

**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.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

In this leaflet:

1. What LUMIGAN 0.1 mg/ml is and what it is used for
2. Before you use LUMIGAN 0.1 mg/ml
3. How to use LUMIGAN 0.1 mg/ml
4. Possible side effects
5. How to store LUMIGAN 0.1 mg/ml
6. Further information

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 high pressure can lead to a disease called glaucoma.

If the high pressure is not reduced, it could eventually damage your sight.

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. LUMIGAN works by increasing the amount of liquid that is drained. This reduces the pressure inside the eye.

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

2. BEFORE YOU USE LUMIGAN 0.1 mg/ml**Do not use LUMIGAN 0.1 mg/ml:**

- if you are allergic (hypersensitive) to bimatoprost or any of the other ingredients of LUMIGAN.
- if you have had to stop using eye drops in the past because of a side effect of the preservative benzalkonium chloride.

Take special care with 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 "Important information about some of the ingredients of LUMIGAN 0.1 mg/ml")
 - 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.

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

Using other medicines:

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

If you use LUMIGAN with another eye drop, leave at least five minutes between putting in LUMIGAN and then the other drops.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. LUMIGAN should not be used during pregnancy unless your doctor still recommends it.

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.

Important information about some of the ingredients of LUMIGAN 0.1 mg/ml

Do not use the drops when you are wearing your lenses. Wait 15 minutes after using the drops before you put your lenses back in. A preservative in LUMIGAN called benzalkonium chloride may cause eye irritation and can discolour soft contact lenses.

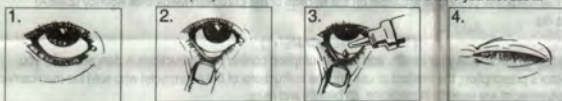
3. HOW TO USE LUMIGAN 0.1 mg/ml

LUMIGAN should only be applied to the eye. Always use LUMIGAN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual 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, apply the LUMIGAN eye drop first and wait 5 minutes before applying the second eye medicine.

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.

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.

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 use 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, LUMIGAN 0.1 mg/ml can have side effects, although not everybody gets them. Most of the side effects are not serious.

Very common side effects

These may affect one or more users in 10

Affecting the eye

- Slight redness (up to 29 % of people)

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

Affecting the skin

- Inflamed, 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 of on the edge of the eyelid
- Swelling of the eyelid
- Itching

Affecting the body

- Headache
- Feeling of sickness

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):

An allergic reaction in the eye; sensitivity to light; darker eyelashes; pain; a feeling that something is in your eye; sticky eyes; difficulty in seeing clearly; burning; tears; dryness; an increase in blood-test results that show how your liver is working; increased blood pressure; cystoid macular oedema (swelling of the retina within the eye leading to worsening vision); inflammation within the eye; retinal bleeding.

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.

5. HOW TO STORE LUMIGAN 0.1 mg/ml

Keep out of the reach and sight of children.

Do not use LUMIGAN 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.

Store at or below 25°C.

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.

6. FURTHER 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 to slightly yellow, 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.

Marketing Authorisation Holder and Manufacturer

Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, Co. Mayo, Ireland.

This leaflet was last approved in 01/2010.

Detailed information on this medicinal product is available on the website of the European Medicines Agency (EMA) <http://www.emea.europa.eu/>

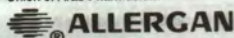
(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefit and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Ministers

Union of Arab Pharmacists



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