Allergan Product Information

Below are downloadable materials with information about Allergan eye care products. Print the materials as handouts to educate your patients about their treatment and proper administration of the products.

Click any of the product names below to review downloadable product information.

To view PDF files, *Adobe® Reader®* must be installed on your computer. Do not have this program? Download here.

RESTASIS® (cyclosporine ophthalmic emulsion) 0.05%

REFRESH® Brand (OTC)

LUMIGAN® (bimatoprost ophthalmic solution) 0.01%

ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1%

COMBIGAN® (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5%

LATISSE® (bimatoprost ophthalmic solution) 0.03%

INDICATION(S) AND IMPORTANT SAFETY INFORMATION
Click the links to go to each product's Indication(s) and Important Safety Information.

ACUVAIL® 0.45% ALPHAGAN® P 0.1% COMBIGAN® 0.2%/0.5% LASTACAFT® 0.1%

LATISSE® 0.03% LUMIGAN® 0.01% RESTASIS® 0.05% ZYMAXID® 0.5%

ACUVAIL® (ketorolac tromethamine ophthalmic solution) 0.45% Important Information

INDICATION
ACUVAIL® ophthalmic solution is a nonsteroidal anti-inflammatory indicated for the treatment of pain and inflammation following cataract surgery.

Important Safety Information

CONTRAINDICATIONS
ACUVAIL® solution is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation.

WARNINGS AND PRECAUTIONS
Delayed Healing
Topical nonsteroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Potential for Cross-Sensitivity
There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs.

Increased Bleeding Time
With some NSAIDs, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

Corneal Effects
Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration, or corneal perforation. These events may be sight threatening.

Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (eg, dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events, which may become sight threatening.

Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to surgery or use beyond 14 days postsurgery may increase patient risk for the occurrence and severity of corneal adverse events.

ACUVAIL® should not be administered while wearing contact lenses.

ADVERSE REACTIONS
The most common adverse events were reported in 1% to 6% of patients and included increased intraocular pressure, conjunctival hyperemia and/or hemorrhage, corneal edema, ocular pain, headache, tearing, and vision blurred. Some of these events may be the consequence of the cataract surgical procedure.

Please click here for the full Prescribing Information for ACUVAIL®.

ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% or 0.15% Important Information

INDICATIONS AND USAGE
ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% or 0.15% is an alpha-adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Neonates and Infants (under the age of 2 years): ALPHAGAN® P is contraindicated in neonates and infants (under the age of 2 years).

Hypersensitivity Reactions: ALPHAGAN® P is contraindicated in patients who have exhibited a hypersensitivity reaction to any component of this medication in the past.

WARNINGS AND PRECAUTIONS
Potentiation of Vascular Insufficiency: ALPHAGAN® P may potentiate syndromes associated with vascular insufficiency. ALPHAGAN® P should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.

Severe Cardiovascular Disease: Although brimonidine tartrate ophthalmic solution had minimal effect on the blood pressure of patients in clinical studies, caution should be exercised in treating patients with severe cardiovascular disease.

Contamination of Topical Ophthalmic Products After Use: 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.

DRUG INTERACTIONS
Antihypertensives/Cardiac Glycosides: Because ALPHAGAN® P may reduce blood pressure, caution in using drugs such as antihypertensives and/or cardiac glycosides with ALPHAGAN® P is advised.

CNS Depressants: Although specific drug interaction studies have not been conducted with ALPHAGAN® P, the possibility of an additive or potentiating effect with CNS depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics) should be considered.

Tricyclic Antidepressants: Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with ALPHAGAN® P in humans can lead to resulting interference with the IOP-lowering effect. Caution is advised in patients taking tricyclic antidepressants, which can affect the metabolism and uptake of circulating amines.

Monoamine Oxidase Inhibitors: Monoamine oxidase (MAO) inhibitors may theoretically interfere with the metabolism of brimonidine and potentially result in an increased systemic side effect such as hypotension. Caution is advised in patients taking MAO inhibitors, which can affect the metabolism and uptake of circulating amines.

