

Package leaflet: Information for the user

Bimatoprost Brown & Burk 0.3 mg/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 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 Brown & Burk 0.3 mg/mL single-dose is and what it is used for
2. What you need to know before you use Bimatoprost Brown & Burk 0.3 mg/mL single-dose
3. How to use Bimatoprost Brown & Burk 0.3 mg/mL single-dose
4. Possible side effects
5. How to store Bimatoprost Brown & Burk 0.3 mg/mL single-dose
6. Contents of the pack and other information

1. What Bimatoprost Brown & Burk 0.3 mg/mL single-dose is and what it is used for

Bimatoprost Brown & Burk 0.3 mg/mL single-dose is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

Bimatoprost Brown & Burk 0.3 mg/mL single-dose eye drops are 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 Brown & Burk 0.3 mg/mL single-dose

Do not use this medicine:

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 you use Bimatoprost Brown & Burk 0.3 mg/mL single-dose.

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, Bimatoprost 0.3 mg/mL single-dose 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 0.3 mg/mL single-dose. Bimatoprost Brown & Burk 0.3 mg/mL single-dose 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

Bimatoprost Brown & Burk 0.3 mg/mL single-dose 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 Brown & Burk 0.3 mg/mL single-dose

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 might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Bimatoprost Brown & Burk 0.3 mg/mL single-dose 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 Bimatoprost Brown & Burk 0.3 mg/mL single-dose.

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

This medicine contains less than 1 mmol sodium (23 mg) per 0.3 mg/ml , that is to say essentially 'sodium-free'.

3. How to use Bimatoprost Brown & Burk 0.3 mg/mL single-dose

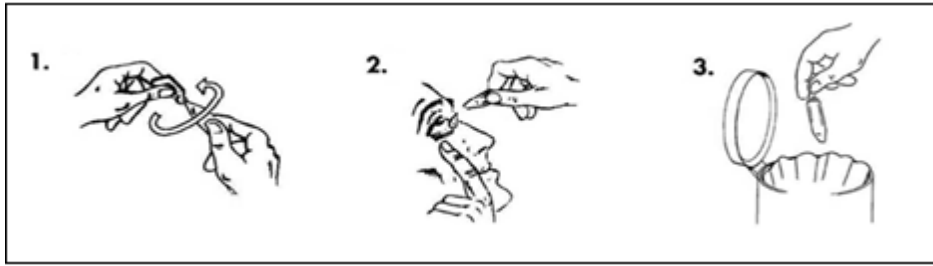
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one drop once daily, in the evening, once daily in each eye that needs treatment. Bimatoprost Brown & Burk 0.3 mg/mL single-dose should only be applied to the eye

If you use Bimatoprost Brown & Burk 0.3 mg/mL single-dose with another eye medicine, wait at least 5 minutes between using Bimatoprost Brown & Burk 0.3 mg/mL single-dose and the other eye medicine.

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

Wash your hands before 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.



1. Take one single-dose container from the pouch and hold it upright (with the cap pointing upwards) and twist off the cap.
2. Gently pull down the lower eyelid to form a pocket. Turn the single-dose container upside down and squeeze it to release 1 drop into the affected eye(s).
3. Throw away the single-dose container after you have used it, even if there is some solution left.

Wipe off any excess that runs down the cheek.

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 Brown & Burk 0.3 mg/mL single-dose 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 Brown & Burk 0.3 mg/mL single-dose

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 Bimatoprost Brown & Burk 0.3 mg/mL single-dose

Bimatoprost Brown & Burk 0.3 mg/mL single-dose should be used every day to work properly. If you stop using Bimatoprost Brown & Burk 0.3 mg/mL eye drops, solution, in single-dose container 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

- 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 Brown & Burk 0.3 mg/mL single-dose the following side effects have been seen with the preserved multi-dose formulation of Bimatoprost Brown & Burk 0.3 mg/mL single-dose and may occur in patients taking Bimatoprost Brown & Burk 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

This medicine contains 0.949 mg phosphates in each mL which is equivalent to 0.379 mg/0.4 mL.

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 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 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.

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5. How to store Bimatoprost Brown & Burk 0.3 mg/mL single-dose

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

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

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

This medicinal product does not require any special storage condition. However, once the pouch is opened use within 30 days.

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 to protect the environment.

6. Contents of the pack and other information

What Bimatoprost Brown & Burk 0.3 mg/mL single-dose contains

The active substance is bimatoprost. One mL of solution contains 0.3 mg bimatoprost.

- The other ingredients are sodium chloride, disodium phosphate heptahydrate (E339), citric acid monohydrate (E330) and water for injection. Small amounts of hydrochloric acid (E507) or sodium hydroxide (E524) may be added to keep the level of acid (pH levels) normal.

What Bimatoprost Brown & Burk 0.3 mg/mL single-dose looks like and contents of the pack

Bimatoprost Brown & Burk 0.3 mg/mL single-dose is a clear colourless to pale yellow solution supplied in single-dose natural translucent low density polyethylene (LDPE) containers, each containing 0.4 mL of solution.

Pack sizes:

30 x 0.4 mL (6 pouches with 5 single-dose containers each) in a carton.

90 x 0.4 mL (18 pouches with 5 single-dose containers each) in a carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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PL 25298/0255

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