REMEMBER THE GREEN BOTTLE

Use ALPHAGAN® P 0.1%
Every Day, the Right Way

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.

Please see additional Important Safety Information inside.

A medication diary and helpful tips for using your eyedrops
Remember to use ALPHAGAN® P 0.1% every day as directed

Use these tips to help you remember to use your eyedrops:

- Set a daily clock or watch alarm that can remind you to use your eyedrops
- Associate using your eyedrops with other daily routines you’ve established for yourself, such as brushing your teeth
- Ask a friend or family member to remind you when it’s time to use your eyedrops
- Keep this medication diary handy as a reminder to take and track each dose

Use ALPHAGAN® P 0.1% the right way

Administering your eyedrops

1. Wash your hands. Tilt your head back so you are looking at the ceiling.*
2. Gently pull down your lower eyelid with your index finger, forming a pocket.
3. Gently squeeze 1 drop of medication into the pocket. Do not touch the bottle tip to your eye, your fingers, or anything else.
4. Close your eyes and lightly press your fingers on the inside corners of your eyes.
5. Carefully blot away any excess liquid that may be on the skin around your eye.

*With certain glaucoma eyedrops, first you will need to remove your contact lenses, if you wear them. Wait 15 minutes after using your eyedrops before you put your contact lenses back into your eyes.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Potentiation of Vascular Insufficiency: ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% or 0.15% 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.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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.

Please see additional Important Safety Information on the following pages.
Ensure you get the GREEN BOTTLE

Your doctor specifically prescribed ALPHAGAN® P 0.1%

- ALPHAGAN® P 0.1% is specifically formulated to contain a lower concentration of brimonidine (the active drug) with the same eye pressure-lowering effects as original ALPHAGAN® 0.2%¹
- In clinical trials, ALPHAGAN® P 0.1% had fewer patients discontinue treatment due to side effects than ALPHAGAN® 0.2% (8.8% of 215 patients compared to 15.1% of 218 patients)¹

Save with ALPHAGAN® P 0.1%

- Visit www.AlphaganP.com for savings up to $25 and more product information
- Ask your doctor to prescribe the largest covered bottle size. It may save on your monthly co-pays
- Ask your doctor or eye care technician about additional savings programs available at the office

IMPORTANT SAFETY INFORMATION (continued)

DRUG INTERACTIONS

**Antihypertensives/Cardiac Glycosides:** Because ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% or 0.15% 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 (brimonidine tartrate ophthalmic solution) 0.1% or 0.15% 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.

Please see additional Important Safety Information on back cover.

Check your prescription at the pharmacy to ensure you get the GREEN BOTTLE—ALPHAGAN® P 0.1%

Remember, there is no FDA-approved generic formulation for ALPHAGAN® P 0.1%²

Ask your doctor to prescribe the largest bottle size of ALPHAGAN® P 0.1% covered under your insurance plan—you could save on your monthly co-pays
Tracking each dose of **ALPHAGAN® P 0.1%**

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- PM

**Medication 2**

- AM
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**Medication 3**

- AM
- midday
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Tracking each dose of **ALPHAGAN® P 0.1%**

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Notes
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Please see the Indication and Important Safety Information on pages 1 to 5 and on the back cover.
## Tracking each dose of ALPHAGAN® P 0.1%

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Please see the Indication and Important Safety Information on pages 1 to 5 and on the back cover.
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.

Please see additional Important Safety Information inside.

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 see the Indication and additional Important Safety Information on pages 1 to 5.

Please see accompanying full Prescribing Information.
IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

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Please see the Indication and additional Important Safety Information on pages 1 to 5.

Please see accompanying full Prescribing Information.
5.3 Contamination of Topical Ophthalmic Products After Use

In clinical studies, caution should be exercised in treating patients with severe cardiovascular disease. Although brimonidine tartrate ophthalmic solution had minimal effect on the blood pressure of patients with severe cardiovascular disease, such as Raynaud's phenomenon, orthostatic hypotension, or thromboangiitis obliterans, ALPHAGAN is contraindicated in patients who have exhibited a hypersensitivity reaction to any component of this medication in the past.

5 WARNINGS AND PRECAUTIONS

The following reactions were reported in less than 1% of subjects: corneal erosion, hordeolum, nasal irritation, eye discharge, eye pain, eyelid edema, eyelid erythema, fatigue, flu syndrome, follicular conjunctivitis, blurred vision, cataract, conjunctival edema, conjunctival hemorrhage, conjunctivitis, cough, dizziness, dyspnea, dyspepsia, epiphora, eye discharge, eye dryness, eye irritation, eye pain, eyelid edema, eyelid erythema, fatigue, flu syndrome, follicular conjunctivitis, foreign body sensation, gastrointestinal disorder, headache, hypercholesterolemia, hypotension, infection (primarily cold and respiratory infections), insomnia, keratitis, lid disorder, pharyngitis, photophobia, rash, rhinitis, sinus infection, sinusitis, somnolence, stinging, superficial punctate keratopathy, tearing, visual field defect, vitreous detachment, vitreous disorder, vitreous floaters, and worsened visual acuity. The following reactions were reported in less than 1% of subjects: corneal erosion, hordeolum, nasal dryness, and taste perversion.

