

LUMIGAN[®] 0.01%

bimatoprost (0.01%) ophthalmic solution

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1. What LUMIGAN[®] 0.01% is used for

LUMIGAN[®] 0.01% is used to reduce high pressure in the eye.

2. How LUMIGAN[®] 0.01% works

LUMIGAN[®] 0.01% increases the amount of fluid flowing out of the eye which reduces the internal eye pressure.

3. Before you use LUMIGAN[®] 0.01%

- When you must not use it

Do not use LUMIGAN[®] 0.01%:

- if you are allergic (hypersensitive to bimatoprost, or any of the other ingredients of LUMIGAN[®] 0.01%. (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[®] 0.01% if you are pregnant unless your doctor still recommends it.

LUMIGAN[®] 0.01% may get into breast milk so you should not breast-feed while you are taking LUMIGAN[®] 0.01%.

Children:

LUMIGAN[®] 0.01% has not been tested in children under the age of 18 and therefore must not be used by patients under 18 years.

- Before you start to use it

Take special care with LUMIGAN[®] 0.01%. Talk to your doctor if:

- You have any eye surgery or suffered trauma or infection to the eye.
- You have 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 had low blood pressure or low heart rate
- You have had a viral infection or inflammation of the eye

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 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[®] 0.01%, 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[®] 0.01%

- How much to use

The recommended dosage is one drop in the affected eye(s) once daily in the evening. The dosage of LUMIGAN[®] 0.01% should not exceed once daily since it has been shown that more frequent administration may decrease the eye 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.

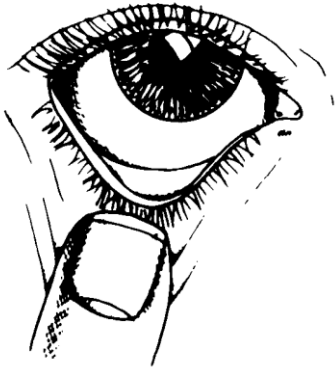
- Instructions for use

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

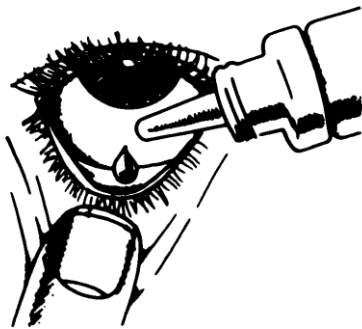
1. Wash your hands. Tilt your head back and look at the ceiling.



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® 0.01% for as long as your doctor recommends. LUMIGAN® 0.01% 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® 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.

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® 0.01%.

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® 0.01% 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® 0.01%. You should not drive or use machines until your sight is clear again.

Using contact lenses:

LUMIGAN® 0.01% 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® 0.01% eye drops and wait at least 15 minutes before putting your lenses back in.

6. Side effects

Like all medicines, LUMIGAN® 0.01% can cause side effects, although not everybody gets them.

Very common side effects: These may affect one or more users in 10

Affecting the eyes: red eyes

Common side effects: These may affect 1 to 9 users in 100

Affecting the eyes: Small breaks in the surface of the eye, with or without inflammation, eyelid redness, eye irritation, itchy eyes or eyelids, longer eyelashes, inflammation of the surface of the eye, eyelash growth, irritation when drop is put into the eyes

Affecting the skin: eyelash growth, darker skin colour around the eye, hair growth around the eye

Uncommon side effects: These may affect 1 to 9 users in 1000

Affecting the eye: Darker Iris colour, Tired eye, Swelling of the surface of the eye, Blurred vision, Loss of eye lashes

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 with unknown frequency:

Eye pain, blurred vision, headache, symptoms of allergic reaction (swelling, redness of the eye and rash of the skin), darker eyelid colour, dry eyes, sticky eyes, eye swelling, swelling of eyelid, a feeling that something is in your eye, watery eye, swelling of the retina at the back of the eye, eye discomfort, darker iris colour, dizziness, high blood pressure, light sensitivity, asthma, worsening of asthma, worsening of the lung disease called chronic obstructive pulmonary disease (COPD), shortness of breath, deepening of the eyelid sulcus due to loss of fat in the eye region which can lead to sunken eyes, drooping eyelids, and incomplete closure of the eyelids.

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 visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of LUMIGAN® 0.01%

- Storage

Keep out of the reach and sight of children.

Do not use LUMIGAN® 0.01% after the expiry date which is stated on the bottle label and the bottom of the carton after EXP.

Store below 30°C. Discard unused contents 4 weeks 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® 0.01% is an eye drop solution in a pack containing 1 plastic bottle with a screw cap. Each bottle contains 3mL of solution.

LUMIGAN® 0.01% is supplied sterile in opaque white *low density polyethylene* ophthalmic dispenser bottles and tips with turquoise polystyrene caps in the following sizes: 3 mL fills in a 5 mL container

- Ingredients

- Active ingredient
bimatoprost

- Inactive ingredients
benzalkonium chloride, sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate, and purified water. Small amounts of hydrochloric acid or sodium hydroxide may be added to keep the level of acid (pH levels) normal.

- MAL number:

MAL16035016ARZ

9. Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
Ireland

Product Registration Holder

ABBVIE SDN BHD
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47410 Petaling Jaya Selangor, Malaysia

10. Date of revision

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