

ALPHAGAN[®] EYE DROPS

[brimonidine tartrate]

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ALPHAGAN[®] eye drops, including how to use the eye drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using ALPHAGAN[®] eye drops against the benefits they expect it will have for you.

If you have any concerns about using/taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ALPHAGAN[®] eye drops are used for

ALPHAGAN[®] eye drops are used to lower raised pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal

eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

ALPHAGAN[®] eye drops are used, either alone or in combination with other eye drops/medicines, to lower raised pressure within your eye(s).

Mechanism of action:
ALPHAGAN[®] eye drops lower the pressure in the eye by decreasing the fluid produced and helping the flow of fluid out of the eye chamber.

Your doctor may have prescribed ALPHAGAN[®] eye drops for another reason. Ask your doctor if you have any questions about why ALPHAGAN[®] eye drops have been prescribed for you.

Before you use ALPHAGAN[®] eye drops

When you must not use it

Do not use ALPHAGAN eye drops if:

1. you have an allergy to ALPHAGAN[®] eye drops or any of the ingredients listed at the end of this leaflet,
2. you are taking monoamine oxidase antidepressant medication.

Check with your doctor if:

1. you are taking other medication for depression, or
2. you have liver or kidney disease, or
3. you have a severe, uncontrolled heart condition, or
4. you are breast-feeding. Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

Do not use ALPHAGAN[®] eye drops if:

- the seal around the cap is broken,
- the bottle/packaging shows signs of tampering,
- the product does not look quite right,
- the expiry date on the bottle or carton has passed.

If you use this medicine after the expiry date has passed, it may not work.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in ALPHAGAN[®] eye drops (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used ALPHAGAN[®] eye drops.

If you are not sure whether you should start using ALPHAGAN[®] eye drops, talk to your doctor.

Safety and effectiveness in paediatric patients have not been established.

Before you start to 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. If you have not told your doctor about any of the above, tell them before you use ALPHAGAN[®] eye drops.
3. you have or have had any medical conditions, especially the following:
 - severe heart disease
 - disease affecting your blood vessels, including Raynaud's phenomenon or fainting.

Like most medicines, ALPHAGAN[®] eye drops are not recommended during pregnancy, unless the benefits outweigh the risk to the baby.

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[®] eye drops may interfere with each other. These include:

- medicines for high blood pressure,
- certain medicines to treat depression, such as monoamine oxidase inhibitors and tricyclics,
- medicines to relieve strong pain or anesthetics,
- any sedative-type medicines, including alcohol and antihistamines
- any sympathomimetic medicines.

Medicines used to treat asthma, severe headaches or coughs and colds may belong in the sympathomimetic group. These medicines may be affected by ALPHAGAN[®] eye drops, 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[®] eye drops.

How to use ALPHAGAN[®] eye drops

How much to use

The usual dosage of eye drops is one drop in the eye(s) every twelve hours. If you are using more than one eye drop product, wait 5 to 10 minutes before using the second product so that the first eye drop is not washed out by, or interacts with the second.

Your doctor will tell you how many drops you need to use each day. Use ALPHAGAN eye drops only when prescribed by your doctor.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Use ALPHAGAN[®] eye drops every day, at about the same time each day, unless your doctor tells

you otherwise. Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How to use it

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

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

To open a new bottle of ALPHAGAN[®] eye drops, first tear off the protective seal from the bottle. 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.

You may feel a slight burning sensation in the eye shortly after using the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

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

How long to use it

ALPHAGAN[®] eye drops help control your condition but does not cure it. Therefore ALPHAGAN[®] eye drops must be used every day. Continue using ALPHAGAN[®] eye drops for as long as your doctor prescribes.

For some people ALPHAGAN[®] eye drops may have been prescribed for a short time before or after eye surgery.

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/taking 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.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of ALPHAGAN[®] eye drops, immediately telephone your doctor

or Poisons Information Centre (**telephone 13 11 26**) for advice, or go to casualty at your nearest hospital. In New Zealand call the National Poisons Information Centre (**telephone 0800 POISON or 0800 764 766**)

Do this even if there are no signs of discomfort or poisoning.

While you are using ALPHAGAN[®] eye drops

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure ALPHAGAN[®] eye drops 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[®] eye drops because of possible contamination of the old one, or may advise you to stop your treatment with ALPHAGAN[®] eye drops.

If you become pregnant while using ALPHAGAN[®] eye drops 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[®] eye drops.

Things you must not do

Do not give ALPHAGAN[®] eye drops to anyone else, even if they have the same condition as you.

Do not stop using ALPHAGAN[®] eye drops 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

Be careful driving or operating machinery until you know how ALPHAGAN[®] eye drops affect you.

ALPHAGAN[®] eye drops generally do not cause any problems with your ability to drive a car or

operate machinery. However, ALPHAGAN[®] eye drops may cause blurred vision/ dizziness/ drowsiness/ tiredness in some people. Make sure you know how you react to ALPHAGAN[®] eye drops or that your vision is clear before driving a car or operating machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ALPHAGAN[®] eye drops.

ALPHAGAN[®] eye drops help most people with high eye pressure and glaucoma, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- redness and swelling of the eye (s)
- redness and swelling of the eyelids and surrounding area
- discomfort
- watering of the eye(s)
- feeling of something in the eye(s)
- itching
- conjunctivitis (discharge with itching of the eye and crusty eyelids)
- dry eyes
- blurred vision
- irritation of the eye(s)
- burning and stinging of the eye(s)
- excessive sensitivity to bright light
- eye ache/pain
- whitening of the eye(s)

- abnormal vision
- headache
- dizziness
- fatigue/drowsiness
- nasal dryness
- oral dryness
- abnormal taste
- upper respiratory symptoms
- systemic allergic reactions
- gastro-intestinal symptoms
- depression
- weakness

These are usually mild side effects that may occur occasionally.

Tell your doctor immediately if you notice any of the following:

- dizziness and light-headedness, which may be due to low blood pressure,
- fast or irregular heart beat, also called palpitations

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

After using ALPHAGAN[®] eye drops

Storage

Keep your eye drops in a cool place where the temperature stays below 25°C. Do not freeze the eye drops.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Do not carry the eye drops in pockets of your clothes. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave the top/lid off the bottle for any length of time to

avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

The eye drops come in a 5 mL sterile plastic bottle.

Ingredients

Active ingredient: brimonidine tartrate.

Inactive ingredients:

benzalkonium chloride, polyvinyl alcohol, sodium chloride, sodium citrate, citric acid, and purified water.

Manufacturer/Supplier

Allergan Australia Pty Ltd
810 Pacific Highway
Gordon, NSW 2072
Allergan New Zealand Ltd,
Auckland

ARTG number: AUST R 60297

For more information about glaucoma, contact Glaucoma Australia on 1800 500 880 or Glaucoma New Zealand on 09 373 8779.

Date of preparation: April 2008

®Marks owned by Allergan, Inc