are allergic to the active ingredient 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 Bimatoprost.

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

During treatment, this medicine may cause a loss of fat around the eye, which may cause your eyelid crease to deepen, your eye to appear sunken (enophthalmos), your upper eyelid to droop (ptosis), the skin around your eye to tighten (involution of dermatochalasis) and the lower white part of your eye to become more visible (inferior scleral show). The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking Bimatoprost. This medicine may also 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. These changes may be permanent. The change may be more noticeable if you are only treating one eye.

Children and adolescents

This medicine 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 Bimatoprost

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 this medicine. You should not drive or use machines until your sight is clear again.

This medicine contains a phosphate buffer

This medicine contains 0.95mg phosphates in each ml of solution, which is equivalent to 2.68mg disodium hydrogen phosphate heptahydrate.

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Bimatoprost

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 once daily, in the evening, in each eye that needs treatment. This medicine should only be applied to the eye.

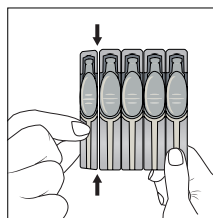
If you use this medicine with another eye medicine, wait at least 5 minutes between using this medicine and the other eye medicine.

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

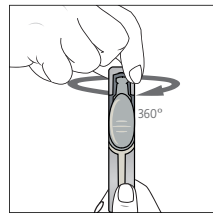
Instructions for Use:

Open the sachet which contains a strip of 5 individual single-dose containers.

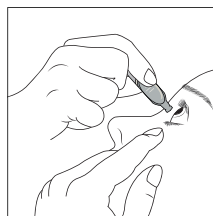
1. Wash your hands.
2. Take the strip of containers from the sachet.
3. Detach one single-dose container from the strip.



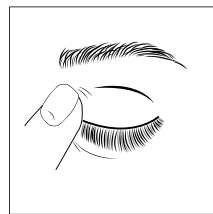
4. Put the remaining strip back in the pouch and fold the edge to close the pouch.
5. Twist the lid to open the container. Continue twisting until the lid detaches. **Do not pull** the lid to remove.



6. Hold the container between your thumb and index finger.
7. Check for any sharp edges or burrs around the container opening before administering a drop.
8. Tilt your head backwards or lie down. Look up and pull the lower eyelid downwards with the other hand. Do not allow any part of the container to touch your eye or any area around your eye. Gently squeeze the container to let one drop fall into the space between the lid and the eye. Do not blink while applying the drop to your eye. Each single-dose container contains enough solution for both eyes.



9. 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.



10. Wipe off any excess solution from the skin around the eye.

If your doctor has told you to use drops in both eyes, repeat steps 7 to 10 for your other eye. After putting the drop into the eye(s), throw away the used single-dose container even if there is solution remaining to avoid contamination of the preservative free solution.

Store the remaining containers in the sachet; the remaining containers must be used within 7 days after opening of the sachet. If there are any containers left 7 days after opening the sachet they should be safely thrown away and a fresh sachet opened. It is important to continue to use the eye drops as prescribed by your doctor.

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

If you wear contact lenses, take your lenses out before using this medicine. Wait 15 minutes after using the drops, and before you put your lenses back in.

If you use more Bimatoprost 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 Bimatoprost

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 this medicine

This medicine solution should be used every day to work properly. If you stop using this medicine 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

Affecting the eye:

- Slight redness (up to 24% of people)

Affecting the eye region:

- Loss of fat in the eye region which can lead to deepening of your eyelid crease, sunken eye (enophthalmos), drooping eyelid (ptosis), tightening of the skin around your eye (involution of dermatochalasis), and the lower white part of your eye to become more visible (inferior scleral show).

Common: may affect up to 1 in 10 people

Affecting the eye:

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

Affecting the eye:

- 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

Affecting the body:

- Headaches
- Hair growth around the eye

Not known: frequency cannot be estimated from the available data

Affecting the eye:

- Sticky eyes
- Ocular discomfort

Affecting the body:

- 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)
- Dizziness
- Increased blood pressure
- Skin discolouration (periocular)

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

- 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
- 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 the Yellow Card Scheme (website: 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 Bimatoprost

Keep out of the sight and reach of children.

Store in the original package to protect from light.

This medicine is for single use only and does not contain preservatives. Do not keep any unused solution.

After first opening the foil pouch, use the single-dose containers within 7 days. The single-dose container must be used immediately after opening.

Do not use this medicine after the expiry date which is stated on the single-dose container and carton after the expiry date (EXP:). The expiry date refers to the last day of that month.

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 Bimatoprost contains

- The active substance is bimatoprost. One ml of solution contains 0.3mg bimatoprost.
- The other ingredients are: sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate, sodium hydroxide or hydrochloric acid (for pH adjustment), water for injections.

What Bimatoprost looks like and contents of the pack

This medicine is a clear, colourless solution. Each sachet contains 5 low density polyethylene single-dose containers containing 0.4ml of solution.

Pack sizes:

- 5 x 0.4ml (1 sachet with 5 single-dose containers)
- 30 x 0.4ml (6 sachets with 5 single-dose containers)
- 90 x 0.4ml (18 sachets with 5 single-dose containers)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Aspire Pharma Ltd
Unit 4, Rotherbrook Court, Bedford Road
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Manufacturer

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