ADVERSE REACTIONS
Adverse reactions occurring in approximately 10% to 20% of the subjects receiving brimonidine ophthalmic solution (0.1% to 0.2%) included: allergic conjunctivitis, conjunctival hyperemia, and eye pruritus. Adverse reactions occurring in approximately 5% to 9% included: burning sensation, conjunctival folliculosis, hypertension, ocular allergic reaction, oral dryness, and visual disturbance.

Please click here for the full Prescribing Information for ALPHAGAN® P.

COMBIGAN® (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5% Important Information

INDICATIONS AND USAGE: COMBIGAN® (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5% is an alpha-adrenergic receptor agonist with a beta-adrenergic receptor inhibitor indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunctive or replacement therapy due to inadequately controlled IOP; the IOP-lowering of COMBIGAN® dosed twice a day was slightly less than that seen with the concomitant administration of 0.5% timolol maleate ophthalmic solution dosed twice a day and 0.2% brimonidine tartrate ophthalmic solution dosed three times per day.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: COMBIGAN® is contraindicated in patients with bronchial asthma; a history of bronchial asthma; severe chronic obstructive pulmonary disease; in patients with sinus bradycardia; second or third degree atrioventricular block; overt cardiac failure; in neonates and infants (under the age of 2 years); in patients with a hypersensitivity reaction to any component of COMBIGAN® in the past.

WARNINGS AND PRECAUTIONS: COMBIGAN® contains timolol maleate. COMBIGAN® is administered topically, but can be absorbed systemically. The adverse reactions with systemic administration of beta-adrenergic blocking agents may occur with topical use (eg, severe respiratory reactions including death due to bronchospasm in patients with asthma have been reported with systemic or ophthalmic administration of timolol maleate).

Sympathetic stimulation may be essential to support the circulation in patients with diminished myocardial contractility and its inhibition by beta-adrenergic receptor blockade may precipitate more severe failure. In patients with no history of cardiac failure, continued depression of the myocardium with beta-blocking agents over time can lead to cardiac failure. Discontinue COMBIGAN® at the first sign or symptom of cardiac failure.

Patients with chronic obstructive pulmonary disease (eg, chronic bronchitis, emphysema) of mild or moderate severity, bronchospastic disease, or a history of bronchospastic disease should not receive beta-blocking agents, including COMBIGAN®.

COMBIGAN® may potentiate syndromes associated with vascular insufficiency. Use caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans.

Patients taking beta-blockers with a history of atopy or severe anaphylactic reactions to a variety of allergens may be more reactive to repeated accidental, diagnostic, or therapeutic challenge with such allergens. Such patients may be unresponsive to the usual doses of epinephrine used to treat anaphylactic reactions.

Beta-adrenergic blockade can potentiate muscle weakness with myasthenic symptoms (eg, diplopia, ptosis, and generalized weakness). Although rare, timolol can increase muscle weakness in some patients with myasthenia gravis or myasthenic symptoms.

Beta-adrenergic receptor blocking agents may mask the signs and symptoms of acute hypoglycemia and clinical signs (eg, tachycardia) of hyperthyroidism. Use caution in patients subject to spontaneous hypoglycemia or to diabetic patients (especially those with labile diabetes) who are receiving insulin or oral hypoglycemic agents. Carefully manage patients that may develop thyrotoxicosis to avoid abrupt withdrawal of beta-adrenergic blocking agents that might precipitate a thyroid storm.

Ocular hypersensitivity has occurred with brimonidine tartrate ophthalmic solutions 0.2% (eg, increase in IOP).

Some authorities recommend gradual withdrawal of beta-adrenergic receptor blocking agents due to impairment of beta-adrenergically mediated reflexes during surgery. If necessary during surgery, the effects of beta-adrenergic blocking agents may be reversed by sufficient doses of adrenergic agonists.

ADVERSE REACTIONS: The most frequent reactions with COMBIGAN® in about 5% to 15% of patients included: allergic conjunctivitis, conjunctival folliculosis, conjunctival hyperemia, eye pruritus, ocular burning, and stinging.

DRUG INTERACTIONS: COMBIGAN® may reduce blood pressure. Use caution in patients on antihypertensives and/or cardiac glycosides.

