

Bimatoprost 0.3 mg/ml, eye drops, solution, in single-dose container

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
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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

The name of your medicine is Bimatoprost 0.3 mg/ml, eye drops, solution, in single-dose container called Bimatoprost throughout this leaflet.

Bimatoprost is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

Bimatoprost 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, thus reducing the pressure inside the eye. If the high pressure is not reduced, it could lead to a condition 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 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 Bimatoprost.

Please tell your doctor or pharmacist if you

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

During treatment, Bimatoprost 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. Bimatoprost 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 darken. These changes may be permanent. The change may be more noticeable if you are only treating one eye.

Children and adolescents

Bimatoprost 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 using, have recently used or might use any other medicines.

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.

Bimatoprost should not be used during pregnancy unless clearly necessary.

Bimatoprost may pass into breast milk so you should not breast-feed while you are using this medicine

Driving and using machines

Your sight may become blurred for a short time just after using Bimatoprost single dose.

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

Bimatoprost 0.3 mg/ml contains phosphates

This medicine contains 0.95 mg in each ml of solution.

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.

Dosage

The recommended dose for adults is **one drop once daily, in the evening**, in each eye that needs treatment. One container is sufficient to treat both eyes.

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

Method of administration

Bimatoprost should only be applied to the eye.

Duration of use

Bimatoprost should be used every day to work properly.

Instructions for use

Make sure that the single-dose container is intact before use. The solution should be used immediately after opening. To avoid contamination, do not let the open-end of the single-dose container touch your eye or anything else.

Apply your eye drops in the following way:

1. First wash your hands and sit or stand comfortably, then open the aluminium foil sachet which contains one strip of 5 individual single-dose containers.

2. Remove the single-dose container from the strip by applying light pressure from the opposite side to the opening of the vial (fig. 1).
3. Open the single-dose container by twisting the cap, making a full turn of 360° (fig. 2).
4. Tilt your head back and pull your lower eyelid down slightly with a finger to form a pocket between your eyelid and eye.
5. Position the tip of the single dose container next to your eye, without touching it; gently squeeze the container to put one drop in the affected eye(s) as directed by your doctor (fig. 3). If the drop misses your eye, try again.
6. After using the product, close your eye and press your finger against the inner corner where the eye meets the nose, and hold for one minute (fig. 4). Wipe off any excess that runs down your cheek.
7. After putting the drop into your eye, throw away the used single-dose container even if there is solution remaining, to avoid contamination of the preservative free solution.
8. Store the remaining containers in the outer carton and in the aluminium 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.

Fig. 1

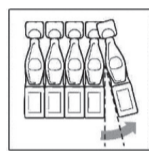


Fig. 2

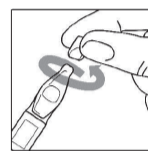


Fig. 3

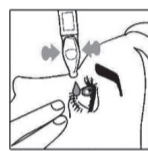


Fig. 4



Contact lens wearers

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 Bimatoprost with other eye medicine

Wait at least 5 minutes between using Bimatoprost and the other eye medicine.

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. Use your next dose 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 use a double dose to make up for a forgotten dose.

If you stop using Bimatoprost

If you stop using Bimatoprost 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.

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

Affecting the eye region

- slight redness (up to 24% of people)
- 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 discoloration (periocular)

In addition to the side effects for bimatoprost 0.3 mg/mL single-dose, the following side effects have been seen with the preserved multi-dose formulation of bimatoprost 0.3 mg/mL and may occur in patients using bimatoprost 0.3 mg/mL single-dose:

- burning sensation in the eye
- an allergic reaction in the eye
- inflamed eyelids
- difficulty in seeing clearly
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at 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 this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the single-dose container, the sachet and the carton after 'Exp'. The expiry date refers to the last day of that month.

Store the single-dose containers in the original carton and in the sachet in order to protect from light.

After first opening of the sachet, use within 7 days. Discard any unused single dose containers after that time. Single use containers must be used immediately after opening, any residual product must be discarded.

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 0.3 mg bimatoprost

The other ingredients are: sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate, water for injection, hydrochloric acid or sodium hydroxide (for pH adjustment).

What Bimatoprost looks like and contents of the pack

Bimatoprost is a clear, colourless solution supplied in 0.4 ml transparent polyethylene single-dose containers in PET/ aluminium /PE peelable sachets. Each sachet contains 5 single-dose containers.

Pack sizes

30 x 0.4 ml (6 sachets with 5 single-dose containers)

90 x 0.4 ml (18 sachets with 5 single-dose containers)

100 x 0.4 ml (20 sachets with 5 single-dose containers)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer

Genetic S.p.A., Pharmaceutical Manufacturing Site, Nucleo Industriale, Contrada Canfora, 84084 Fisciano (SA), Italy

Other formats

To request a copy of this leaflet in braille, large print or audio please call 01484 848164.

This leaflet was last revised in April 2022