

# ALPHAGAN®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using ALPHAGAN®?

ALPHAGAN® eye drops contains the active ingredient brimonidine tartrate. ALPHAGAN® is used to lower raised pressure in the eye(s) and to treat glaucoma.

For more information, see Section [1. Why am I using ALPHAGAN®?](#) in the full CMI.

### 2. What should I know before I use ALPHAGAN®?

Check the list of ingredients at the end of the CMI. Do not use ALPHAGAN® eye drops if you have ever had an allergic reaction to any of them.

**Talk to your doctor before you use this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ALPHAGAN®?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with ALPHAGAN® eye drops and affect how it works, or ALPHAGAN® may interfere with other medicines and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use ALPHAGAN® ?**

Your doctor will tell you how many drops you need to use each day. The usual dosage of eye drops is one drop in the eye(s) two times a day. More instructions can be found in Section [4. How do I use ALPHAGAN® ?](#) in the full CMI.

### **5. What should I know while using ALPHAGAN® ?**

#### **Things you should do**

- Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using ALPHAGAN® eye drops
- Continue to use ALPHAGAN® every day

	<p>unless your doctor tells you to stop</p> <ul style="list-style-type: none"> <li>• Keep all your appointments so your condition can be checked.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not touch the dropper tip against your eye, eye lid or any surface</li> <li>• Do not stop using ALPHAGAN® eye drops without checking with your doctor.</li> <li>• Do not use ALPHAGAN® drops while you are wearing soft contact lenses.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Wait for your vision to clear after using ALPHAGAN® eye drops before you drive or use machines.</li> <li>• Do not drive or operate machines if you feel tired or drowsy while using ALPHAGAN® .</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• ALPHAGAN® eye drops may cause drowsiness and this can be made</li> </ul>

	worse by drinking alcohol.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Follow all instructions on the carton and bottle label.</li> <li>• Store below 25C, away from moisture, heat, or sunlight.</li> </ul>

For more information, see Section [5. What should I know while using ALPHAGAN ?](#) in the full CMI.

## **6. Are there any side effects?**

The most common side effects reported in the eye include a range of ocular symptoms such as redness of the eyes or eyelids, eyelid swelling, burning, stinging, and feeling something in the eye(s). Other common side effects include dry mouth, headache, and fatigue/drowsiness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ALPHAGAN® (al-fah gan)

**Active ingredient:** brimonidine tartrate (brim-on-id-deen tar-trate)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using ALPHAGAN® eye drops . **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ALPHAGAN® .**

**Where to find information in this leaflet:**

- [1. Why am I using ALPHAGAN® ?](#)
- [2. What should I know before I use ALPHAGAN® ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ALPHAGAN® ?](#)
- [5. What should I know while using ALPHAGAN ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ALPHAGAN® ?

**ALPHAGAN® contains the active ingredient brimonidine tartrate.**

**ALPHAGAN® is 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.

Eye 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 lower the pressure in the eye by decreasing the fluid produced and helping the flow of fluid out of the eye chamber.

Although ALPHAGAN eye drops help control your glaucoma, it does not cure it.

ALPHAGAN eye drops are used, either alone or together with other eye drops/medicines, to lower raised pressure within your eye(s).

ALPHAGAN belongs to a family of medicines called alpha-adrenergic agonists.

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.

## **2. What should I know before I use ALPHAGAN® ?**

### **Warnings**

#### **Do not use ALPHAGAN® if:**

- You are allergic to brimonidine tartrate, or any of the ingredients listed at the end of this leaflet.
- You are taking monoamine oxidase antidepressant medication
- Do not use in children younger than 2 years of age.
- 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.

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



### **Check with your doctor if you:**

Have had an allergy to any other medicine or any other medicines or any other foods, preservatives, or dyes.

Have or have had any medical conditions, especially the following:

- liver or kidney disease
- severe, uncontrolled heart disease or poor blood flow to the heart
- poor blood flow to the brain
- depression
- Raynaud's syndrome. This is a condition marked by numbness, tingling and colour change (white, blue, then red) in the fingers when they are exposed to cold
- Dizziness on standing up, especially when getting up from a sitting or lying position

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed. Your doctor will discuss the possible risks

and benefits of using ALPHAGAN® when pregnant or breast-feeding.

## Use in children

- Children 2 years of age and above, especially those weighing  $\leq$  20 kg, should be treated with caution and closely monitored.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with ALPHAGAN® and affect how it works, while ALPHAGAN® may affect how other medicines work.**

**Do not take ALPHAGAN® if you are taking any of the following medicines:**

- specific medicines to treat depression called "monoamine oxidase (MAO) inhibitors", such as phenelzine, tranylcypromine

**Medicines where ALPHAGAN® may increase their effect include:**

- barbiturates, traditionally used to treat epilepsy (seizures, fits)
- medicines used to relieve strong pain (such as opiates)
- medicines used to calm or put you to sleep

- anesthetics
- medicines used to treat high blood pressure, including beta blockers
- certain medicines used to treat asthma, severe headaches or coughs and colds, known as sympathomimetics.
- alcohol

Other medicines that are broken down by the liver may interact with ALPHAGAN® .

