LUMIGAN® EYE DROPS

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using LUMIGAN® eye drops?

LUMIGAN® eye drops contains the active ingredient bimatoprost. LUMIGAN® eye drops is used to lower raised pressure in the eye and to treat glaucoma.

For more information, see Section 1. Why am I using LUMIGAN® eye drops? in the full CMI.

2. What should I know before I use LUMIGAN® eye drops?

Check the list of ingredients at the end of the CMI. Do not use LUMIGAN® eye drops if you have ever had an allergic reaction to any of them.

Talk to your doctor before you use this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or

are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use LUMIGAN® eye drops? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LUMIGAN® eye drops and affect how it works, or LUMIGAN® eye drops may interfere with other medicines and affect how they work.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use LUMIGAN® eye drops?

- Use one drop in your affected eye(s), according to your doctor's instructions
- Use the drops each evening.

More instructions can be found in Section 4. How do I use LUMIGAN® eye drops? in the full CMI.

5. What should I know while using LUMIGAN® eye drops?

Things you should do

 Remind any doctor, dentist, pharmacist, or optometrist you

	visit that you are using LUMIGAN® eye drops Continue to use LUMIGAN® eye drops every evening unless your doctor tells you to stop Keep all your appointments so your condition can be checked.
Things you should not do	 Do not touch the dropper tip against your eye, eye lid or any surface Do not stop using LUMIGAN® eye drops without checking with your doctor Do not use LUMIGAN® eye drops while you are wearing contact lenses.
Driving or using machines	 Wait until your vision clears after using LUMIGAN® eye drops before driving or using machines.
Drinking alcohol	There is no information on the effects of using

	LUMIGAN® eye drops with alcohol.
Looking after your medicine	 Follow all instructions on the carton and label Store it in a cool dry place, below 25°C, away from moisture, heat, or sunlight.

For more information, see Section <u>5. What should I know while using LUMIGAN® eye drops?</u> in the full CMI.

6. Are there any side effects?

The most common side effects include red, congested eyes, growth of eyelashes, itching or irritation of the eye. Note that side effects can occur in other parts of the body, including serious allergic reaction (anaphylaxis).

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> effects? in the full CMI.

LUMIGAN® EYE DROPS (loom-ig-gan)

Active ingredient: *bimatoprost* (bim-at-oh-prost)

Consumer Medicine Information (CMI)

This leaflet provides important information about using LUMIGAN® eye drops. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LUMIGAN® eye drops.

Where to find information in this leaflet:

- 1. Why am I using LUMIGAN® eye drops?
- 2. What should I know before I use LUMIGAN® eye drops?
- 3. What if I am taking other medicines?
- 4. How do I use LUMIGAN® eye drops?
- 5. What should I know while using LUMIGAN® eye drops?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using LUMIGAN® eye drops?

LUMIGAN® eye drops contain the active ingredient bimatoprost.

LUMIGAN® eye drops are used to lower raised pressure in the eye and to treat glaucoma.

Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

LUMIGAN® eye drops lower the pressure in the eye by helping the flow of fluid out of the eye chamber.

LUMIGAN® eye drops can be used alone or together with other eyedrops/medicines to lower raised pressure within your eyes.

Although LUMIGAN® eye drops help control your condition, they will not cure it.

Your doctor may have prescribed this medication for another reason. Ask your doctor if you have any questions about why LUMIGAN® eye drops have been prescribed for you.

2. What should I know before I use LUMIGAN® eye drops?

Warnings

Do not use LUMIGAN® eye drops if:

- you are allergic to bimatoprost, or any of the ingredients listed at the end of this leaflet.
- the seal around the cap is broken, the bottle/ packaging shows signs of tampering, or the product does not look quite right.