6.2 Postmarketing Experience

The following reactions have been identified during postmarketing use of brimonidine tartrate ophthalmic solutions in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to brimonidine tartrate ophthalmic solutions, or a combination of these factors, include: bradycardia, depression, hypersensitivity, iritis, keratoconjunctivitis sicca, miosis, myopia, skin reactions (including erythema, eye pain, rash), vasodilatation, syncope, and tachycardia. Apnea, bradycardia, coma, hypotension, hypertension, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported in infants receiving brimonidine tartrate ophthalmic solutions.

7 DRUG INTERACTIONS

7.1 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.

7.2 CNS Depressants

Use with CNS depressants may result in an additive or potentiating effect.

7.3 Tricyclic Antidepressants

Tricyclic antidepressants may potentially blunt the hypotensive effect of systemic clonidine.

7.4 Monoamine Oxidase Inhibitors

Monoamine oxidase inhibitors may result in increased hypotension.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 09/2013
7.2 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.

7.3 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.

7.4 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 hypertension. Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B. Teratogenicity studies have been performed in animals. Brimonidine tartrate was not teratogenic when given orally during gestation days 6 through 15 in rats and days 6 through 18 in rabbits. The highest doses of brimonidine tartrate in rats (2.5 mg/kg/day) and rabbits (0.5 mg/kg/day) resulted in UCB exposure values 360- and 20-fold higher, or 260- and 15-fold higher, respectively, than similar values estimated in humans treated with ALPHAGAN® P 0.1% or 0.15%, 1 drop in both eyes three times daily.

There are no adequate and well-controlled studies in pregnant women; however, in animal studies, brimonidine crossed the placenta and entered into the fetal circulation to a limited extent. Because animal reproduction studies are not always predictive of human response, ALPHAGAN® P should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

8.2 Nursing Mothers

It is not known whether brimonidine tartrate is excreted in human milk. Although in animal studies, brimonidine tartrate has been shown to be excreted in breast milk. Because of the potential for serious adverse reactions from ALPHAGAN® P in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

ALPHAGAN® P is contraindicated in children under the age of 2 years (see CONTRAINDICATIONS, 4.1). During postmarketing surveillance, apnea, bradycardia, coma, hypotension, hypothermia, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported in infants receiving brimonidine. The safety and effectiveness of brimonidine tartrate have not been studied in children below the age of 2 years.

In a well-controlled clinical study conducted in pediatric glaucoma patients (ages 2 to 7 years) the most commonly observed adverse reactions with brimonidine tartrate ophthalmic solution 0.2% dosed three times daily were somnolence (50-83% in patients ages 2 to 6 years) and decreased alertness. In pediatric patients 7 years of age (20 kg), somnolence appears to occur less frequently (25%). Approximately 16% of patients on brimonidine tartrate ophthalmic solution discontinued from the study due to somnolence.

8.5 Geriatric Use

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

8.6 Special Populations

ALPHAGAN® P has not been studied in patients with hepatic impairment. ALPHAGAN® P has not been studied in patients with renal impairment. The effect of dialysis on brimonidine pharmacokinetics in patients with renal failure is not known.

10 OVERDOSAGE

Very limited information exists on accidental ingestion of brimonidine or by accidental oral ingestion (see NOT FOR ORAL USE). Very limited information exists on accidental ingestion of brimonidine in adults; the only adverse effect reported in neonates, infants, and children receiving brimonidine is hypotonicity, lethargy, pallor, respiratory depression, and somnolence in infants receiving brimonidine. The safety and effectiveness of brimonidine tartrate have not been studied in patients with renal impairment. The effect of dialysis on brimonidine pharmacokinetics in patients with renal failure is not known.

11 DESCRIPTION

ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% or 0.15%, sterile, is a relatively selective alpha-2 adrenergic receptor agonist (topical intraocular pressure lowering agent).

The structural formula of brimonidine tartrate is:

Br

N

H

NH

 HO

CH

CH

N

COOH

In solution, ALPHAGAN® P (brimonidine tartrate ophthalmic solution) has a clear, greenish-yellow color. It has an osmolality of 250-350 mOsmol/kg and a pH of 7.4-8.0 (0.1%) or 6.9-7.4 (0.15%).

Brimonidine tartrate appears as an off-white to pale-yellow powder and is soluble in both water (0.6 mg/mL) and in the product vehicle (1.4 mg/mL) at pH 7.7.

