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## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

Schedule 4

### Proprietary name, Strength and Pharmaceutical Form

**LUMIGAN® 0,03 %, bimatoprost 0,3 mg/ml, eye drops**

### Read all of this leaflet carefully before you start using LUMIGAN® 0,03 %

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- LUMIGAN® 0,03 % 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® 0,03 % CONTAINS

The active substance is: Bimatoprost

The other ingredients are: Benzalkonium chloride 0,005 % m/v (a preservative), sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate and purified water.

### 2. WHAT LUMIGAN® 0,03 % IS USED FOR

LUMIGAN® 0,03 % is prescribed to control glaucoma, which is high pressure in the eye. Bimatoprost belongs to a group of medicines called prostamides.

LUMIGAN® 0,03 % works by increasing the amount of liquid that is drained. This reduces the pressure inside the eye.

LUMIGAN® 0,03 % may be used on its own or with other drops called beta-blockers which also reduce pressure.

### 3. BEFORE YOU USE LUMIGAN® 0,03 %

#### Do not use LUMIGAN® 0,03 %

- If you are hypersensitive (allergic) to bimatoprost or any of the other ingredients of LUMIGAN® 0,03 %.

#### Take special care with LUMIGAN® 0,03 %

Before you use this medicine, 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 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® 0,03 %').

LUMIGAN® 0,03 % 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® 0,03 % solution has been repeatedly in contact with the skin surface. This is why it is important to apply LUMIGAN® 0,03 % as instructed and to avoid it running onto the cheek or other skin areas.

LUMIGAN® 0,03 % should not be used in people under 18.

### **Pregnancy and breastfeeding**

Always tell your healthcare provider if you are taking any other medicine.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using LUMIGAN® 0,03 %.

The safety of LUMIGAN® 0,03 % in pregnancy has not been established. LUMIGAN® 0,03 % should not be used during pregnancy unless your doctor still recommends it.

LUMIGAN® 0,03 % should not be used if you are breastfeeding because LUMIGAN® 0,03 % may get into breast milk.

### **Driving and using machinery**

Your sight may become blurred for a short time just after using LUMIGAN® 0,03 %. You should not drive or use machines until your sight is clear again.

### **Important information about some of the ingredients of LUMIGAN® 0,03 %**

Contact lenses should be removed prior to using LUMIGAN® 0,03 % in the eyes and may be reinserted 15 minutes following use of the eye drops. LUMIGAN® 0,03 % should not be administered while wearing contact lenses. A preservative in LUMIGAN® 0,03 % called benzalkonium chloride may cause eye irritation and can discolour soft contact lenses.

### **Using other medicines with LUMIGAN® 0,03 %**

Always tell your healthcare provider if you are taking any other medicines. (This includes complementary or traditional medicines.)

If you use LUMIGAN® 0,03 % with another eye medicine, leave at least 5 minutes between

putting in LUMIGAN® 0,03 % and the other medicine.

#### 4. HOW TO USE LUMIGAN® 0,03 %

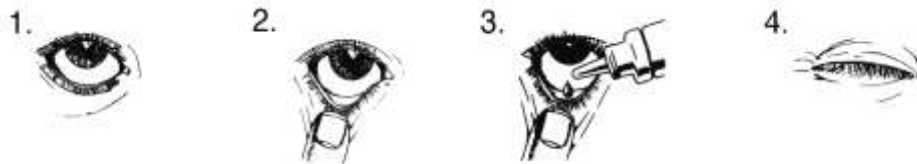
Do not share medicines prescribed for you with any other person.

Always use LUMIGAN® 0,03 % exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of LUMIGAN® 0,03 % is too strong or too weak, tell your doctor or pharmacist.

LUMIGAN® 0,03 % should only be applied to the eye.

The usual dose is one drop in each eye that needs treatment, once every day, in the evening, following the instructions for use below.

#### Instructions for use



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 help prevent infections, 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® 0,03 % than you should

If you use more LUMIGAN® 0,03 % 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 control centre.

#### If you forget to use LUMIGAN® 0,03 %

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 a forgotten dose.

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

**Effects when treatment with LUMIGAN® 0,03 % is stopped**

LUMIGAN® 0,03 % should be used every day to work properly.

**5. POSSIBLE SIDE EFFECTS**

LUMIGAN® 0,03 % can have side effects. Not all side effects reported for LUMIGAN® 0,03 % are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using LUMIGAN® 0,03 %, please consult your healthcare provider for advice.

***Frequent side effects***

Affecting the eye:

- Longer eyelashes
- Redness
- Itchiness
- An allergic reaction in the eye
- Tired eyes
- Sensitivity to light
- Darker skin colour around the eye
- Darker eyelashes
- Pain
- A feeling that something is in your eye
- Sticky eyes
- Darker iris colour
- Difficulty in seeing clearly
- Worsening of vision
- Blurred vision
- Irritation
- Burning
- Inflamed, red and itchy eyelids
- Tears
- Dryness
- Swelling of the see-through layer which covers the surface of the eye
- Cataract
- Small breaks in the surface of the eye, with or without inflammation

Affecting the body:

- Abnormal liver function tests

***Less frequent side effects***

Affecting the eye:

- Inflammation within the eye
- Retinal bleeding
- Eyelid twitching

Affecting the body:

- Hair growth around the eye
- Weakness
- Swelling in the arms and/or legs
- Colds

***Side effects where the frequency is not known***

Affecting the eye:

- Eye discomfort
- Eyelid shrinking, moving away from the surface of the eye
- Eyes appear sunken
- Skin redness around the eye
- Swollen eyelid
- Macular oedema (swelling of the retina within the eye leading to worsening vision)

Affecting the body

- Abnormal hair growth
- Skin discolouration
- Nausea
- Symptoms of allergic reaction (swelling, redness of the eye and rash of the skin)
- Dizziness
- Headaches
- Asthma
- Worsening of asthma
- Shortness of breath
- Increased blood pressure

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

**6. STORING AND DISPOSING OF LUMIGAN® 0,03 %**

- Store at or below 25 °C.
- Store all medicines out of reach of children.

- Once opened, solutions may become contaminated, which can cause eye infections. Therefore, you must throw away the bottle 4 weeks (28 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.
- Do not use the eye drops after the expiry date printed on the carton and bottle.
- Keep bottle tightly closed when you are not using it to prevent contamination.
- 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® 0,03 %**

3 ml solution filled into a white opaque low density polyethylene bottle with a polystyrene screw cap. Each bottle is packed into an outer carton.

#### **8. IDENTIFICATION OF LUMIGAN® 0,03 %**

Clear colourless to slightly yellow solution with no foreign particles.

#### **9. REGISTRATION NUMBER**

36/15.4/0157

#### **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Allergan Pharmaceuticals (Pty) Ltd  
30 New Road (entrance off Bavaria Road)  
Randjespark Ext 11, Midrand, 1682  
Johannesburg, Gauteng  
South Africa

Tel. 011 545 6600

#### **11. DATE OF PUBLICATION**

Date of registration: 7 March 2003

Date of the most recently revised Patient Information Leaflet as approved by the Authority: 21 June 2013

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](mailto:SA_Complaints@Allergan.com)