Check with your doctor if:

- you have or have had inflammation in the eye, such as uveitis
- you have had eye surgery
- your eye does not have a lens
- your eye has an artificial lens, following cataract surgery
- the capsule ("bag") that normally holds the eye's lens in place is torn, or ruptured

- you have had other problems with your eyes, such as inflammation or swelling of the light sensitive part of the eye known as the macula
- you have a diabetes-related eye condition, such as diabetic retinopathy or blockage of a retinal vein
- you have or have had low blood pressure or a slow heartbeat
- you have or have had problems with your lungs or airways
- you have or have had problems with your liver or kidneys
- you take any medicines for any other condition.
- you have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

It is not known if LUMIGAN® eye drops are safe and useful for children and adolescents under 18 years.

Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed.

Cosmetic effects

Before you start using LUMIGAN® eye drops your doctor should tell you that some changes to your eyes may occur which may be permanent.

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, your upper eyelid to droop, the skin around your eye to tighten and the lower white part of your eye to become more visible. The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking LUMIGAN®.

Eyelashes may also grow longer and thicker, and eyelashes, the skin around the eye and the coloured part of the eye (iris) may become darker. If only one eye is being treated the cosmetic differences between the eyes may be noticeable. None of these changes affect vision. If you have any concerns, ask your doctor or pharmacist.

Hair may grow where LUMIGAN® contacts the skin. It is important to use as directed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with LUMIGAN® eye drops and affect how it works, while LUMIGAN® eye drops may affect how other medicines work.

Medicines that may <u>reduce</u> the effect of LUMIGAN® eye drops and where LUMIGAN® eye drops may <u>reduce</u> their effect include:

 other eye drops in the same class as LUMIGAN® eye drops, such as latanoprost, tafluprost, and travoprost.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LUMIGAN® eye drops.

4. How do I use LUMIGAN® eye drops?

Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.

How much to use

- Your doctor will tell you how many drops you need to use each day. Use LUMIGAN® eye drops only as prescribed by your doctor.
- The usual dose of LUMIGAN® eye drops is one drop in your affected eye(s), according to your doctor's instructions.

When to use LUMIGAN® eye drops

Use the drops each evening.

Use LUMIGAN® eye drops every day, at about the same time each day, unless your doctor tells you otherwise. Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

In some instances, LUMIGAN® eye drops need to be used with other eye drops. Your doctor will let you know which drops, how to use them, and how long to use them.

If you are using more than one eye drop product, wait 5 minutes before using the second product. If you are also using an eye ointment, instill the eye ointment last.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How to use LUMIGAN® eye drops

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in LUMIGAN® eye drops (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used LUMIGAN® eye drops.

These drops are for use in your eyes only.

You may find it easier to put drops in your eye while you are sitting or lying down.

To open a new bottle of LUMIGAN® eye drops first tear off the protective seal from the bottle. The contents are sterile if the seal is intact.

The seal will break and you can pull it off and then throw it away.

- 1. Wash your hands well with soap and water.
- 2. Remove the lid/cap.
- 3. Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
- 4. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
- 5. Tilt your head back and look up.
- 6. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
- 7. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
- 8. Close your eye. Do not blink or rub your eye.
- 9. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.
- 10Replace the lid/cap, sealing it tightly.
- 11Wash your hands again with soap and water to remove any residue.

If a drop misses your eye, try again. Wipe off any excess that runs down the cheek.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid injury and contaminating the eye drops.

If you forget to use LUMIGAN® eye drops

It is important that you use LUMIGAN® eye drops at the same time each evening.

If you forget to use LUMIGAN® eye drops and it is almost time for your next dose, use your drops at the usual time the next evening.

If you miss your dose and remember through the night or in the morning, use the drops as soon as you remember and go back to using them at your usual time.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the number of drops to make up for the dose you missed.

If you use too much LUMIGAN® eye drops

Immediately rinse your eyes with warm water.

If LUMIGAN® eye drops is accidentally swallowed

You should immediately:

- phone the Poisons Information Centre
 (by calling 13 11 26 in Australia or 0800 POISON (0800 764 766) in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appear to be no signs of discomfort or poisoning.

