Comprendre le glaucome

- Le glaucome est une maladie grave des yeux et une cause majeure de cécité évitable chez l’adulte aux États-Unis.1
- Il se caractérise par une pression élevée dans l’œil, aussi appelé « pression intraoculaire » (PIO).
- Cette pression intraoculaire élevée peut léser le nerf optique et donner lieu à une perte de vision permanente.

Les études montrent que les médicaments réducteurs de PIO peuvent contribuer à retarder ou à réduire le risque de glaucome et la perte de vision qui lui est associée.2-4

Pourquoi LUMIGAN® 0.01% ?

Le traitement le plus courant pour réduire une PIO élevée est l’application de gouttes médicamenteuses dans les yeux. Votre médecin vous a prescrit une fois par jour du LUMIGAN® 0.01% (collyre de bimatoprost), un médicament approuvé par la FDA qui a montré son efficacité pour faire baisser la PIO.

Qu'attendre de votre traitement au LUMIGAN® 0.01% ?

Le LUMIGAN® 0.01% peut avoir des effets secondaires - yeux rouges (hyperémie), pousse des cils ou démangeaison des yeux le plus souvent. Les yeux peuvent devenir rouges, mais en général ils ne sont ni douloureux ni irrités. En cas de démangeaison persistante des yeux, consultez votre médecin. Dans le cadre des études cliniques, environ 0.5 à 3 % des patients (soit 1 à 3 sur 100) ont arrêté leur traitement parce qu’ils avaient les yeux rouges suite à la prise de LUMIGAN® 0.01% ou 0.03%.

Avant le traitement

Il est possible que certaines rougeurs oculaires soient antérieures au début de votre traitement.

Au début du traitement

Certains patients traités pourront constater des rougeurs accrues.

Après un mois de traitement

D’ordinaire, ces rougeurs disparaissent au bout de quelques semaines ou d’un mois.

Les résultats avec le collyre LUMIGAN® 0.01% peuvent varier selon les individus.

IMPORTANT : Parlez à votre médecin avant d’arrêter votre traitement au LUMIGAN® 0.01% pour une raison quelconque.

Rappel : 0.01%.

Assurez-vous qu'on vous donne du LUMIGAN® 0.01% à la pharmacie, tout comme votre médecin vous l'a prescrit.

Le LUMIGAN® 0.01% et 0.03% (collyre de bimatoprost) est utilisé pour le traitement de la pression élevée dans l’œil, également appelée pression intraoculaire (PIO), chez les patients atteints de glaucome à angle ouvert ou d’hypertension oculaire.

Consignes de sécurité importantes

Il a été signalé que le LUMIGAN® (collyre de bimatoprost) 0.01% et 0.03% pouvait provoquer un assombrissement (pigmentation) de la couleur de l’iris, de la peau des paupières et des cils, ainsi qu’un allongement des cils. Les changements de pigmentation peuvent augmenter tant que l’utilisation du LUMIGAN® 0.01% et 0.03% continue. Après l’arrêt du LUMIGAN® 0.01% et 0.03%, l’assombrissement de la couleur de l’iris sera probablement permanent, tandis que celui de la peau des paupières et les modifications qui touchent les cils peuvent être réversibles. Les effets d’une pigmentation accrue au-delà de 5 ans ne sont pas connus.

Consulter les informations de sécurité importantes au verso.
Le collyre LUMIGAN® 0.01% ne sera efficace que si vous l’utilisez tous les jours et correctement, en suivant scrupuleusement les instructions de votre médecin. Engagez-vous à prendre tous les jours votre traitement au LUMIGAN® 0.01% pour aider à baisser votre PIO et réduire le risque de cécité.

Le glaucome est incurable.
Le glaucome est une maladie permanente. Les gouttes ophtalmiques sur ordonnance ne sont pas un produit utilisable pendant quelques mois pour faire disparaître le glaucome. Elles exigent un engagement à long terme. Intégrez le collyre LUMIGAN® 0.01% à votre routine quotidienne.

Astuces pour vous rappeler de prendre vos gouttes LUMIGAN® 0.01%
Si vous avez besoin d’un pense-bête pour ne pas oublier de prendre votre dose quotidienne, voici quelques suggestions qui pourront vous être utiles :
- Associez la prise de vos gouttes à d'autres habitudes quotidiennes établies - au brossage des dents, par exemple.
- Mettez le réveil pour vous rappeler de prendre vos gouttes.
- Demandez à un proche de vous rappeler quand il est temps pour vous de prendre vos gouttes.