Observe patients receiving a beta-adrenergic blocking agent orally and COMBIGAN® for additive effects of beta-blockade, both systemic and on intraocular pressure. Concomitant use of two topical beta-adrenergic blocking agents is not recommended.

Use caution in the co-administration of beta-adrenergic blocking agents (eg, COMBIGAN®) and oral or intravenous calcium antagonists due to possible atrioventricular conduction disturbances, left ventricular failure, and hypotension. Avoid co-administration in patients with impaired cardiac function.

Observe patients closely when a beta-blocker is administered to patients receiving catecholamine-depleting drugs (eg, reserpine) due to possible additive effects and the production of hypotension and/or marked bradycardia, which may result in vertigo, syncope, or postural hypotension.

Specific drug interaction studies have not been conducted with COMBIGAN®, but consider the possibility of an additive or potentiating effect with CNS depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics).

Concomitant use of beta-adrenergic blocking agents with digitalis and calcium antagonists may have additive effects in prolonging atrioventricular conduction time.

Potentiated systemic beta-blockade (eg, decreased heart rate, depression) has been reported with combined use of CYP2D6 inhibitors (eg, quinidine, SSRIs) and timolol.

Tricyclic antidepressants (TCAs) can blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of TCAs with COMBIGAN® in humans can interfere with the IOP-lowering effect. Caution is advised in patients taking TCAs, which can affect the metabolism and uptake of circulating amines.

Monoamine oxidase (MAO) inhibitors may theoretically interfere with the metabolism of brimonidine and potentially increase systemic side effect such as hypotension. Use caution in patients taking MAO inhibitors, which can affect the metabolism and uptake of circulating amines.

Please click here for the full Prescribing Information for COMBIGAN®.

LASTACAFT® (alcaftadine ophthalmic solution) 0.25% Important Information

INDICATIONS AND USAGE
LASTACAFT® (alcaftadine ophthalmic solution) 0.25% is an H_1 histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis.

MECHANISM OF ACTION
Alcaftadine is an H_1 histamine receptor antagonist and inhibitor of the release of histamine from mast cells. Decreased chemotaxis and inhibition of eosinophil activation have also been demonstrated.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS
To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

Patients should be advised not to wear a contact lens if their eye is red.

LASTACAFT® should not be used to treat contact lens-related irritation.

Remove contact lenses prior to instillation of LASTACAFT®. The preservative in LASTACAFT®, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of LASTACAFT®.

LASTACAFT® is for topical ophthalmic use only.

ADVERSE REACTIONS
The most frequent ocular adverse reactions, occurring in < 4% of LASTACAFT® treated eyes, were eye irritation, burning and/or stinging upon instillation, eye redness, and eye pruritus.

The most frequent non-ocular adverse reactions, occurring in < 3% of subjects with LASTACAFT® treated eyes, were nasopharyngitis, headache, and influenza. Some of these events were similar to the underlying disease being studied.

Please click here for the full Prescribing Information for LASTACAFT®.

LATISSE® (bimatoprost ophthalmic solution) 0.03% Important Information

Indication
LATISSE® (bimatoprost ophthalmic solution) 0.03% is indicated to treat hypotrichosis of the eyelashes by increasing their growth, including length, thickness, and darkness.

Important Safety Information

Warnings and Precautions: In patients using **LUMIGAN®** (bimatoprost ophthalmic solution) or other prostaglandin analogs for the treatment of elevated intraocular pressure (IOP), the concomitant use of **LATISSE®** may interfere with the desired reduction in IOP. Patients using prostaglandin analogs including **LUMIGAN®** for IOP reduction should only use **LATISSE®** after consulting with their physician and should be monitored for changes to their intraocular pressure.

Increased iris pigmentation has occurred when bimatoprost solution was administered. Patients should be advised about the potential for increased brown iris pigmentation, which is likely to be permanent.

Bimatoprost has been reported to cause pigment changes (darkening) to periorbital pigmented tissues and eyelashes. The pigmentation is expected to increase as long as bimatoprost is administered, but has been reported to be reversible upon discontinuation of bimatoprost in most patients.

There is the potential for hair growth to occur in areas where **LATISSE®** solution comes in repeated contact with skin surfaces. Apply **LATISSE®** only to the skin of the upper eyelid margin at the base of the eyelashes.

