PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

LUMIGAN 0,01 %, bimatoprost 0,1 mg/ml eye drops

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 or your pharmacist.
- 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.

1. WHAT LUMIGAN 0,01 % CONTAINS

Active ingredient: Bimatoprost

Inactive ingredients: 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.

2. WHAT LUMIGAN 0,01 % 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.

3. 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 %.

Take special care with LUMIGAN 0,01 %

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 'Important information about some of the ingredients of LUMIGAN 0,01 %').

LUMIGAN 0,01 % may 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 over time. These changes may be permanent. The change 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.

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

Pregnancy and breast-feeding
Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breast-feeding your baby, please consult your healthcare 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 breast-feeding.

Driving and using machinery
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.

Important information about some of the ingredients of LUMIGAN 0,01 %
Contact lenses should be removed prior to using LUMIGAN 0,01 % in the eyes and may be reinserted 15 minutes following use of the eye drops. LUMIGAN 0,01 % should not be administered while wearing contact lenses. A preservative in LUMIGAN 0,01 % called benzalkonium chloride may cause eye irritation and can discolour soft contact lenses.

Using other medicines with LUMIGAN 0,01 %
Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines.)

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

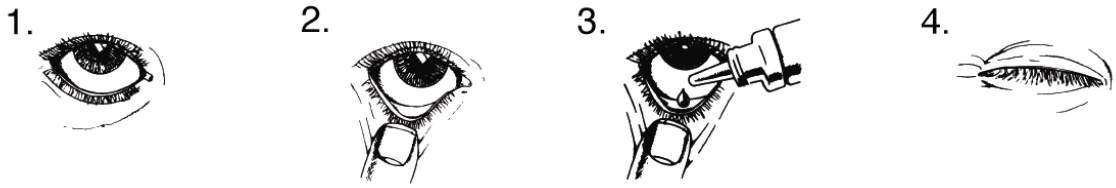
4. HOW TO USE LUMIGAN 0,01 %

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

Always use LUMIGAN 0,01 % exactly as your doctor has instructed you. You should check with your doctor if you are unsure.

If you have the impression that the effect of LUMIGAN 0,01 % is too strong or too weak, talk to your doctor or pharmacist.

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



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.

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 over-dosage, consult your doctor or pharmacist. If neither is available, contact

the nearest hospital or poison control centre.

If you forget to use LUMIGAN 0,01 %
Do not use a double dose to make up for the forgotten individual doses. Use a single drop as soon as you remember, and then go back to your regular routine.
If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

Effects when treatment with LUMIGAN 0,01 % is stopped
LUMIGAN 0,01 % should be used every day to work properly.

5. 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 healthcare provider for advice.

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

Affecting the eye
Frequent: Eye redness, eye irritation, itchy eyes, redness and/or itching of the eyelids, small breaks in the surface of the eye with or without inflammation, longer eyelashes, irritation when the drop is put in the eye
Less frequent: Tired eye, swelling and/or disorder of the conjunctiva (see through layer that covers the eye), crusting on the edge of the eyelid, loss of eyelashes, blurred vision
Frequency unknown: Darker eyelid colour, dry eyes, sticky eye, eye swelling, eyelid swelling, eye pain, a feeling of something in the eye, darker eye (iris) colour, tears, changes around the eyes and eyelids such as eyes appearing sunken or eyelid shrinking and moving away from the surface of the eye, macular swelling (swelling of the retina at the back of the eye which may lead to worsening vision), eye discomfort, sensitivity to light

Affecting the skin
Frequent: Abnormal hair growth around the eye, darker skin colour
Less frequent: Itching of skin

Affecting the body
Less frequent: Feeling of sickness (nausea)
Frequency unknown: Symptoms of allergic reaction (swelling, redness of the eye and rash of the skin), headache, asthma, worsening of asthma, shortness of breath, dizziness, 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 %):

Affecting the eye
An allergic reaction in the eye, inflamed eyelids, eyelid twitching, cataract (clouding of the lens inside the eye), corneal erosion (disorder of the clear layer at the front of the eye), cystoid macular oedema (swelling of the retina within the eye leading to worsening vision), darker eyelashes, inflammation within the eye, eye burning, darker skin colour around the eye, retinal bleeding (bleeding at the back of the eye), difficulty in seeing clearly, worsening of vision, skin redness around the eye

Affecting the skin
Abnormal or excessive hair growth

Affecting the body
Colds and upper airway infections, abnormal liver function tests, weakness, peripheral oedema (swelling in the arms and legs)

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

6. STORING AND DISPOSING OF 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).

7. PRESENTATION OF LUMIGAN 0,01 %

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.

8. IDENTIFICATION OF LUMIGAN 0,01 %

Clear colourless solution with no foreign particles.

9. REGISTRATION NUMBER

42/15.4/0835

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Allergan Pharmaceuticals (Pty) Ltd
30 New Road (entrance off Bavaria Road)
Randjespark Ext. 11, Midrand, 1682
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11. DATE OF PUBLICATION

Date of registration: 25 November 2011
Date of revision of the most recently revised Patient Information Leaflet as approved by the Authority: 25 November 2011

Professional Information can be accessed via http://www.allergan.co.za/en-za/products
In case of an adverse event, please contact +27 11 545 6600 or send an email to SA_Complaints@Allergan.com