Appuyez-vous sur un réseau de soutien.
Vos amis, votre famille, votre médecin et le site Web LUMIGAN® peuvent vous fournir le soutien dont vous pouvez avoir besoin pour suivre votre traitement. Notre site Web fourmille d’informations sur le glaucome, suggère des outils éducatifs et vous offre un bon de réduction.

Prenez tous les jours votre traitement réducteur de la PIO.
Pour plus de renseignement et une offre de remise, consultez www.lumigan.com.

Consignes de sécurité importantes (suite)
Quand un seul œil est traité, il existe un risque de modification des cils dans l’œil traité au LUMIGAN® 0.01% et 0.03%. Ces changements peuvent donner lieu à des différences de longueur, d’épaisseur et de couleur des cils, dans le nombre de cils et/ou le sens de pousse des cils. Ces changements sont généralement réversibles dès l’arrêt du traitement au LUMIGAN® 0.01% et 0.03%.
Évitez de toucher l’œil, le pourtour de l’œil, les doigts ou toute autre surface avec l’embout de l’applicateur pour éviter la contamination par des bactéries courantes connues pour causer des infections oculaires. L’emploi de solutions contaminées peut causer des lésions oculaires et une cécité.
En cas d’intervention chirurgicale sur l’œil ou de réactions oculaires (trauma ou infection, par exemple), consultez immédiatement votre médecin pour savoir si vous pouvez continuer à prendre du LUMIGAN® 0.01% ou 0.03%.
Si vous portez des verres de contact, ôtez-les avant d’utiliser le LUMIGAN® 0.01% ou 0.03%. Attendez 15 minutes après l’application de LUMIGAN® 0.01% ou 0.03% avant de les remettre.
Les effets secondaires les plus fréquents sont la rougeur des yeux, l’allongement des cils et les yeux irrités.

Pour des informations complètes concernant la prescription, nous vous invitons à consulter votre médecin.

The entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris pigmentation around the pupil spreads concentrically towards the periphery of the iris and Iris color change may not be noticeable for several months to years. Typically, the brown not known.

The long term effects of increased pigmentation are

After discontinuation of bimatoprost, pigmentation of the iris is likely to be permanent, (5.1)

possibility of increased pigmentation. The long term effects of increased pigmentation are

Pigmentation

Gradual change to eyelashes including increased length, thickness and number of lashes. Usually reversible, (5.2)

• Pigmentation

Pigmentation of the iris, perilobital tissue (eyelid) and eyelashes can occur. Iris pigmentation is likely to be permanent. (5.1)

Eyelash Changes

increased iris pigmentation, these patients should be examined regularly (see PATIENT COUNSELING INFORMATION, 17.1).

Eyelash Changes

Eyelash changes are usually reversible upon discontinuation of treatment.

Contract lenses should be removed prior to instillation of

5.4 Macular Edema

Macular edema, including cystoid macular edema, has been reported during treatment with bimatoprost ophthalmic solution. LUMIGAN® 0.01% and 0.03% should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

5.5 Angle-closure, Inflammatory or Neovascular Glaucoma

LUMIGAN® 0.01% and 0.03% has not been evaluated for the treatment of angle-closure, inflammatory or neovascular glaucoma.

5.6 Bacterial Keratitis

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface (see PATIENT COUNSELING INFORMATION, 17.3).

5.7 Use with Contact Lenses

Contact lenses should be removed prior to instillation of LUMIGAN® 0.01% and 0.03% and may be reinserted 15 minutes following its administration.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Approximately 0.5% to 3% of patients discontinued therapy due to conjunctival hyperemia with 0.01% or 0.03% bimatoprost 0.01% AND 0.03%.

6.2 Other Ophthalmic Drug Products

Gradual change to eyelashes including increased length, thickness and number of lashes. Usually reversible upon discontinuation of treatment.

6.3 Initial Ophthalmic Solutions

irrigation with maximum effect reached within approximately 8 to 12 hours.