5. What should I know while using LUMIGAN® eye drops?

Things you should do

- Continue to use LUMIGAN® eye drops every evening unless your doctor tells you to stop. LUMIGAN® eye drops help to control your condition but does not cure it.
- Use all the medication prescribed to treat your eye condition.
- Keep all your doctor's appointments so that your condition can be monitored, and your eye pressure can be checked.
- Tell your doctor if you think your condition is not improving while using LUMIGAN® eye drops.

Call your doctor straight away if you:

 develop any problems with your eye(s), such as, trauma, change of vision, infection in the eye or eyelid, or have eye surgery • become pregnant while using LUMIGAN® eye drops. Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using LUMIGAN® eye drops.

Things you should not do

- Do not touch the dropper tip against your eye, eyelid or anything else, to avoid contaminating the eye drops.
- Do not stop using LUMIGAN® eye drops without checking with your doctor. Your eye pressure can rise again and may cause damage to your eye.

Driving or using machines

Your vision may be blurred after using LUMIGAN® eye drops. Wait until your vision clears before driving or using machines.

Looking after your medicine

Follow the instructions on the carton and label on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

Ensure the lid is closed tightly after each use.

Keep it where young children cannot reach it.

When to discard your medicine

Discard the bottle 28 days after first opening it.

Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date has passed.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Effects on the eye(s): red, congested eyes itching or irritation of the eye 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
 feeling of something in the eye 	
• dry eye	
growth of eyelashes	
redness in or around eye or eyelid	
watery eyes	
inflamed eyelids	
eye discomfort	
eye strain	
 burning of the eye and nearby eyelid 	
itchy eye and eyelid	
inflammation inside the eye	
 swelling of the surface of the eye 	
sensitivity to light	
 darkening of the area around the eye 	
eyelash darkening	
 darkening of the coloured part of the eye (iris) 	
 more often, the following effects have been seen: loss of fat in the eye region which can lead 	

Less serious side effects	What to do
to deepening of your eyelid crease, sunken eye, drooping eyelid, tightening of the skin around your eye, and the lower white part of your eye to become more visible.	
Effects on the body as a whole:	
 headache feeling weak and tired symptoms of a cold such as runny nose or nasal congestion excessive or abnormal hair growth in areas where the product repeatedly comes into contact with the skin nausea dizziness allergic skin reaction (rash, itching, hives) 	

Serious side effects

Serious side effects	What to do
 eye discharge eye pain small spots on the eye surface blurred vision or changes in/disturbance of vision macular edema (build-up of fluid at the back of the eye, which causes vision to become blurry) spasm of the eyelids where there is uncontrolled blinking and squeezing of eyelid Effects on the body as a whole: 	Call your doctor straight away, if you notice any of these serious side effects.
 high blood pressure asthma or worsening of asthma difficulty breathing depression (low mood, feelings of worthlessness) 	

Serious side effects	What to do
Effects on the body as a whole: • severe allergic reaction, including swelling of the tongue, lips and throat, difficulty breathing	Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or to https://nzphvc.otago.ac.nz/reporting/ in New Zealand. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LUMIGAN® eye drops contains

Active ingredient (main ingredient)	• bimatoprost
Other ingredients (inactive ingredients)	 benzalkonium chloride citric acid monohydrate dibasic sodium phosphate heptahydrate hydrochloric acid purified water sodium chloride sodium hydroxide

Do not use this medicine if you are allergic to any of these ingredients.

What LUMIGAN® eye drops looks like

LUMIGAN® eye drops is a sterile, clear, colourless solution. It is supplied in plastic dropper bottles containing 3 mL, 5 mL or 7.5 mL of solution. (AUST R 80657).

(Not all presentations may be available).

Who distributes LUMIGAN® eye drops?

LUMIGAN® eye drops eye drops are distributed in Australia by:

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020

Australia

LUMIGAN® eye drops eye drops are distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington, 6011

New Zealand

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