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALPHAGAN® .**

## **4. How do I use ALPHAGAN® ?**

### **How much to use**

- Your doctor will tell you how many drops you need to use each day.
- The usual dosage of eye drops is one drop in the eye(s) two times a day (approximately every 12 hours).

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

### **When to use ALPHAGAN®**

- 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.

In some instances, ALPHAGAN® needs to be used with other eye drops. Your doctor will let you know which drops, how to use them, and how long to use them.

Wait at least 5 to 10 minutes after using ALPHAGAN® before using other eye drops.

## **How to use ALPHAGAN®**

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 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 or eyelid.
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 or eyelid.
- 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.
- 13 If you wear contact lenses, 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 contaminating the eye drops.

Contaminated eye drops may give you an eye infection.

ALPHAGAN® eye drops are for use in eyes only.

**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.**

## **If you forget to use ALPHAGAN®**

It is important that you use ALPHAGAN® at the same time each day.

**If you forget to use ALPHAGAN® and 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.**

**Do not take a double dose to make up for the dose you missed.**

## **If you use too much ALPHAGAN®**

Immediately rinse your eyes with warm water.

## **If ALPHAGAN® is accidentally swallowed**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there appear to be no signs of discomfort or poisoning.**

## **5. What should I know while using ALPHAGAN® ?**

### **Things you should do**

- Continue to use ALPHAGAN® as instructed by your doctor. ALPHAGAN® helps to control your condition but does not cure it.
- Use all the medication prescribed to treat your eye condition.
- Keep all your doctor's appointments so that your condition can be monitored, and your eye pressure can be checked.
- 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.

### **Call your doctor straight away if you:**

- suspect an eye infection (e.g. redness, discharge, pain)
- become pregnant while using ALPHAGAN® .

Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using ALPHAGAN® .

## **Things you should not do**

- Do not touch the dropper tip against your eye, eyelid or anything else, to avoid contaminating the eye drops.
- Do not stop using ALPHAGAN® without checking with your doctor. Your eye pressure can rise again and may cause damage to your eye.
- 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.

## **Driving or using machines**

- Wait for your vision to clear after using ALPHAGAN® before you drive or use machines.
- Do not drive or operate machines if you feel fatigued or drowsy while using ALPHAGAN® .

## **Drinking alcohol**

ALPHAGAN® may cause drowsiness and this can be made worse by drinking alcohol.

## **Looking after your medicine**

Store below 25°C.

To avoid contamination of the solution, keep container tightly closed. Do not touch the dropper tip to any surface. Contents are sterile if seal is intact.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on windowsills.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

**Discard the bottle 4 weeks after first opening it.**

Write the date on the bottle when you open the eye drops and throw out the 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.

## **Getting rid of any unwanted medicine**

If your doctor advises that you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not open the bottle to use this medicine after the expiry date has passed.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Effects on the eye(s)</b></p> <ul style="list-style-type: none"><li>● redness and swelling of the eye(s), eyelids, and surrounding areas</li><li>● watering of the eye(s)</li><li>● feeling of something in the eye(s)</li><li>● itching</li><li>● conjunctivitis (discharge with itching of the eye and crusty eyelids)</li><li>● dry eyes</li><li>● blurred vision</li><li>● irritation of the eye(s)</li><li>● burning and stinging of the eye(s)</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● excessive sensitivity to bright light</li> <li>● eye ache/pain</li> <li>● whitening of the eye(s)</li> <li>● distorted vision</li> </ul> <p><b>Effects on the body as a whole:</b></p> <ul style="list-style-type: none"> <li>● headache</li> <li>● dizziness</li> <li>● fatigue/drowsiness</li> <li>● nasal dryness</li> <li>● dry mouth</li> <li>● abnormal taste</li> <li>● cold-like symptoms</li> <li>● symptoms involving the stomach and digestion</li> <li>● depression</li> <li>● feeling weak</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop using any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What ALPHAGAN® contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>● Brimonidine tartrate</li></ul>
<b>Preservative</b>	benzalkonium chloride
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● polyvinyl alcohol,</li><li>● sodium chloride,</li><li>● sodium citrate dihydrate,</li><li>● citric acid</li><li>● purified water</li></ul>

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|--|--|
|  | <ul style="list-style-type: none"><li>• and hydrochloric acid and/or sodium hydroxide may be added to adjust pH.</li></ul> |
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**Do not USE this medicine if you are allergic to any of these ingredients.**

## **What ALPHAGAN® looks like**

ALPHAGAN® is a clear, greenish-yellow solution. It is supplied in a plastic dropper bottle containing either 2.5mL or 5 mL of liquid.

(AUST R 60297).

Not all presentations may be marketed.

## **Who distributes ALPHAGAN®?**

ALPHAGAN® is distributed in Australia by:

AbbVie Pty Ltd

Mascot NSW 2020

Australia

Toll-free: 1800 252 224

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