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1. What LUMIGAN[®] 0.03% is used for

LUMIGAN[®] 0.03% is used to reduce high pressure in the eye when other eye-pressure lowering medications when used alone are not enough.

2. How LUMIGAN[®] 0.03% works

LUMIGAN[®] 0.03% increases the amount of fluid flowing out of the eye which reduces the internal eye pressure.

3. Before you use LUMIGAN[®] 0.03%

- When you must not use it

Do not use LUMIGAN[®]:

- If you are allergic (hypersensitive to bimatoprost, or any of the other ingredients of LUMIGAN[®]. (for a full list of ingredients, see section 8 "PRODUCT DESCRIPTION").
- if you have had to stop using eye drops in the past because of a side effect of the preservative benzalkonium chloride

- Pregnancy and lactation

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 this medicine. Do not use LUMIGAN[®] 0.03% if you are

pregnant unless your doctor still recommends it.

LUMIGAN[®] 0.03% may get into breast milk so you should not breast-feed while you are taking LUMIGAN[®] 0.03%.

- Children

LUMIGAN[®] 0.03% has not been tested in children under the age of 18 and therefore must not be used by patients under 18 years.

The safety and effectiveness in pediatric patients have not been established and therefore use is not recommended in children or adolescents.

- Before you start to use it

Take special care with LUMIGAN[®] 0.03%.

- Talk to your doctor if: You have any eye surgery or suffered trauma or infection to the eye
- You have any breathing problems
- You have liver or kidney problems
- You have dry eyes
- You have or have had any problems with your cornea (front transparent part of the eye)
- You wear contact lenses
- You have or have had low blood pressure or low heart rate
- You have had a viral infection or inflammation of the eye

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 eyeball may also go darker over time.

These changes may be permanent. The change may be more noticeable if you are only treating one eye.

- Taking other medicines

If you have to use any other eye medicine during treatment with LUMIGAN[®] 0.03%, the medicines should be administered at least five (5) minutes apart.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

4. How to use LUMIGAN[®] 0.03%

- How much to use

The recommended dosage is one drop in the affected eye(s) once daily in the evening. The dosage of LUMIGAN[®] 0.03% should not exceed once daily since it has been shown that more frequent administration may decrease the intraocular pressure lowering effect.

Reduction of the eye pressure starts approximately 4 hours after the first administration with maximum effect reached within approximately 8 to 12 hours.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

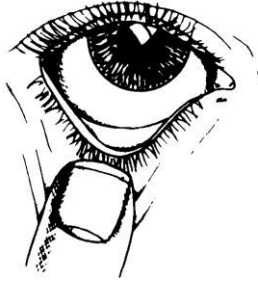
- Instructions for use

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

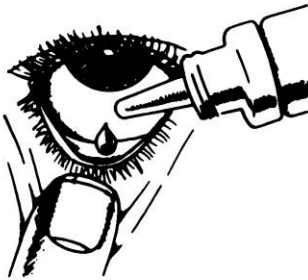
1. Wash your hands. Tilt your head back and look at the ceiling.



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.



Wipe off any excess that runs down the cheek.

If a drop misses your eye, try again.

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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking LUMIGAN® 0.03% for as long as your doctor recommends. LUMIGAN® 0.03% should be used every day to work properly.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you use more LUMIGAN® 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.

5. While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking LUMIGAN® 0.03%.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give LUMIGAN® 0.03% to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

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.

Using contact lenses:

LUMIGAN® 0.03% contains benzalkonium chloride as a preservative, which is known to discolour soft contact lenses and can cause eye irritation. If you wear soft contact lenses you must remove them before using LUMIGAN® 0.03% eye drops and wait at least 15 minutes before putting your lenses back in.

6. Side effects

Like all medicines, LUMIGAN® 0.03% can cause side effects, although not everybody gets them.

Affecting the eyes:

Occurring in approximately 15% - 45% of patients:

Red eye, growth of eyelashes, and itchy eyes.

Occurring in approximately 3% - 10% of patients:

Dry eyes, visual disturbance, eye burning, a feeling that something is in your eye, eye pain, darker skin colour around the eye, red, itchy eyelids, cloudy lens inside the eye, inflammation of the surface of the eye, eyelid skin redness, eye irritation, and eyelash darkening.

Occurring in approximately 1% - 3% of patients:

Eye discharge, tearing, light sensitivity, eye allergy, tired eyes, increases in iris colouring, and eye swelling.

Occurring in less than 1% of patients:
Inflammation inside the eye

Affecting other parts of the body:

Occurring in approximately 10% of patients:

Infections (primarily colds and upper respiratory tract infections).

Occurring in approximately 1 - 5% of patients, (in descending order of incidence):

Headaches, abnormal liver function tests, feeling weak and excess facial and body hair.

Side effects with unknown frequency:

Watery eyes, changes to eye lid and area around the eye, including eyes appearing sunken, swelling of the retina at the back of the eye, swelling of the eyelid, abnormal hair growth, asthma, shortness of breath, nausea, high blood pressure.

If any of the side effects get serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI).

7.Storage and Disposal of LUMIGAN®

- Storage

Keep out of the reach and sight of children.

Do not use LUMIGAN® 0.03% after the expiry date which is stated on the bottle label and the bottom of the carton after EXP.

Store below 30°C. Protect from light. For topical ophthalmic use only.

Discard contents one month after opening.

- Disposal

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.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- What it looks like

LUMIGAN® 0.03% is a colourless clear eye drop solution.

LUMIGAN® is supplied sterile in opaque white plastic dropper bottles in the following sizes: 3, 5 or 7.5mL.

Not all pack sizes may be marketed.

- Ingredients

- Active ingredient
bimatoprost

- Inactive ingredients
benzalkonium chloride, sodium chloride, sodium phosphate, dibasic, citric acid, and purified water

- MAL number:

MAL20032241AZ

9. Manufacturer

Allergan Sales, LLC
8301 Mars Drive,
Waco, Texas 76712, U.S.A.

Product Registration Holder

Allergan Malaysia Sdn Bhd
Level 5-02, Block A, PJ8, No.23, Jalan Barat, Seksyen 8, 46050 Petaling Jaya, Selangor, Malaysia

10. Date of revision

20/09/2016

Serial Number

NPRA (R1/2) 04012018/003