PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LUMIGAN 0,01 %, 0,1 mg/ml eye drops, solution
Bimatoprost

Read all of this leaflet carefully before you start using LUMIGAN 0,01 %

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LUMIGAN 0,01 % has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LUMIGAN 0,01 % is and what it is used for

LUMIGAN 0,01 % is prescribed to control glaucoma, which is high pressure in the eye. Bimatoprost belongs to a group of medicines called prostamides. 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 it. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up and could eventually damage your sight. LUMIGAN 0,01 % works by increasing the amount of liquid that is drained. This reduces the pressure inside the eye.

2. What you need to know before you use LUMIGAN 0,01 %

Do not use LUMIGAN 0,01 %

- If you are hypersensitive (allergic) to bimatoprost or any of the other ingredients of LUMIGAN 0,01 % (listed in section 6).

Warnings and precautions

Before you use LUMIGAN 0,01 %, tell your doctor:

- If you have any breathing problems;
- If you have or have had low blood pressure or low heart rate;
- If you have any liver or kidney problems;
- If you have had cataract surgery in the past;
- If you have or have had any problems with your cornea (front transparent part of the eye);
- If you have had a viral infection, inflammation of the eye or any other eye condition;
- If you are already using a medicine for glaucoma;
- If you wear contact lenses (see 'LUMIGAN 0,01 % contains benzalkonium chloride').

During treatment, LUMIGAN 0,01 % 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 using LUMIGAN 0,01 %. LUMIGAN 0,01 % 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 changes may be more noticeable if you are only treating one eye.

Hair may grow in areas where LUMIGAN 0,01 % solution has been repeatedly in contact with the skin surface. This is why it is important to apply LUMIGAN 0,01 % as instructed and to avoid it running onto the cheek or other skin areas.

Children and adolescents

LUMIGAN 0,01 % should not be used in people under 18.

Other medicines and LUMIGAN 0,01 %

Always tell your health care provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using LUMIGAN 0,01 %.

LUMIGAN 0,01 % should not be used during pregnancy.
LUMIGAN 0,01 % should not be used if you are breastfeeding.

Driving and using machines

Your sight may become blurred for a short time just after using LUMIGAN 0,01 %. You should not drive or use machines until your sight is clear again.

LUMIGAN 0,01 % contains benzalkonium chloride

LUMIGAN 0,01 % contains 0,6 mg benzalkonium chloride in each 3 ml of solution which is equivalent to 0,2 mg/ml.

Do not use the drops when you are wearing your lenses. A preservative in LUMIGAN 0,01 %, 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 LUMIGAN 0,01 % and wait 15 minutes after using the drops before you put your lenses back in. 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 LUMIGAN 0,01 %, talk to your doctor.

3. How to use LUMIGAN 0,01 %

Do not share medicines prescribed for you with any other person.

Always use LUMIGAN 0,01 % exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

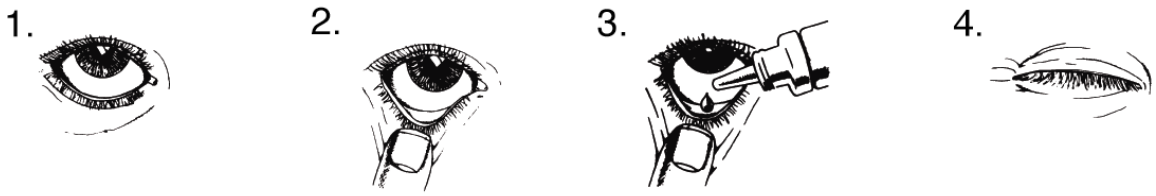
The usual dose is one drop in the evening in each eye that needs treatment.

If you use LUMIGAN 0,01 % with another eye medicine, leave at least 5 minutes between using LUMIGAN 0,01 % and the other medicine.

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

Instructions for use

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



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

If a drop misses your eye, try again.

Wipe off any excess that runs down the cheek.

To avoid contamination, 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.

