Understanding glaucoma

- Glaucoma is a serious eye disease and a leading cause of preventable blindness among adults in the United States.
- It is characterized by elevated pressure inside the eye, also called intraocular pressure (IOP).
- This elevated intraocular pressure can damage the optic nerve and lead to permanent vision loss.

Studies show that IOP-lowering medications can help delay or reduce the risk of glaucoma and its associated vision loss.  

Why LUMIGAN® 0.01%?

The most common treatment to reduce elevated IOP is medicated eyedrops. Your doctor prescribed once-daily LUMIGAN® 0.01% (bimatoprost ophthalmic solution), an FDA-approved medication proven to effectively lower IOP.

What to expect with your LUMIGAN® 0.01% therapy

LUMIGAN® 0.01% can cause side effects, most commonly increased eye redness (hyperemia), eyelash growth, or itchy eyes. Your eyes may get red, but typically won’t hurt or itch. If you develop persistent eye itching, consult your doctor. In clinical studies, about 0.5% to 3% of patients (about 1 to 3 out of 100) stopped therapy due to eye redness with LUMIGAN® 0.01% or 0.03%.

Before Therapy  
Your eyes may have some redness before you begin therapy.

At the Start of Therapy  
Some patients may experience increased redness once on therapy.

After a Month of Therapy  
By the first few weeks or month, the redness usually fades.

Individual results with LUMIGAN® 0.01% ophthalmic solution may vary.  
IMPORTANT: Talk to your doctor before discontinuing your LUMIGAN® 0.01% therapy for any reason.

Remember 0.01%.

Make sure you receive LUMIGAN® 0.01% at the pharmacy, just as your doctor prescribed.

LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) is used for the treatment of high eye pressure, also called intraocular pressure (IOP), in people with open-angle glaucoma or ocular hypertension.

Important Safety Information

LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) has been reported to cause darkening (pigmentation) of eye color, eyelid skin, and eyelashes as well as increased growth of eyelashes. Pigmentation changes can increase as long as LUMIGAN® 0.01% and 0.03% is used. After stopping LUMIGAN® 0.01% and 0.03%, darkening of eye color is likely to be permanent, while darkening of the eyelid skin and eyelash changes may be reversible. The effects of increased darkening beyond 5 years are not known.

Please see additional Important Safety Information on reverse side.
**LUMIGAN® 0.01% ophthalmic solution may work only when you use it daily and correctly by following your doctor’s instructions. Commit to taking your LUMIGAN® 0.01% therapy every day to help lower your IOP and help reduce the risk of vision loss.**

**Glaucoma has no cure**
Glaucoma is a lifelong disease. Prescription eyedrops are not something a person can use for a few months to make the glaucoma disappear. They require a long-term commitment. Make LUMIGAN® 0.01% ophthalmic solution a part of your daily routine.

**Useful tips to help you remember your LUMIGAN® 0.01% eyedrops**
If you need help remembering your daily dose, try following these helpful suggestions:

- Associate using your eyedrops with other daily routines you’ve established for yourself such as brushing your teeth
- Set a daily clock or watch alarm that can remind you to use your eyedrops
- Ask a friend or family member to remind you when it’s time to use your eyedrops

**Rely on your support network**
Friends, family, your doctor, and the LUMIGAN® website can offer the support you need to follow your treatment regimen. Our website is a great source for glaucoma information, educational tools, and a valuable rebate coupon.

**Use your IOP-lowering therapy daily.**
*Visit www.lumigan.com for more information and a money-saving offer.*

**Important Safety Information (continued)**
When only one eye is treated, there is a possibility of eyelash changes in the eye treated with LUMIGAN® 0.01% and 0.03%. These changes may result in differences between the eyes in eyelash length, thickness, darkness, number of eyelashes, and/or direction of eyelash growth. These changes are usually reversible upon stopping LUMIGAN® 0.01% and 0.03% therapy.

Avoid allowing the tip of the dispensing bottle to touch the eye, anything around the eye, fingers, or any other surface in order to avoid contamination by common bacteria known to cause eye infections. Serious damage to the eye and loss of vision may result from using contaminated solutions.

If you have eye surgery or develop any eye reactions (such as trauma or infection), immediately consult with your physician about continuing the use of LUMIGAN® 0.01% and 0.03%.