Ophthalmic solution containing bimatoprost 0.1 mg/mL (LUMIGAN® 0.01%) or containing 0.3 mg/mL bimatoprost (LUMIGAN® 0.03%).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Nursing Mothers

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. (8.4)

See 17 for Patient Counseling Information

Revised: 8/2010

FULL PRESCRIBING INFORMATION: CONTENTS

1 INDICATIONS AND USAGE

1.1 LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

1.2 The recommended dosage is one drop in the affected eye(s) once daily in the evening. (2)

1.3 Ophthalmic solutions. Other common events (>10%) included growth of eyelashes, and

increased iris pigmentation, these patients should be examined regularly (see PATIENT COUNSELING INFORMATION, 17.1).

8.5 Geriatric Use

8.6 Hepatic Impairment

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17.4 When to Seek Physician Advice

17.5 Use with Contact Lenses

17.6 Use with Other Ophthalmic Drugs

1.3 mong the most frequently reported changes have been increased pigmentation of the tissues. The most frequently reported changes have been increased pigmentation of the iris, perilobital tissue (eyelid) and eyelashes. Pigmentation is expected to increase as long as bimatoprost is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. After discontinuation of bimatoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the perilobital tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation. The long term effects of increased pigmentation are not known.

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. While treatment with LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) can be continued in patients who develop noticeably
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, superficial punctate keratitis, episcleritis, allergic conjunctivitis, photophobia, increased intraocular pressure, eye discharge, tearing, ph Sponsored Links, conjunctival hyperemia, and abnormal hair growth. Intracocular inflammation, reported as iritis was reported in less than 1% of patients. Systemic adverse events reported in 1 to 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 anemia.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

Teratogenic effects: In embryofetal developmental studies in pregnant mice and rats, abortion was observed at oral doses of bimatoprost which achieved at least 53 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 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 ALT, AST or bilirubin at baseline, bimatoprost 0.03% had no adverse effect on liver function over 48 months.

10 OVERDOSAGE

No information is available on overdosage in humans. If overdose with LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) occurs, treatment should be symptomatic. In oral (gavage) mouse and rat studies, doses up to 100 mg/kg/day, did not produce any toxicity. This dose expressed as mg/m2 is at least 70 times higher than the accidental dose of one bottle of LUMIGAN® 0.03% for a 10 kg child.

11 DESCRIPTION

LUMIGAN® 0.01% and 0.03% (bimatoprost ophthalmic solution) is a synthetic prostamide analog with ocular hypotensive activity. Its chemical name is \((\text{1E,3S})-3\)-hydroxy-5-phenyl-1-pentenyl\)](https://www.nature.com/articles/s41586-020-2056-8) cyclopentyl\)-5\]-dihydroxy-2-\[(1E,3S)-3-hydroxy-5-phenyl-1-pentenyl\)](https://www.nature.com/articles/s41586-020-2056-8) cyclopentyl\]-5\]-dihydroxy-2-\[(1E,3S)-3-hydroxy-5-phenyl-1-pentenyl\)](https://www.nature.com/articles/s41586-020-2056-8) cyclopentyl\]-5\])); Its chemical structure is:

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Bimatoprost, a prostaglandin analog, is a synthetic structural analog of prostaglandin with ocular hypotensive activity. It selectively mimics the effects of naturally occurring substance prostaglandin F2\alpha. Bimatoprost is believed to lower intraocular pressure (IOP) in humans by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes. Elevated IOP presents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss. LUMIGAN® 0.01% and 0.03% contains Active: bimatoprost 0.01 mg/mL; Preservative: benzalkonium chloride 0.2 mg/mL; Inactives: sodium chloride; sodium phosphate, dibasic; citric acid and purified water. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH. The pH during its shelf life ranges from 6.8-7.8.

12.2 Pharmacokinetics

Absorption: After one drop of bimatoprost ophthalmic solution 0.03% was administered once daily to both eyes of 15 healthy subjects for two weeks, blood concentrations peaked within 10 minutes after dosing and were below the lower limit of detection (0.025 ng/mL) in most subjects within 1.5 hours after dosing. Mean \(C_{max}\) and AUC\(_{0-24h}\) values were similar on days 7 and 14 at approximately 0.08 ng/mL and 0.09 ng·hr/mL, respectively, indicating that steady state was reached during the first week of ocular dosing. There was no significant systemic drug accumulation over time. Metabolism: Bimatoprost is moderately distributed into body tissues with a steady-state volume of distribution of 0.67 L/kg. In human blood, bimatoprost resides mainly in the plasma. Approximately 12% of bimatoprost remains unbound in human plasma.