LATISSE® solution should be used with caution in patients with active intraocular inflammation (eg, uveitis) because the inflammation may be exacerbated.

Adverse Reactions: The most frequently reported adverse events were eye pruritus, conjunctival hyperemia, skin hyperpigmentation, ocular irritation, dry eye symptoms, and erythema of the eyelid. These events occurred in less than 4% of patients.

Postmarketing Experience: The following reactions have been identified during postmarketing use of **LATISSE®** in clinical practice: burning sensation (eyelid), erythema periorbital, eye swelling, eyelid irritation, eyelid edema, eyelid pruritus, iris hyperpigmentation, lacrimation increased, madarosis and trichorrhexis (temporary loss of a few eyelashes to loss of sections of eyelashes, and temporary eyelash breakage, respectively), rash (including macular, erythematous, and pruritic limited to the eyelids and periorbital region), skin discoloration (periorbital), and vision blurred.

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.

Please click here for the full Prescribing Information for LATISSE®.

LUMIGAN® (bimatoprost ophthalmic solution) 0.01% Important Information

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

Important Safety Information

Warnings and Precautions
Pigmentation: Bimatoprost ophthalmic solution has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes. Pigmentation is expected to increase as long as bimatoprost is administered. After discontinuation of bimatoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the periorbital 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.

Intraocular Inflammation: LUMIGAN® 0.01% should be used with caution in patients with active intraocular inflammation (eg, uveitis) because the inflammation may be exacerbated.

Macular Edema: Macular edema, including cystoid macular edema, has been reported during treatment with bimatoprost ophthalmic solution. LUMIGAN® 0.01% 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.

Angle-Closure, Inflammatory, or Neovascular Glaucoma: LUMIGAN® 0.01% has not been evaluated for the treatment of angle-closure, inflammatory, or neovascular glaucoma.

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

Adverse Reactions
In clinical studies with bimatoprost ophthalmic solution (0.01%), the most common adverse event was conjunctival hyperemia (range 25%-45%). Approximately 0.5% to 3% of patients discontinued therapy due to conjunctival hyperemia with 0.01% bimatoprost ophthalmic solution. Other common events (> 10%) included growth of eyelashes and ocular pruritus.

Use in Specific Populations
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.

Please click here for the full Prescribing Information for LUMIGAN®.

RESTASIS® (cyclosporine ophthalmic emulsion) 0.05% Important Information

Indication and Usage
RESTASIS® (cyclosporine ophthalmic emulsion) 0.05% is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Important Safety Information

Contraindications
RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

Warnings and Precautions
Potential for Eye Injury and Contamination: To avoid the potential for eye injury and contamination, individuals prescribed RESTASIS® should not touch the vial tip to their eye or other surfaces.

Use With Contact Lenses: RESTASIS® should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion.

Adverse Reactions
In clinical trials, the most common adverse reaction following the use of RESTASIS® was ocular burning (upon instillation)—17%. Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Please click here for the full Prescribing Information for RESTASIS®.

ZYMAXID® (gatifloxacin ophthalmic solution) 0.5% Important Information

INDICATION
ZYMAXID® (gatifloxacin ophthalmic solution) 0.5% is a topical fluoroquinolone anti-infective indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: *Haemophilus influenzae*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus mitis* group,* *Streptococcus oralis,** and *Streptococcus pneumoniae*.

*Efficacy for this organism was studied in fewer than 10 infections.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS
ZYMAXID® solution should not be introduced directly into the anterior chamber of the eye. As with other anti-infectives, prolonged use of ZYMAXID® may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis or during the course of therapy with ZYMAXID®.

ADVERSE REACTIONS
The most frequently reported adverse reactions occurring in ≥ 1% of patients in the gatifloxacin study population (N = 717) were: worsening of the conjunctivitis, eye irritation, dysgeusia, and eye pain. Additional adverse events reported with other formulations of gatifloxacin ophthalmic solution include chemosis, conjunctival hemorrhage, dry eye, eye discharge, eyelid edema, headache, increased lacrimation, keratitis, papillary conjunctivitis, and reduced visual acuity.

Please click here for the full Prescribing Information for ZYMAXID®.