

PACKAGE LEAFLET

Package leaflet: Information for the user

Bimaprez 0.1 mg/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 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 [Invented name] is and what it is used for
2. What you need to know before you use [Invented name]
3. How to use [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

[Invented name] 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. This liquid is constantly being drained out of the eye and new liquid is made to replace it. 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 high pressure is not reduced, it could lead to a disease called glaucoma and eventually damage your sight.

2. What you need to know before you use [Invented name]

Do not use [Invented name]

- if you are allergic to bimatoprost, benzalkonium chloride or any of the other ingredients of this medicine (listed in section 6).
- if you have had to stop using eye drops in the past because of a side effect of the preservative benzalkonium chloride

Warnings and precautions:

Talk to your doctor or pharmacist before you use [Invented name], if:

- you have any breathing problems
- you have liver or kidney problems

- you have had a cataract surgery in the past
- you have dry eye
- you have or have had any problems with your cornea (front transparent part of the eye)
- you wear contact lenses (see “[Invented name] contains benzalkonium chloride”)
- 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 this medicine.

[Invented name] 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 become darker over time. These changes may be permanent. The changes may be more noticeable if you are only treating one eye.

Children and adolescents

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

Other medicines and [Invented name]

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

[Invented name] may get into the 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.

[Invented name] contains benzalkonium chloride

This medicine contains 0.006 mg of benzalkonium chloride in each drop, which is equivalent to 0.2 mg/ml.

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.

Benzalkonium chloride 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.

[Invented name] contains phosphates

This medicine contains 0.028 mg phosphates in each drop, which is equivalent to 0.95 mg/ml.

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 [Invented name]

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

[Invented name] should only be applied to the eye. The recommended dose is one drop of [Invented name] in the evening, once daily in each eye that needs treatment.

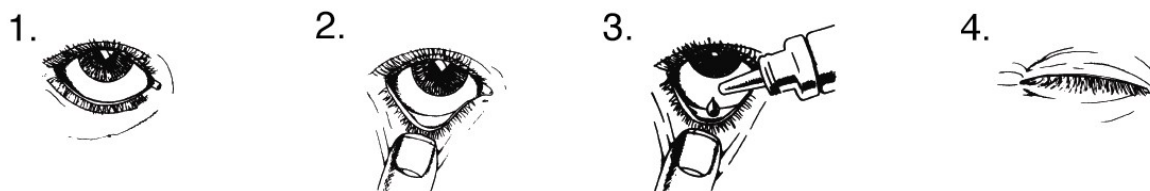
If you use [Invented name] with another eye medicine, wait at least five minutes between using [Invented name] and the other eye medicine.

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

Instructions for use:

Wash your hands and sit or stand comfortably. Remove the tamper-evident ring from the bottle and unscrew the cap.

You must not use the bottle if the tamper-evident ring on the bottle neck is broken before you first use it.



1. Tilt your head back and look at the ceiling. (Figure 1)
2. Gently pull down the lower eyelid until there is a small pocket (Figure 2).
3. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment (Figure 3).
4. Let go of the lower lid and close your eye for 30 seconds (Figure 4).

Wipe off any excess that runs down the cheek.

If a drop misses your eye, try again.

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

If you use more [Invented name] 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 [Invented name]

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 [Invented name]

[Invented name] 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.

Very common side effects

These may affect more than 1 in 10 people

Affecting the eye

- Slight redness (up to 29 % 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 side effects

These 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
- Longer eyelashes
- Irritation, when drop is put in the eye
- Eye pain

Affecting the skin

- Red and itchy eyelids
- Darker skin colour around the eye
- Hair growth around the eye

Uncommon side effects

These may affect up to 1 in 100 people

Affecting the eye

- Darker iris colour
- Tired eyes
- Swelling and/or inflammation of the eye surface
- Blurred vision
- Loss of eyelashes

Affecting the skin

- Dry skin
- Crusting on the edge of the eyelid
- Swelling of the eyelid
- Itching

Affecting the body

- Headache
- Feeling of sickness

Side effects where the frequency is not known (cannot be estimated from the available data)

Affecting the eye

- Macular oedema (swelling of the retina at the back of the eye which may lead to worsening vision)

- Darker eyelid colour
- Dryness
- Sticky eyes
- A feeling that something is in your eye
- Swelling of the eye
- Increased tearing
- Ocular discomfort
- Sensitivity to light

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 of this medicine, the following side effects have been seen with another medicine containing a higher strength of bimatoprost (0.3 mg/ml):

- Ocular burning
- An allergic reaction in the eye
- Inflamed eyelids
- Difficulty in seeing clearly
- Worsening of vision
- Swelling of the see-through layer that covers the eye
- Tears
- Darker eyelashes
- Retinal bleeding
- Inflammation within the eye
- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- 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 **the national reporting system** listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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.

Do not store above 25°C.

You must throw away the bottle at the latest 4 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.

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 [Invented name] contains

- The active substance is bimatoprost. One ml of the solution contains 0.1 mg of bimatoprost, and one drop of the solution contains 2.6 micrograms of bimatoprost.
- The other ingredients are benzalkonium chloride, disodium hydrogen phosphate (E339), citric acid (E330), sodium chloride, hydrochloric acid (E507) (for pH adjustment), sodium hydroxide (E524) (for pH adjustment) and water for injections.

What [Invented name] looks like and contents of the pack

[Invented name] is a colourless, clear eye drop solution. It is available in a 5 mL white plastic dropper bottle with a white screw cap and a tamper evident ring. Each bottle contains 3 mL solution. This is enough for 4 weeks' usage.

This medicine is supplied in a pack containing either 1 bottle or 3 bottles each. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Blumont Ofta Trading limited
33 Old Railway Road
Birkirkara, BKR 1617
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Manufacturer

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