Metabolism: Bimatoprost is the major circulating species in the blood once it reaches the systemic circulation following ocular dosing. Bimatoprost then undergoes oxidation, N-dealkylation and glucuronidation to form a diverse variety of metabolites. Elimination: Following an intravenous dose of radiolabeled bimatoprost (3.12 µg/kg) to six healthy subjects, the maximum blood concentration of unchanged drug was 12.2 µg/mL and decreased rapidly with an elimination half-life of approximately 45 minutes. The total blood clearance of bimatoprost was 1.5 L/hr/kg. Up to 67% of the administered dose was excreted in the urine while 25% of the dose was recovered in the feces.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Bimatoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses of up to 2 mg/kg/day and 1 mg/kg/day respectively (at least 192 and 291 times the recommended human exposure based on blood AUC levels respectively) for 104 weeks. Bimatoprost was not mutagenic or clastogenic in the Ames test, in the mouse lymphoma test, or in the in vivo mouse micronucleus tests. Bimatoprost did not impair fertility in male or female rats up to doses of 0.6 mg/kg/day (at least 103 times the recommended human exposure based on blood AUC levels).

14 CLINICAL STUDIES

In clinical studies of patients with open angle glaucoma or ocular hypertension with a mean baseline IOP of 26 mmHg, the IOP-lowering effect of LUMIGAN® 0.03% (bimatoprost ophthalmic solution) once daily (in the evening) was 7-8 mmHg. In a 3 month clinical study of patients with open angle glaucoma or ocular hypertension with an average baseline IOP of 23.5 mmHg, the IOP-lowering effect of LUMIGAN® 0.01%, once daily (in the evening) was up to 7.5 mmHg and was approximately 0.5 mmHg less effective than LUMIGAN® 0.03%. In this same study, LUMIGAN® 0.01% also had a similar overall safety profile compared with LUMIGAN® 0.03%. After 12 months of treatment, discontinuations were 8.1% for LUMIGAN® 0.01% and 13.4% for LUMIGAN® 0.03%.

15 HOW SUPPLIED/STORAGE AND HANDLING

LUMIGAN® (bimatoprost ophthalmic solution) 0.01% is supplied sterile in opaque white low density polyethylene ophthalmic dispenser bottles and tips with turquiose polyurethane caps in the following sizes:

- 2.5 mL fill in a 5 mL container - NDC 0023-3205-03
- 5 mL fill in a 10 mL container - NDC 0023-3205-05
- 7.5 mL fill in a 10 mL container - NDC 0023-3205-08

LUMIGAN® (bimatoprost ophthalmic solution) 0.03% is supplied sterile in opaque white low density polyethylene ophthalmic dispenser bottles and tips with turquiose polyurethane caps in the following sizes:

- 2.5 mL fill in 5 mL container - NDC 0023-9187-03
- 5 mL fill in 10 mL container - NDC 0023-9187-05
- 7.5 mL fill in 10 mL container - NDC 0023-9187-07

Storage: LUMIGAN® 0.01% and 0.03% should be stored at 2° to 25°C (36° to 77°F).

17 PEDIATRIC PATIENTS

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to avoid contamination of the solution by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

17.2 Potential for Eyelash Changes

Patients should also be informed of the possibility of eyelash and vellus hair changes in the treated eye during treatment with LUMIGAN® 0.01% and 0.03%. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

17.3 Handling the Container

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to avoid contamination of the solution by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

17.4 When to Seek Physician Advice

Patients should also be advised that if they develop an intercurrent ocular condition (e.g., trauma or infection), have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician’s advice concerning the continued use of LUMIGAN® 0.01% and 0.03%.

17.5 Use with Contact Lenses

Patients should be advised that LUMIGAN® 0.01% and 0.03% contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to instillation of LUMIGAN® and may be reinserted 15 minutes following its administration.

17.6 Use with Other Ophthalmic Drugs

If more than one topical ophthalmic drug is being used, the drugs should be administered 5 minutes after each other.

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