If you wear contact lenses, remove them before using LUMIGAN® 0.01% and 0.03%. Then wait 15 minutes after using LUMIGAN® 0.01% and 0.03% before you put your contacts back into your eyes.

The most common side effects are eye redness, growth of eyelashes, and itchy eyes.

**Please see your doctor for full product information.**

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LUMIGAN® 0.01% AND 0.03%  
(bimatoprost ophthalmic solution)

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LUMIGAN® is a prostaglandin analog indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

- Pigmentation
  - Pigmentation of the iris, periocular tissue (eyelid) and eyelashes can occur. Iris pigmentation is likely to be permanent. (5.1)
- Eyelash Changes
  - Gradual change to eyelashes including increased length, thickness and number of lashes. Usually reversible. (5.2)

ADVERSE REACTIONS

Most common adverse reaction (range 25%-45%) is conjunctival hyperemia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-433-8871 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use. (8.4)

See 17 for Patient Counseling Information
Additional ocular adverse events (reported in 1 to 10% of patients) with bimatoprost ophthalmic solutions included ocular dryness, visual disturbance, ocular burning, foreign body sensation, eye pain, pigmentation of the periciliar skin, blepharitis, cataract, suppurative blepharitis, conjunctivitis, epiphora, eyelash darkening, eye discharge, tearing, photophobia, allergic conjunctivitis, asthenopia, increases in iris pigmentation, conjunctival edema, conjunctival hemorrhage, and abnormal hair growth. Intracranial inflammation, reported as iritis was reported in less than 1% of patients.

Systemic adverse events reported in approximately 10% of patients with bimatoprost ophthalmic solutions were infections (primarily colds and upper respiratory tract infections). Other systemic adverse events (reported in 1 to 5% of patients) included headaches, abnormal liver function tests, and asthma.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category C

Teratogenic effects: In embryo/fetal developmental studies in pregnant mice and rats, abortion was observed at oral doses of bimatoprost which achieved at least 33 or 97 times, respectively, the maximum intended human exposure based on blood AUC levels. At doses at least 41 times the maximum intended human exposure based on blood AUC levels, the gestation length was reduced in the dams, the incidence of dead fetuses, late resorptions, peri- and postnatal pup mortality was increased, and pup body weights were reduced. There are no adequate and well-controlled studies of bimatoprost ophthalmic solution administration in pregnant women. Because animal reproductive studies are not always predictive of human response LUMIGAN® should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers
It is not known whether LUMIGAN® 0.01% and 0.03% is excreted in human milk, although in animal studies, bimatoprost has been shown to be excreted in breast milk. Because many drugs are excreted in human milk, caution should be exercised when LUMIGAN® is administered to a nursing woman.

8.4 Pediatric Use
Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

8.5 Geriatric Use
No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

8.6 Hepatic Impairment
In patients with a history of liver disease or abnormal ALT, AST and/or bilirubin at baseline, bimatoprost 0.03% had no adverse effect on liver function over 48 months. In patients with a history of liver disease or abnormal ALT, AST and/or bilirubin at baseline, bimatoprost 0.03% (bimatoprost ophthalmic solution) occurs, treatment should be symptomatic.

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8.7 Renal Impairment
In patients with a history of liver disease or abnormal ALT, AST and/or bilirubin at baseline, bimatoprost 0.03% had no adverse effect on liver function over 48 months. In patients with a history of liver disease or abnormal ALT, AST and/or bilirubin at baseline, bimatoprost 0.03% (bimatoprost ophthalmic solution) occurs, treatment should be symptomatic.

8.8 Combined Use
In patients with a history of liver disease or abnormal ALT, AST and/or bilirubin at baseline, bimatoprost 0.03% had no adverse effect on liver function over 48 months. In patients with a history of liver disease or abnormal ALT, AST and/or bilirubin at baseline, bimatoprost 0.03% (bimatoprost ophthalmic solution) occurs, treatment should be symptomatic.

8.9 Concomitant Use
No overall clinical differences in safety or effectiveness have been observed between patients treated with combination therapy with LUMIGAN® and other ocular hypotensive agents and those treated with LUMIGAN® alone.