

## ALPHAGAN® EYE DROPS

BRIMONIDINE TARTRATE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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### What is in this leaflet?

1. What Alphagan is and what it is used for
2. Before you use Alphagan
3. How to use Alphagan
4. Possible side effects
5. How to store Alphagan
6. Further information

#### 1. WHAT ALPHAGAN IS AND WHAT IT IS USED FOR

Alphagan is used to reduce pressure within the eye.

It can be used either alone, when beta-blocker eye drops are contraindicated, or with another eye drop, when a single medicine is not enough to lower the increased pressure in the eye, in the treatment of open angle glaucoma or ocular hypertension.

The active ingredient in Alphagan is brimonidine tartrate, which works by reducing pressure within the eyeball.

#### 2. BEFORE YOU USE ALPHAGAN

##### **Do not use Alphagan**

- If you are allergic (hypersensitive) to brimonidine tartrate or any of the other ingredients of Alphagan.
- If you are taking monoamine oxidase (MAO) inhibitors or certain antidepressants. You must inform your doctor if you are taking any antidepressant drug.
- If you are breast-feeding.
- In infants/babies (from birth until 2 years).

##### **Take special care with Alphagan**

Before you take this medicine, tell your doctor:

- If you suffer or have suffered from depression, reduced mental capacity, reduced blood supply to the brain, heart problems, a disturbed blood supply of the limbs or a blood pressure disorder.
- If you have or have had in the past kidney or liver problems.
- If being given to a child between the age of 2 and 12 years because Alphagan is not recommended for use in this age group.

### ***Using other medicines***

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor if you are taking any of the following medicines:

- pain killers, sedatives, opiates, barbiturates or are regularly consuming alcohol.
- anaesthetics.
- to treat a heart condition or to lower blood pressure
- that can affect the metabolism like chlorpromazine, methylphenidate and reserpine
- which work on the same receptor as Alphagan, for example isoprenaline and prazosin
- monoamine oxidase (MAO) inhibitors and other antidepressants
- medicines for any condition, even if unrelated to your eye condition
- or if the dose of any of your current medicines is changed.

These could affect your treatment with Alphagan.

### ***Pregnancy and breast-feeding***

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant or planning to become pregnant.

Alphagan should not be used while breast-feeding.

### ***Driving and using machines***

- Alphagan may cause blurred or abnormal vision. This effect may seem worse at night or in reduced lighting.
- Alphagan may also cause drowsiness or tiredness in some patients.
- If you experience any of these symptoms, do not drive or use machinery until the symptoms are cleared.

### ***Important information about some of the ingredients of ALPHAGAN***

A preservative in Alphagan (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.

Therefore, avoid contact with soft lenses. If you wear soft contact lenses take them out before using these eye drops and then wait 15 minutes after using Alphagan before inserting your lenses.

## ***3. HOW TO USE ALPHAGAN***

Always use Alphagan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### ***Adults***

The usual dose is one drop twice daily in the affected eye(s), approximately 12 hours apart.

### ***Children under 12 years***

Alphagan must not be used for infants below 2 years of age.

Alphagan is not recommended for use in children (from 2 years until 12 years).

### ***Instructions for use***

Alphagan comes as eye drops. Always wash your hands before applying eye drops.

Your prescription label tells you how many drops to use at each dose. If you use Alphagan with another eye drop, wait 5-15 minutes before applying the second eye drop.

Apply your eye drops in the following way:



1. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small pocket.
3. Squeeze the upturned dropper bottle to release a drop into your eye.
4. Whilst keeping the affected eye closed, press your finger against the corner of the closed eye (the side where the eye meets the nose) and hold for 1 minute.

Avoid touching the dropper tip against your eye or anything else.

Replace and tighten the cap straight after use.

### ***If you use more Alphagan than you should***

#### ***Adults***

In adults who were instilling more drops than prescribed, the side effects reported were those already known to occur with Alphagan.

Adults who accidentally swallowed Alphagan experienced decrease in blood pressure, which in some patients was followed by the increase in blood pressure.

#### ***Children***

Serious side effects were reported in children who accidentally swallowed Alphagan.

