

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrALPHAGAN®

brimonidine tartrate ophthalmic solution

Read this carefully before you start taking **ALPHAGAN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ALPHAGAN**.

What is ALPHAGAN used for?

- ALPHAGAN eye drops are used to reduce high pressure in the eye in adult patients with:
 - chronic open-angle glaucoma (a condition that causes damage to the optic nerve of your eye).
 - ocular hypertension (high pressure in the eye).

How does ALPHAGAN work?

ALPHAGAN is an eye drop solution that reduces the amount of fluid flowing into the eye and increases the amount of fluid flowing out of the eye. This reduces the pressure inside the eye. It contains a preservative.

What are the ingredients in ALPHAGAN?

Medicinal ingredient: brimonidine tartrate

Non-medicinal ingredients: 0.005% w/v benzalkonium chloride as preservative, citric acid, polyvinyl alcohol, purified water, sodium chloride and sodium citrate. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

ALPHAGAN comes in the following dosage forms:

Ophthalmic solution, 0.2% w/v

Do not use ALPHAGAN if:

- you are allergic to brimonidine tartrate, any of the other ingredients, or to any component of the ALPHAGAN container (See **What are the ingredients in ALPHAGAN?**).
- you are receiving monoamine oxidase (MAO) inhibitor therapy (used to treat depression).
- ALPHAGAN should not be used in children under the age of 2 years.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALPHAGAN. Talk about any health conditions or problems you may have, including if you:

- are breastfeeding a baby, pregnant or intend to become pregnant.
- have or have had heart and blood vessel problems.
- have or have had circulation problems which make the toes and fingers numb and pale. This is called Raynaud's phenomenon.
- have or have had low blood pressure.
- are taking or intend to take other medicines. This is particularly important if you are taking medicine to lower blood pressure or to treat heart disease.
- have or have had liver problems.
- have or have had kidney problems.
- have or have had depression.
- have or have had eye surgery.
- develop an eye condition due to infection or injury.
- wear contact lenses. The preservative in ALPHAGAN may be absorbed by soft (hydrophilic) contact lenses. Lenses should be removed before using ALPHAGAN and kept out for 15 minutes after use.

Other warnings you should know about:

Immediately tell your healthcare professional if you:

- have or have had eye surgery.
- develop an eye condition due to infection or injury.

Ask your healthcare professional for their advice on whether you should continue to use the ALPHAGAN bottle.

Driving and using machines:

ALPHAGAN may cause drowsiness and fatigue or blurred vision. Do not drive, use heavy machinery or participate in dangerous activities or activities requiring you to be alert, until these conditions have passed.

Children (2-18 years of age): The use of ALPHAGAN is currently **not recommended** in children, as several serious side effects have been reported with the use of brimonidine tartrate ophthalmic solution 0.2% in children.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ALPHAGAN:

- antihypertensives (medicines used to treat high blood pressure).
- cardiac glycoside (medicines used to treat heart failure and irregular heartbeats).

- central nervous system depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics).
- clonidine (medicine used to treat high blood pressure and attention deficit hyperactivity disorder [ADHD]).
- heart and blood pressure medications such as alpha-agonists.
- medication such as beta-blockers (ophthalmic and/or systemic, used to treat high blood pressure and irregular heartbeats).
- tricyclic antidepressants (medicines used to treat depression).

How to take ALPHAGAN:

- You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.
- ALPHAGAN contains a preservative called benzalkonium chloride which may change the colour of soft contact lenses. If you wear contact lenses, remove them before using ALPHAGAN. Wait 15 minutes after using the drops before you put your lenses back in.
- Always use ALPHAGAN exactly as your healthcare professional has told you to.
- If you use ALPHAGAN with other eye drops, wait at least five minutes between putting in ALPHAGAN and the other drops.
- To help prevent infections, do not let the tip of the bottle touch your eye or anything else. Put the cap back on and close the bottle immediately after you have used it.

Follow the steps below to help you use ALPHAGAN properly:

1. Wash your hands. Tilt your head back and look at the ceiling. (See image 1)
2. Gently pull down the lower eyelid to create a small pocket. (See image 2)
3. Turn the bottle upside down and squeeze it gently to release one drop into the eyelid pocket. If a drop misses your eye, try again. (See image 3)
4. Let go of the lower lid and close your eye for 30 seconds. (See image 4)



5. Repeat steps 1 – 4 in the other eye if both eyes need treatment.

Usual dose:

Following the instructions for use above, put one drop of ALPHAGAN in the affected eye, twice daily, about 12 hours apart.

Overdose:

If you accidentally use too many drops, just go back to your regular twice a day dosing the next day. If you have any concerns, talk to your doctor or pharmacist.

If you think you, or a person you are caring for, have taken too much ALPHAGAN contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to apply your eye drops at your normal time, simply apply them as soon as you remember. Then go back to the original schedule as directed by your healthcare professional. Do not try to catch up on missed drops by applying more than one dose at a time.

What are possible side effects from using ALPHAGAN?

These are not all the possible side effects you may have when taking ALPHAGAN. If you experience any side effects not listed here, tell your healthcare professional.

- abnormal taste
- abnormal vision
- allergic reaction
- blurred vision
- cold-like symptoms
- constriction of eye's pupil
- depression
- dizziness
- drowsiness
- dry mouth
- dry nose
- erosion on the surface of the eye and staining
- eye discharge
- eye irritation
- eye dryness
- fainting
- general weakness
- headache
- irritation of the eye (eye redness, burning, stinging, a feeling of something in the eye)
- itchy eyes
- local irritation (inflammation and swelling of the eyelid, pain and tearing)
- sensitivity to light
- skin reaction
- symptoms involving the stomach and digestion
- swelling of eye's pupil
- tiredness or sleepiness

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Bradycardia (abnormally slow heartbeat)		✓	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		✓	
Tachycardia (abnormally fast heartbeat): dizziness, light headedness, shortness of breath, racing heart		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

ALPHAGAN should be stored in the original container at 15 to 25°C. Discard unused solution at the end of treatment.

Do not use the drops after the expiry date (marked “Exp”) on the bottle and the box.

Keep out of reach and sight of children.

If you want more information about ALPHAGAN:

- Talk to your healthcare professional.

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.abbvie.ca or by calling 1-888-704-8271.

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