

ALPHAGAN® P OPHTHALMIC SOLUTION

brimonidine tartrate (0.1% w/v)

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What **ALPHAGAN® P 0.1%** is used for

ALPHAGAN® P 0.1% is used to lower pressure in the eye of people with glaucoma or high pressure in the eye.

How **ALPHAGAN® P 0.1%** works

ALPHAGAN® P 0.1% 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.

Before you use **ALPHAGAN® P 0.1%**

- When you must not use it

Do not use **ALPHAGAN® P 0.1%**:

- If you are allergic (hypersensitive to brimonidine tartrate, or any of the other ingredients of **ALPHAGAN® P 0.1%**. (for a full list of ingredients, see section "PRODUCT DESCRIPTION").
- If you are taking monoamine oxidase antidepressant medication (MAO)
- For neonates and infants (children under the age of 2 years)

If you are not sure whether you should start using **ALPHAGAN® P 0.1%**, talk to your doctor.

- Pregnancy and lactation

Discuss with your doctor the possible risks and benefits of using **ALPHAGAN® P 0.1%** during pregnancy.

Discuss with your doctor the possible risks and benefits of using **ALPHAGAN® P 0.1%** when breast-feeding.

- Children

The safe and effective use of **ALPHAGAN® P 0.1%** in children under the age of 2 has not been established.

- Before you start use it

Tell your doctor if:

1. You have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - Liver or kidney disease
 - Severe, uncontrolled heart disease, poor blood flow to the heart or recurring inflammation and clotting of small and medium blood vessels of the hands and feet.
 - Poor blood flow to the brain
 - Depression
 - Raynaud's phenomenon. This is a condition marked by numbness, tingling and colour change (white, blue, then red in the fingers when they are exposed to cold or stress.
 - Dizziness on standing up, especially when getting up from a sitting or lying position.
3. You are consuming alcohol.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that

you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and **ALPHAGAN® P 0.1%** may interfere with each other. These include:

- Medicines that cause sleepiness or prevent pain (barbiturates, opiates, sedatives, or anesthetics)
- Medicines that reduce blood pressure (alpha-agonists, beta-blockers)
- Medicines for heart problem (cardiac glycosides)
- Tricyclic antidepressants

These medicines may be affected by **ALPHAGAN® P 0.1%**, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using **ALPHAGAN® P 0.1%**.

If more than one eye drops/ointment is to be used, the different medicines should be instilled at least 5 minutes apart.

How to use **ALPHAGAN® P 0.1%**

- How much to use

The recommended dose is one drop of **ALPHAGAN® P 0.1%** in the affected eye(s) three times daily, approximately 8 hours apart.

- Instructions for use

You may find it easier to put drops in your eye while you are sitting or lying down.

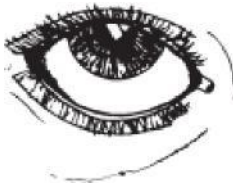
To open a new bottle of **ALPHAGAN® P 0.1%**, first tear off the protective seal from the bottle.

The contents are sterile if seal is intact. The seal will break and you can pull it off and then throw it away.

1. Wash your hands well with soap and water.
2. Shake the bottle gently.
3. Remove the cap.
4. Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
5. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.



6. Tilt your head back and look up.



7. Put the tip of the bottle close to your lower eyelid. Do not let the tip touch your eye.
8. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.



9. Close your eye. Do not blink or rub your eye.



10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.
11. Replace the cap, sealing it tightly.
12. Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid eye injury or contaminating the eye drops. Contaminated eye drops may give you an eye infection.

ALPHAGAN® P 0.1% are for use in eyes only.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using **ALPHAGAN® P 0.1%** for as long as your doctor prescribes.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

- If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

Low blood pressure has been reported resulting from accidental ingestion. Symptoms of overdose similar to the side effects stated under 'Children Use' have been reported in neonates, infants and children.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have swallowed any or all of the contents of a bottle of **ALPHAGAN® P 0.1%**. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Have your eye pressure checked when your eye specialist says, to make sure **ALPHAGAN® P 0.1%** are working.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of **ALPHAGAN® P 0.1%** because of possible contamination of the old one, or may advise you to stop your treatment with **ALPHAGAN® P 0.1%**.

If you become pregnant while using **ALPHAGAN® P 0.1%**, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using **ALPHAGAN® P 0.1%**.

- Things you must not do

Do not give **ALPHAGAN® P 0.1%** to anyone else, even if they have the same condition as you.

Do not stop using **ALPHAGAN® P 0.1%** without first talking to your doctor. If you stop using your eye

drops, your eye pressures may rise again and damage to your eye may occur.

- Things to be careful of

Driving and using machines:

Be careful driving or operating machinery until you know how **ALPHAGAN® P 0.1%** affect you. **ALPHAGAN® P 0.1%** generally do not cause any problems with your ability to drive a car or operate machinery.

However, **ALPHAGAN® P 0.1%** may cause blurred vision / dizziness / drowsiness / tiredness in some people. Make sure you know how you react to **ALPHAGAN® P 0.1%**, or that your vision is clear before driving a car or operating machinery.

Side effects

Like all medicines, **ALPHAGAN® P 0.1%** can cause side effects, although not everybody gets them. None of the side effects are likely to be serious; most side effects are likely to be mild and only affect the eye.

Occurs in approximately 10-20% of people:

Eye allergy, red eye, and itchy eyes.

Occurs in in approximately 5-9% of the people:

Development of lymph follicles in the eyes.

Occurs in approximately 1-4% of people:

Feeling weak, burning sensation in the eye, eye inflammation, eyelid redness, eye pain, foreign body sensation, eye dryness, itchy eyes, mouth dryness and sleepiness, and superficial punctate keratitis.

The following side effects have been identified during post-marketing use of **ALPHAGAN® P 0.1%** in clinical practice:

Increase in tear production, blurred vision, dizziness and headache.

Children use:

Temporary cessation of breathing, slow heartbeat, loss of consciousness, low blood pressure, low body temperature, decreased muscle strength, paleness, difficult or slow breathing, and sleepiness.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -* Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ALPHAGAN® P 0.1%

- Storage

Keep out of the reach and sight of children.

Do not use **ALPHAGAN® P 0.1%** after the expiry date which is stated on the bottle label and the bottom of the carton after EXP.

Do not leave the lid off the bottle for any length of time to avoid contaminating the eye drops.

Keep your eye drops in a cool place where the temperature stays below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

ALPHAGAN® P 0.1% is a clear, greenish-yellow color solution in a

plastic bottle with a purple cap in 5 mL in 10 mL bottle pack size.

- Ingredients

- Active ingredient
brimonidine tartrate

- Inactive ingredients
Purite, carmellose sodium, boric acid, sodium borate decahydrate, sodium chloride, potassium chloride, calcium chloride, magnesium chloride, hydrochloric acid / sodium hydroxide and purified water.

- MAL number:

MAL20096002ARZ

Manufacturer

Allergan Sales, LLC
Waco, Texas, U.S.A.

Product Registration Holder

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