Signs included sleepiness, floppiness, low body temperature, paleness and breathing difficulties. Should this happen, contact your doctor immediately.

#### ***Adults and Children***

If Alphagan has been accidentally swallowed or if you have used more Alphagan than you should, please contact your doctor immediately.

### ***If you forget to use Alphagan***

If you forget to take a dose, apply it as soon as you remember. If, however, it is almost time for your next dose, you should omit the missed dose altogether and then follow your normal routine.

### ***If you stop using Alphagan***

To be effective Alphagan must be used every day. Do not stop using Alphagan until your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Alphagan can cause side effects, although not everybody gets them. The chance of having a side effect is described by the following categories:

Very common	Occurs in more than 1 out of 10 patients
Common	Occurs in fewer than 1 out of 10 patients
Uncommon	Occurs in fewer than 1 out of 100 patients
Rare	Occurs in fewer than 1 out of 1,000 patients
Very Rare	Occurs in fewer than 1 out of 10,000 patients

The following eye side effects may be seen with Alphagan.

##### ***Affecting the eye***

###### **Very common:**

- Irritation of the eye (eye redness, burning, stinging, a feeling of something in the eye, itching, follicles or white spots on the see-through layer which covers the surface of the eye)
- Blurred vision
- An allergic reaction in the eye

###### **Common:**

- Local irritation (inflammation and swelling of the eyelid, swelling of the see-through layer which covers the surface of the eye, sticky eyes, pain and tearing)
- Sensitivity to light
- Erosion on the surface of the eye and staining
- Eye dryness
- Whitening of the see-through layer which covers the surface of the eye
- Abnormal vision
- Inflammation of the see-through layer which covers the surface of the eye

###### **Very rare:**

- Inflammation within the eye
- Reduction in pupil size

###### **Side effects where the occurrence is unknown:**

- Itching of eyelids

##### ***Affecting the body***

###### **Very common:**

- Headache
- Dry mouth
- Tiredness/drowsiness

###### **Common:**

- Dizziness
- Cold-like symptoms
- Symptoms involving the stomach and digestion
- Abnormal taste
- General weakness

###### **Uncommon:**

- Depression
- Palpitations or changes in heart rate
- Dry nose
- General allergic reactions

###### **Rare:**

- Shortness of breath

**Very rare:**

- Sleeplessness
- Fainting
- High blood pressure
- Low blood pressure

**Side effects where the occurrence is unknown:**

- Skin reactions including redness, face swelling, itching, rash and widening of blood vessels

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

**United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**5. HOW TO STORE ALPHAGAN**

- KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton label or bottle label after EXP:. The expiry date refers to the last day of that month.
- Do not use the drops if the tamper-evident seal on the bottle is broken before first use.
- Discard the contents 28 days after first opening the bottle.
- Alphagan eye drops should be stored below 25°C.
- If your doctor tells you to stop using the drops, please take them back to the pharmacist for safe disposal. Only keep the drops if your doctor tells you to.
- If your drops become discoloured or cloudy or show any signs of deterioration you should consult your pharmacist who will advise you what to do.
- 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.

**6. FURTHER INFORMATION**

Your medicine is called Alphagan eye drops. Each millilitre contains 2mg of the active ingredient, brimonidine tartrate (equivalent to 1.32mg of brimonidine base) in a clear colourless solution.

Alphagan eye drops also contain the following inactive ingredients:

Liquifilm (polyvinyl alcohol), benzalkonium chloride (as preservative), sodium chloride, sodium citrate dihydrate, citric acid monohydrate, sodium hydroxide, hydrochloric acid and purified water.

Alphagan eye drops are available in 5ml plastic dropper bottles of sterile ophthalmic solution.

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This product is manufactured by Allergan Pharmaceuticals (Ireland) Ltd., Westport, Co Mayo, Ireland and is procured from within the EU and repackaged by the Product Licence holder:

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Alphagan is a registered trademark of ALLERGAN Inc

***Further information about glaucoma is available from:***

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(The IGA is an organisation which helps glaucoma patients and their relatives, and is not associated with Allergan Ltd or Waymade Plc.)