Package leaflet: Information for the user

LUMIGAN 0.1 mg/ml, eye drops, solution
Bimatoprost

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What LUMIGAN 0.1 mg/ml is and what it is used for

LUMIGAN is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

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

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 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. What you need to know before you use LUMIGAN 0.1 mg/ml

Do not use LUMIGAN 0.1 mg/ml:
- if you are allergic to bimatoprost or any of the other ingredients of this medicine (listed in section 6).
- if you have had to stop using eye drops in the past because of a side effect of the preservative benzalkonium chloride.

Warnings and precautions:
Talk to your doctor or pharmacist before you use LUMIGAN 0.1 mg/ml
Talk to your 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 “LUMIGAN 0.1 mg/ml contains benzalkonium chloride”)
- You have or have had low blood pressure or low heart rate

- You have had a viral infection or inflammation of the eye

During treatment, LUMIGAN may cause a loss of fat around the eye, which may cause your eyelid crease to deepen, your eye to appear sunken (enophthalmos), your upper eyelid to droop (ptosis), the skin around your eye to tighten (involution of dermatochalasis) and the lower white part of your eye to become more visible (inferior scleral show). The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking LUMIGAN. LUMIGAN may also 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. These changes may be permanent. The changes may be more noticeable if you are only treating one eye.

Children and adolescents
LUMIGAN has not been tested in children under the age of 18 and therefore should not be used by patients under 18 years.

Other medicines and LUMIGAN
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

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

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

Driving and using machines
Your sight may become blurred for a short time just after using LUMIGAN. You should not drive or use machines until your sight is clear again.

LUMIGAN 0.1 mg/ml contains benzalkonium chloride
This medicine contains 0.6 mg benzalkonium chloride in each 3 ml of solution which is equivalent to 0.2 mg/ml.
Do not use the drops when you are wearing your lenses. A preservative in LUMIGAN, ~~called~~ benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and wait 15 minutes after using the drops before you put your lenses back in. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use LUMIGAN 0.1 mg/ml

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

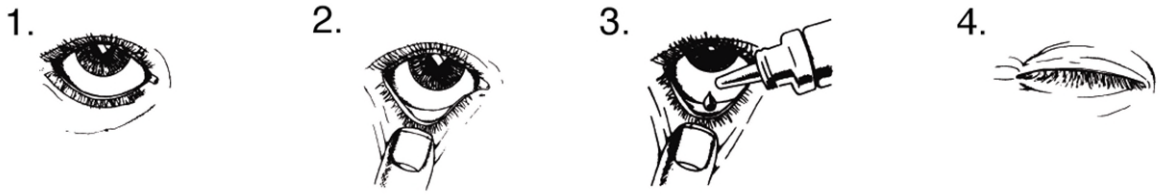
LUMIGAN should only be applied to the eye. The recommended dose is one drop of LUMIGAN in the evening, once daily in each eye that needs treatment.

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.

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 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 you have used it.

If you use more LUMIGAN 0.1 mg/ml than you should
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.

If you forget to use LUMIGAN 0.1 mg/ml
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.

If you stop using LUMIGAN 0.1 mg/ml
LUMIGAN should be used every day to work properly. If you stop using LUMIGAN the pressure inside your eye may go up, therefore talk to your doctor before stopping this treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects
These may affect one or more users in 10
Affecting the eye
- Slight redness (up to 29 % of people)
- Loss of fat in the eye region which can lead to deepening of your eyelid crease, sunken eye (enophthalmos), drooping eyelid (ptosis), tightening of the skin around your eye (involution of dermatochalasis), and the lower white part of your eye to become more visible (inferior scleral show)

Common side effects

These may affect 1 to 9 users in 100
Affecting the eye
- Small breaks in the surface of the eye, with or without inflammation
- Irritation
- Itchy eyes
- Longer eyelashes
- Irritation, when drop is put in the eye
- Eye pain

Affecting the skin
- Red and itchy eyelids
- 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 where the frequency is not known
Affecting the eye
- Macular oedema (swelling of the retina at the back of the eye which may lead to worsening vision)
- Darker eyelid colour
- Dryness
- Sticky eyes
- A feeling that something is in your eye
- Swelling of the eye
- Increasing tears
- Ocular discomfort
- Sensitivity to light

Affecting the body
- Asthma
- Worsening of asthma
- Worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- Shortness of breath
- Symptoms of allergic reaction (swelling, redness of the eye and rash of the skin)

- Dizziness
- Increased blood pressure
- Skin discoloration (periocular)
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In addition to the side effects for LUMIGAN 0.1 mg/ml, the following side effects have been seen with another medicine containing a higher strength of bimatoprost (0.3 mg/ml):

- Ocular burning
- An allergic reaction in the eye
- Inflamed eyelids
- Difficulty in seeing clearly
- Worsening of vision
- Swelling of the see-through layer that covers the eye
- Tears
- Darker eyelashes
- Retinal bleeding
- Inflammation within the eye
- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- Skin redness around the eye
- Weakness
- An increase in blood-test results that show how your liver is working

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.

Reporting side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

UK
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of the medicine.

5. How to store LUMIGAN 0.1 mg/ml

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and the carton after EXP. The expiry date refers to the last day of that month.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What LUMIGAN 0.1 mg/ml contains

- The active substance is bimatoprost. One ml of solution contains 0.1 mg bimatoprost.
- The other ingredients are benzalkonium chloride (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 keep the level of acid (pH levels) normal.

What LUMIGAN 0.1 mg/ml looks like and contents of the pack
LUMIGAN is a colourless clear eye drop solution in a pack containing either 1 plastic bottle or 3 plastic bottles each with a screw cap. Each bottle is approximately half full and contains 3 millilitres of solution. This is enough for 4 weeks' usage. Not all pack sizes may be marketed.

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For any information about this medicine, please contact the local representative of the marketing authorisation holder.

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