

Package Leaflet: Information for the user

LUMIGAN 0.3 mg/mL, eye drops, solution, in single-dose container

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 0.3 mg/mL single-dose is and what it is used for
2. What you need to know before you use LUMIGAN 0.3 mg/mL single-dose
3. How to use LUMIGAN 0.3 mg/mL single-dose
4. Possible side effects
5. How to store LUMIGAN 0.3 mg/mL single-dose
6. Contents of the pack and other information

1. What LUMIGAN 0.3 mg/mL single-dose is and what it is used for

LUMIGAN 0.3 mg/mL single-dose is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

LUMIGAN 0.3 mg/mL single-dose 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.

This medicine does not contain a preservative.

2. What you need to know before you use LUMIGAN 0.3 mg/mL single-dose

Do not use this medicine:

- If you are allergic to bimatoprost or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before you use LUMIGAN 0.3 mg/mL single-dose.

Please tell your doctor or pharmacist, if:

- You have any breathing problems
- You have liver or kidney problems
- You have had a cataract surgery in the past
- You have or have had low blood pressure or low heart rate
- You have had a viral infection or inflammation of the eye

LUMIGAN 0.3 mg/mL single-dose 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 0.3 mg/mL single-dose 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 0.3 mg/mL single-dose

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

Pregnancy, breast-feeding and fertility

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 this medicine.

LUMIGAN 0.3 mg/mL single-dose may get into breast milk so you should not breast-feed while you are taking this medicine.

Driving and using machines

Your sight may become blurred for a short time just after using LUMIGAN 0.3 mg/mL single-dose. You should not drive or use machines until your sight is clear again.

3. How to use LUMIGAN 0.3 mg/mL single-dose

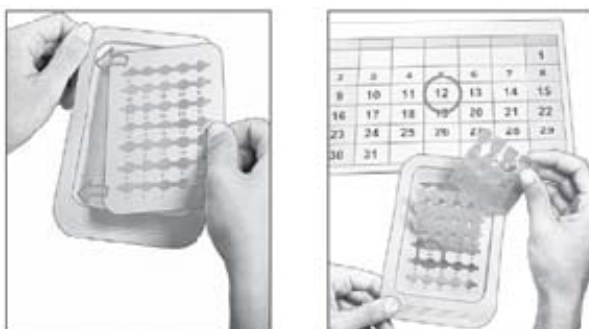
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one drop once daily, in the evening, once daily in each eye that needs treatment. LUMIGAN 0.3 mg/mL single-dose should only be applied to the eye

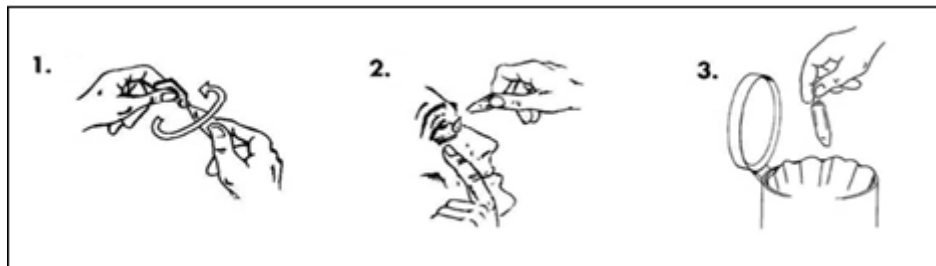
If you use LUMIGAN 0.3 mg/mL single-dose with another eye medicine, wait at least 5 minutes between using LUMIGAN 0.3 mg/mL single-dose and the other eye medicine.

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

A calendar card is provided in the pack, numbered 1-31 for each day of the month. Place the calendar card on the top of the plastic tub and push down to snap it into place. The 30 vials in the pack should be separated from each other and fitted into the numbered spaces starting with the space that is numbered with today's date. If you have any remaining vials, start over with the spot labelled "1" which will take you into the next month. Each day, the vial should be taken from the numbered spot that matches the calendar day to make sure a daily dose is not missed.



Wash your hands before use. Make sure that the single-dose container is intact before use. The solution should be used immediately after opening. To avoid contamination, do not let the open-end of the single-dose container touch your eye or anything else.



1. Take one single-dose container from the numbered spot that matches the calendar day and hold it upright (with the cap pointing upwards) and twist off the cap.
2. Gently pull down the lower eyelid to form a pocket. Turn the single-dose container upside down and squeeze it to release 1 drop into the affected eye(s).
3. Throw away the single-dose container after you have used it, even if there is some solution left.

Wipe off any excess that runs down the cheek.

If you wear contact lenses, take your lenses out before using this medicine. Wait 15 minutes after using the drops, and before you put your lenses back in.

If you use more LUMIGAN 0.3 mg/mL single-dose than you should

If you use more of this medicine 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 0.3 mg/mL single-dose

If you forget to use this medicine, 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 0.3 mg/mL single-dose

LUMIGAN 0.3 mg/mL single-dose should be used every day to work properly. If you stop using LUMIGAN 0.3 mg/mL single-dose 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, 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 24% 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
- Pain
- Dryness
- A feeling that something is in your eye
- Longer eyelashes

- Darker skin colour around the eye
- Red eyelids

Uncommon side effects

These may affect 1 to 9 users in 1000

Affecting the eye

- Tired eyes
- Sensitivity to light
- Darker iris colour
- Itchy and swollen eyelids
- Tears
- Swelling of the see-through layer which covers the surface of the eye
- Blurred vision

Affecting the body

- Headaches
- Hair growth around the eye

Side effects where the frequency is not known

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)

In addition to the side effects for LUMIGAN 0.3 mg/mL single-dose, the following side effects have been seen with the preserved multi-dose formulation of LUMIGAN 0.3 mg/mL and may occur in patients taking LUMIGAN 0.3 mg/mL single-dose:

- Dizziness
- Burning sensation in the eye
- An allergic reaction in the eye
- Inflamed eyelids
- Difficulty in seeing clearly
- Sticky eyes
- Worsening vision
- Darker eyelashes
- Retinal bleeding
- Inflammation within the eye
- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Iris inflammation
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- Eyes appear sunken
- Increased blood pressure
- Nausea
- 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 of the 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

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store LUMIGAN 0.3 mg/mL single-dose

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

This medicine is for single use only and does not contain preservatives. Do not keep any unused solution.

Do not use this medicine after the expiry date which is stated on the single-dose container and the tray after the expiry date (EXP):. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition. However once the pack is opened use within 30 days.

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 0.3 mg/mL single-dose contains

- The active substance is bimatoprost. One ml of solution contains 0.3 mg bimatoprost.
- The other ingredients are 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 0.3 mg/mL single-dose looks like and contents of the pack

LUMIGAN 0.3 mg/mL single-dose is a clear, colourless solution supplied in single-dose plastic containers, each containing 0.4 ml of solution.

Each pack contains 5,30 or 90 single-dose containers. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Allergan Pharmaceuticals Ireland

Castlebar Road
Westport
Co. Mayo
Ireland.

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

Ireland/Malta/United Kingdom

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Detailed information on this medicinal product is available on the European Medicines Agency website: <http://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.