Bimatoprost contains benzalkonium chloride. This medicine contains 0.05mg benzalkonium chloride in each ml of solution. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Bimatoprost may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

Bimatoprost contains a preservative buffer. This medicine contains 0.05mg phosphates 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 calcification but does not 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. This medicine should only be applied to the eye. The recommended dose is one drop of Bimatoprost in the evening, once daily in each eye that needs treatment.

If you use Bimatoprost with another eye medicine, wait at least five minutes between using Bimatoprost and the other eye medicine. Do not use together for more than once a day as the effectiveness of treatment may be reduced.

Instructions for use:

You must use the bottle if the tamper-proof seal on the bottle is broken before you first use it.

- Take the bottle (picture 1) out of the carton box.

1. Wash your hands. Tilt your head back and look at the ceiling (picture 2).

2. Gently pull down the lower eyelid until there is a small pocket (picture 3).

3. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment (picture 4).

4. Let go of the lower lid and close your eye for 10 seconds (picture 5).

5. Wipe off any excess that runs down the cheek. If a drop misses your eye, do not try to correct this.

To help prevent infections and avoid eye injury, do not let the tip of the bottle touch your eye or anything else. Put the bottle back in the carton and close the bottle straight after you have used it.

If you use more Bimatoprost than you should:

If you use more Bimatoprost 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 Bimatoprost, use a single drop as soon as you remember. This is unlikely to cause you any serious harm. Put your next dose in at the usual time.

If you use more Bimatoprost than you should, it is unlikely to cause you any serious harm. You must not use the bottle if the tamper-proof seal on the bottle is broken before you first use it.

If you forget to use Bimatoprost, use a single drop as soon as you remember. This is unlikely to cause you any serious harm. Put your next dose in at the usual time.

If you stop using Bimatoprost:

If you stop using Bimatoprost, 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.

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
  - Long-term effects
    - Slight redness up to 4% of people
    - Redness up to 1% of people
  - Other effects
    - Itchiness up to 14% of people

Common: may affect up to 1 in 10 people

- Affecting the eye
  - An allergic reaction in the eye
  - Tired eye
  - Sensitivity to light
  - Darker skin colour around the eye
  - Darker eyelashes
  - Pain
  - A feeling that something is in your eye
  - Sticky eyes
  - Darker irid colour
  - Gloucy seeing clearly
  - Irritation
  - Burning
  - Inflamed, red and itchy eyelids

- Common
  - Dryness
  - Worsening of vision
  - Blurred vision
  - Swelling of the eye

- Rare
  - Small breaks in the surface of the eye, with or without inflammation
Affecting the body
- Headaches
- An increase in blood-test results that show how your liver is working
- Increased blood pressure

Uncommon: may affect up to 1 in 100 people

Affecting the eye
- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Inflammation within the eye
- Retinal bleeding
- Swollen eyelids
- Eyelid twitching
- Eyelid shrinking, moving away from the surface of the eye
- Skin redness around the eye

Affecting the body
- Nausea
- Dizziness
- Weakness
- Hair growth around the eye

Not known: frequency cannot be estimated from the available data

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 bottle label and the carton after EXP. The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.
After first opening of the container, the product may be stored for 4 weeks. You must throw away the bottle at the latest four weeks after you first opened it, even if there are still some drops left. This will prevent infections. To help you remember, write down the date you opened it in the space on the box and bottle. 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 benzalkonium chloride (preservative), sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate and water for injections. Small amounts of hydrochloric acid or sodium hydroxide may be added to keep the level of acid (pH levels) normal.

What Bimatoprost looks like and contents of the pack
Bimatoprost is a clear, colourless solution, free from visible particles in a white opaque low density polyethylene vial for eye drops containing 3ml of the ophthalmic solution sealed with a white opaque LDPE plug applicator and a white HDPE/LDPE cap with a tamper-proof seal. The following pack sizes are available: cartons containing 1 or 3 bottles of 3ml solution. Not all pack sizes may be marketed.

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Marketing Authorisation Holder: Aspire Pharma Ltd
Unit 4, Rotherbrook Court
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