Each mL of ALPHAGAN® P contains the active ingredient brimonidine tartrate 0.1% (1 mg/mL) or 0.15% (1.5 mg/mL) with the inactive ingredients sodium carboxymethylcellulose; sodium borate; boric acid; sodium chloride; potassium chloride; calcium chloride; magnesium chloride; PURIT® 0.005% (0.05 mg/mL) as a preservative; purified water; and hydrochloric acid and/or sodium hydroxide to adjust pH.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

ALPHAGAN® P is a relatively selective alpha-2 adrenergic receptor agonist with a peak ocular hypotensive effect occurring at two hours post-dosing.

Fluorophotometric studies in animals and humans suggest that brimonidine tartrate has a dual mechanism of action by reducing aqueous humor production and increasing uveoscleral outflow.

12.2 Pharmacokinetics

Absorption

After ocular administration of either a 0.1% or 0.2% solution, plasma concentrations peaked within 0.5 to 2.5 hours and declined with a systemic half-life of approximately 2 hours.

Distribution

The protein binding of brimonidine has not been studied.

Metabolism

In humans, brimonidine is extensively metabolized by the liver.

Excetration

Urinary excretion is the major route of elimination of brimonidine and its metabolites. Approximately 87% of an orally-administered radioactive dose of brimonidine was eliminated within 120 hours, with 74% found in the urine.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No compound-related carcinogenic effects were observed in either mice or rats following a 21-month and 24-month study, respectively. In these studies, dietary administration of brimonidine tartrate at doses up to 2.5 mg/kg/day in mice and 1 mg/kg/day in rats achieved 120 and 120 times or 90 and 80 times, respectively, the plasma Cmax drug concentration in humans treated with one drop of ALPHAGAN® P 0.1% or 0.15% into both eyes three times per day, the recommended dosing for the agent.

Brimonidine tartrate was not mutagenic or clastogenic in a series of in vitro and in vivo studies including the Ames bacterial reversion test, chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells, and three in vivo studies in CD-1 mice: a host-mediated assay, cytogenetic study, and dominant lethal assay. Reproduction and fertility studies in rats with brimonidine tartrate demonstrated no adverse effect on male or female fertility at doses which achieve up to approximately 125 and 90 times the systemic exposure following the maximum recommended human ophthalmic dose of ALPHAGAN® P 0.1% or 0.15%, respectively.

14 CLINICAL STUDIES

Elevated IOP presents a major risk factor in glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss. Brimonidine tartrate has the action of lowering intraocular pressure with minimal effect on cardiovascular and pulmonary parameters.

Clinical studies were conducted to evaluate the safety, efficacy, and acceptability of ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.15% compared with ALPHAGAN® P administered three times daily in patients with open-angle glaucoma or ocular hypertension. Those results indicated that ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.15% is comparable in IOP lowering effect to ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.2%, and effectively lowers IOP in patients with open-angle glaucoma or ocular hypertension by approximately 2-6 mmHg.

A clinical study was conducted to evaluate the safety, efficacy, and acceptability of ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% compared with ALPHAGAN® P administered three-times-daily in patients with open-angle glaucoma or ocular hypertension. Those results indicated that ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.1% is equivalent in IOP lowering effect to ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.2%, and effectively lowers IOP in patients with open-angle glaucoma or ocular hypertension by approximately 2-6 mmHg.

16 HOW SUPPLIED/STORAGE AND HANDLING

ALPHAGAN® P is supplied sterile, in teal opaque plastic LDPE bottles and tips, with purple high impact poly styrene (HIPS) caps as follows:

- 0.1%: 5 mL in 10 mL bottle NDC 0023-9321-05
  10 mL in 10 mL bottle NDC 0023-9321-10
  15 mL in 15 mL bottle NDC 0023-9321-15
- 0.15%: 5 mL in 10 mL bottle NDC 0023-9177-05
  10 mL in 10 mL bottle NDC 0023-9177-10
  15 mL in 15 mL bottle NDC 0023-9177-15


17 PATIENT COUNSELING INFORMATION

Patients should be instructed that ocular solutions, if handled improperly or if the tip of the dispensing container contacts the eye or surrounding structures, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions (see WARNINGS AND PRECAUTIONS, 5.9). Always replace the cap after using. If solution changes color or becomes cloudy, do not use. Do not use the product after the expiration date marked on the bottle.

Patients also should be advised that if they have ocular surgery or develop an intercurrent ocular condition (e.g., trauma or infection), they should immediately seek their physician’s advice concerning the continued use of the present multidose container.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

As with other similar medications, ALPHAGAN® P may cause fatigue and/or drowsiness in some patients. Patients who engage in hazardous activities should be cautioned of the potential for a decrease in mental alertness.

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Made in the U.S.A.

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