Your doctor will tell you how long your treatment with LUMIGAN 0,01 % will last. Do not stop treatment early because the pressure inside your eye may go up. If you have the impression that the effect of LUMIGAN 0,01 % is too strong or too weak, tell your doctor or pharmacist.

If you use more LUMIGAN 0,01 % than you should

If you use more LUMIGAN 0,01 % 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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use LUMIGAN 0,01 %

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 forgotten individual doses. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop using LUMIGAN 0,01 %

LUMIGAN 0,01 % should be used every day to work properly.

4. Possible side effects

LUMIGAN 0,01 % can have side effects. Not all side effects reported for LUMIGAN 0,01 % are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using LUMIGAN 0,01 %, please consult your health care provider for advice.

The following side effects may be seen with LUMIGAN 0,01 %:

Frequent side effects

Affecting the eye:

- Eye redness
- 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)
- Small breaks in the surface of the eye with or without inflammation
- Eye irritation
- Itchy eyes
- Longer eyelashes
- Eye pain
- Red and itchy of the eyelids
- Irritation when the drop is put in the eye

Affecting the skin

- Darker skin colour
- Abnormal hair growth around the eye

Less frequent side effects

Affecting the eye:

- Tired eye
- Blurred vision
- Swelling and/or disorder of the surface of the eye
- Darker eye (iris) colour
- Loss of eyelashes

Affecting the skin:

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

Affecting the body:

- Headache
- Feeling of sickness (nausea)

Frequency unknown

Affecting the eye:

- Darker eyelid colour
- Macular swelling (swelling of the retina at the back of the eye which may lead to worsening vision)
- Dry eye
- Sticky eye
- Eye swelling
- A feeling of something in the eye
- Tearing
- Eye discomfort
- Sensitivity to light
- Eyelid swelling

Affecting the skin

- Skin discolouration around the eyes

Affecting the body:

- Dizziness
- Asthma or 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)
- Increased blood pressure

In addition to the side effects for LUMIGAN 0,01 %, the following side effects have been seen with another medicine containing a higher strength of bimatoprost (0,03 %):

- Corneal erosion (disorder of the clear layer at the front of the eye)
- Eye burning
- An allergic reaction in the eye
- Inflamed eyelids
- Worsening of vision
- Difficulty in seeing clearly
- Darker eyelashes
- Cataract (clouding of the lens inside the eye)
- Retinal bleeding (bleeding at the back of the eye)
- Inflammation within the eye (uveitis or iritis)
- 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
- Darker skin colour around the eye
- Abnormal or excessive hair growth
- Weakness
- Peripheral oedema (swelling in the arms and legs)
- Abnormal liver function tests
- Colds and upper airway infections

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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of LUMIGAN 0,01 %.

You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.com

5. How to store LUMIGAN 0,01 %

- Store at or below 25 ºC.
- Store all medicines out of reach of children.
- Do not use the eye drops after the expiry date printed on the carton and bottle.
- Once opened, solutions may become contaminated, which can cause eye infections. Therefore, you must throw away the bottle 4 weeks (30 days) after you first opened it, even if some solution is left. To help you remember, write down the date that you opened it in the space on the carton.
- Keep bottle tightly closed when you are not using it.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LUMIGAN 0,01 % contains

- The active substance is bimatoprost. One ml of solution contains 0,1 mg bimatoprost.
- The other ingredients are benzalkonium chloride 0,02 % m/v (a preservative), sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate and purified water. Small amounts of hydrochloric acid or sodium hydroxide may be added to bring the solution to the correct pH level.

What LUMIGAN 0,01 % looks like and contents of the pack

LUMIGAN 0,01 % eye drops, solution is a clear colourless solution with no foreign particles, supplied as 2,5 ml filled in 5 ml; 5 ml and 7,5 ml filled in 10 ml white opaque low density polyethylene bottles with a turquoise polystyrene screw cap. Each bottle is packed into an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

AbbVie (Pty) Ltd
Abbott Place
219 Golf Club Terrace
Constantia Kloof, 1709
Johannesburg, Gauteng
SOUTH AFRICA
Tel: +27 11 831 3200

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Access to corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com