

This leaflet was formatted according to Ministry of Health guidelines. It was reviewed and approved by the Ministry of Health in December 2016 and revised in March 2019 in accordance with Ministry of Health guidelines

Patient Package Leaflet in Accordance with the Pharmacists' Regulations (Preparations) – 1986

The dispensing of this medicine requires a doctor's prescription

LUMIGAN

Solution for eye treatment

Active ingredient: bimatoprost 0.3 mg/ml (0.03%)

Inactive ingredients and allergens in the medicine: see Section 2, in the subsection "Important information about some of the ingredients of LUMIGAN" and Section 6, "FURTHER INFORMATION".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

LUMIGAN is an anti-glaucoma medicine used to reduce high pressure in the eye. This medicine may be used on its own or with other drops called beta-blockers which are also used to reduce pressure in the eye.

Therapeutic group: prostaglandin analogues called prostamides.

Your eye contains a clear, watery liquid that feeds the inside of the eye. The liquid is constantly being drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up. This medicine works by increasing the amount of liquid that is drained. This reduces the pressure inside the eye. If the high pressure is not reduced, it could lead to a disease called glaucoma and eventually damage your sight.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to bimatoprost or to any of the other ingredients of the medicine – see Section 6 "FURTHER INFORMATION".
- You have had to stop using eye drops in the past because of side effects caused by the preservative benzalkonium chloride.

Special warnings regarding use of this medicine

Before beginning treatment with LUMIGAN, tell the doctor if:

- You have any breathing problems
- You have liver or kidney problems
- You have had a cataract surgery in the past
- You have dry eye
- You have or have had any problems with your cornea (front transparent part of the eye)
- You wear contact lenses (see “Important information about some of the ingredients of LUMIGAN”)
- You have or have had low blood pressure or low heart rate
- You have had a viral infection or inflammation of the eye

LUMIGAN 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.

Children and adolescents

LUMIGAN has not been tested in children and adolescents under the age of 18 and therefore should not be used in this population.

Interactions with other medicines:

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking any medicine.

LUMIGAN may get into breast milk so you should not breast-feed while you are taking LUMIGAN.

Driving and using machinery

Your sight may become blurred for a short time just after using LUMIGAN. **You should not drive or operate dangerous machinery while using LUMIGAN** until your sight is clear again.

Important information about some of the ingredients of LUMIGAN

1 ml of LUMIGAN solution contains 0.05 mg of a preservative called benzalkonium chloride. Benzalkonium chloride may cause eye irritation and can discolour soft contact lenses. Do not use the drops when you are wearing contact lenses. Wait 15 minutes after using the drops before you put your lenses back in your eyes.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about your dosage or about how to take this medicine.

The dosage and treatment regimen will be determined by the doctor only.

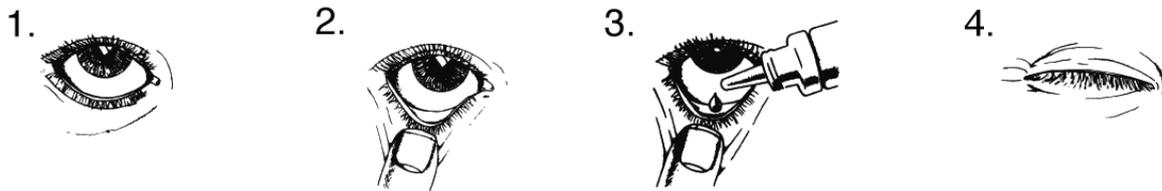
LUMIGAN should only be applied to the eye. The recommended dose is usually one drop of LUMIGAN in the evening, once daily in each eye that needs treatment.

If you use LUMIGAN with another eye medicine, wait at least five minutes between using LUMIGAN and the other eye medicine.

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

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 eyelid, 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 infection spreading and avoid eye injury, 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 use.

If you accidentally take too high a dosage

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, consult your doctor or pharmacist.

If a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine

If you forget to use LUMIGAN, use a single drop as soon as you remember, and then go back to your regular routine. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by the doctor.

If you stop using the medicine

LUMIGAN should be used every day to work properly. If you stop using LUMIGAN, the pressure inside your eye may go up, therefore consult your doctor before stopping this treatment.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of LUMIGAN may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

Very common side effects

Effects that appear in more than one user in 10

Affecting the eye

- Longer eyelashes (up to 45% of people)
- Slight redness (up to 44% of people)
- Itchiness (up to 14% of people)

Common side effects

Effects that appear in 1 - 10 users in 100

Affecting the eye

- 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
- Irritation
- Burning
- Inflamed, red and itchy eyelids
- Tears
- Dryness
- Worsening of vision
- Blurred vision
- Swelling of the see-through layer which covers the surface of the eye
- Small breaks in the surface of the eye, with or without inflammation

Affecting the body

- Headaches
- An increase in blood-test results that show how your liver is working
- Increased blood pressure

Uncommon side effects

Effects that appear in 1 - 10 users in 1000

Affecting the eye

- Cystoid macular oedema (swelling of the retina of the eye leading to worsening vision)
- Inflammation within the eye
- Bleeding in the retina of the eye
- Swollen eyelids
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- Skin redness around the eye

Affecting the body

- Nausea
- Dizziness
- Weakness
- Hair growth around the eye

Side effects whose frequency is unknown (effects whose frequency has not yet been determined)

Affecting the eye

- Eyes appear sunken
- Ocular discomfort

Affecting the body

- Asthma
- Worsening of asthma
- Worsening of lung disease called chronic obstructive pulmonary disease (COPD)
- Shortness of breath
- Symptoms of allergic reaction (swelling, redness of the eyes and rash of the skin)
- Skin discoloration (periocular)

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 experience any side effect, if any of the side effects get serious, or if you notice any side effects not mentioned in this leaflet, please consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by clicking on the link: "Reporting side effects due to medical treatment" that is found on the homepage of the Ministry of Health website (www.health.gov.il) and using the online form for reporting side effects, or by using the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use this medicine after the expiry date (exp. date) which is stated on the bottle. The expiry date refers to the last day of that month.

Store at 2°C to 25°C.

You must throw away the bottle, at the latest, 30 days after you first opened it, even if there are still some drops left. This will help prevent infections. To help you remember, write down the date you opened it in the space on the box.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate, benzalkonium chloride (preservative), hydrochloric acid or sodium hydroxide (to adjust pH), purified water.

What LUMIGAN looks like and contents of the pack:

LUMIGAN eye solution is colourless and clear. The pack contains a plastic bottle with a screw cap. The bottle is approximately half full and contains 3 millilitres of solution. This is enough for 4 weeks' usage.

Registration holder's name and address: Allergan Israel Ltd., 32 Shacham St., POB 6869 Petach Tikva.

Manufacturer's name and address: Allergan Inc., 2525 Dupont Drive, Irvine, California, USA.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 125 37 30463.