

Package Leaflet: Information for the user

ALPHAGAN 0.2% w/v (2 mg/ml) eye drops, solution

brimonidine tartrate

Read all of this leaflet carefully before you start using 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. See section 4.

What is in this leaflet:

1. What ALPHAGAN is and what it is used for
2. What you need to know before you use ALPHAGAN
3. How to use ALPHAGAN
4. Possible side effects
5. How to store ALPHAGAN
6. Contents of the pack and other information

1. What ALPHAGAN is and what it is used for

ALPHAGAN is used to reduce pressure within the eye. The active ingredient in ALPHAGAN is brimonidine tartrate which belongs to a group of medicines called alpha-2 adrenergic receptor agonists and works by reducing pressure within the eyeball.

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. It is used in the treatment of open angle glaucoma or ocular hypertension.

2. What you need to know before you use ALPHAGAN

Do not use ALPHAGAN

- If you are allergic (hypersensitive) to brimonidine tartrate or any of the other ingredients of this medicine (listed in section 6).
- If you are taking monoamine oxidase (MAO) inhibitors or certain other 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).

Warnings and precautions

Talk to your doctor before using ALPHAGAN

- 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.

Children and adolescents

ALPHAGAN is not recommended for use in children between the ages of 2 and 12 years.

ALPHAGAN should not usually be used in adolescents aged 12 to 17 as clinical studies have not been performed in this age group.

Other medicines and ALPHAGAN

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not use ALPHAGAN if you are pregnant unless your doctor considers it necessary.

Do not use ALPHAGAN if you are 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 have cleared.

ALPHAGAN contains benzalkonium chloride

ALPHAGAN contains 0.25 mg benzalkonium chloride in each 5 ml of solution which is equivalent to 0.05 mg/ml.

Benzalkonium chloride is a preservative which may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

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 recommended dose is one drop twice daily in the affected eye(s), approximately 12 hours apart. Do not change the dose or stop taking ALPHAGAN without speaking to your doctor.

Children under 12 years

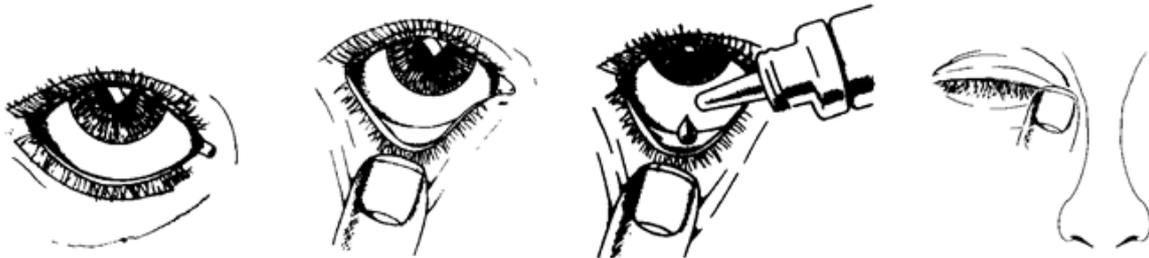
ALPHAGAN must not be used for infants below 2 years of age.

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.

If a drop misses your eye, try again.

To avoid contamination, do not let the tip of the bottle touch your eye or anything else. Replace and tighten the cap straight after use.

If you use more ALPHAGAN than you should

Adults

In adult patients who used more drops than they were prescribed, the side effects reported were those already known to occur with ALPHAGAN.

Adults who accidentally swallowed ALPHAGAN experienced a drop in blood pressure, which in some patients was followed by an 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, 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following eye side effects may be seen with ALPHAGAN.

Affecting the eye

Very common (may affect more than 1 in 10 people)

- 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 (may affect up to 1 in 10 people)

- Local irritation (inflammation, redness and discomfort in the eye, 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
- Small bulges on the back surface of the eyelids due to inflammation

Very rare (may affect up to 1 in 10 000 people)

- Inflammation within the eye
- Reduction in pupil size

Not known (frequency cannot be estimated from the available data)

- Itching of eyelids

Affecting the body

Very common (may affect more than 1 in 10 people)

- Headache
- Dry mouth
- Tiredness/drowsiness

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

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

Rare (may affect up to 1 in 1 000 people)

- Shortness of breath

Very rare (may affect up to 1 in 10 000 people)

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

Not known (frequency cannot be estimated from the available data)

- 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:

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting Website: <https://medicinesauthority.gov.mt/adrportal>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ALPHAGAN

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine if the tamper proof seal on the bottle neck is broken before you first begin to use it.
- Do not use this medicine after the expiry date which is stated on the bottle label and carton after 'EXP'. The expiry date refers to the last day of that month.
- **Throw the bottle away 28 days after opening, even if there is solution remaining.**

Do not throw away any medicines 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. Contents of the pack and other information

What ALPHAGAN contains

- The active substance is brimonidine tartrate. One ml solution contains 2.0 mg brimonidine tartrate, equivalent to 1.3 mg of brimonidine.
- The other ingredients are benzalkonium chloride as a preservative, poly(vinyl alcohol), sodium chloride, sodium citrate dihydrate, citric acid monohydrate, purified water and sodium hydroxide or hydrochloric acid for pH-adjustment.

What ALPHAGAN looks like and contents of the pack

ALPHAGAN is a clear, greenish-yellow to light greenish-yellow eye drop solution in a plastic bottle. Each bottle contains either 2.5 ml, 5 ml or 10 ml of the medicine.

ALPHAGAN is available in packs of 1, 3 or 6 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder Ireland:

AbbVie Limited, Citywest Business Campus, Dublin 24, Ireland

Marketing Authorisation Holder Malta:

AbbVie Pharmaceuticals S.A., 41-45 Marinou Antypa Ave., 141 21 Neo Irakleio, Greece

Manufacturer

Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, Co. Mayo, Ireland

This leaflet was last revised in ((mm /yyyy)).

Other sources of information

Detailed information on this medicine is available on the website of:

Ireland

Health Products Regulatory Authority; <https://www.hpra.ie/>

Malta

Malta Medicines Authority; <https://medicinesauthority.gov.mt/>

To listen to or request a copy of this leaflet in <Braille>, <large print> or <audio>, please contact the local representative of the Marketing Authorisation Holder.