PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ALPHAGAN® Purite®, brimonidine tartrate 1,5 mg/ml ophthalmic solution

Read all of this leaflet carefully before you start using ALPHAGAN® Purite®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ALPHAGAN® Purite® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ALPHAGAN® PURITE® CONTAINS

- The active substance is brimonidine tartrate
- The other ingredients are boric acid, calcium chloride, magnesium chloride, potassium chloride, purified water, sodium borate, sodium carboxymethylcellulose, sodium chloride and Purite® (stabilised oxychloro complex) 0,005 % m/v as preservative.

2. WHAT ALPHAGAN® PURITE® IS USED FOR

ALPHAGAN® Purite® ophthalmic solution helps fluid flow out of the eye chamber and also decreases the fluid produced by the eye. This lowers the pressure in the eye. ALPHAGAN® Purite® can be used either alone or with another eye drop which lowers pressure in the eye for the treatment of high pressure in the eye in glaucoma or ocular hypertension.

3. BEFORE YOU USE ALPHAGAN® PURITE®

Do not use ALPHAGAN® Purite®

- If you are hypersensitive (allergic) to brimonidine tartrate or any of the ingredients of ALPHAGAN® Purite®.

ALPHAGAN® Purite® should not be used in neonates and infants under the age of 2 years.

Take special care with ALPHAGAN® Purite®

- If you have any diseases associated with the heart.

- If you have any diseases that affect the kidney or liver.
- If you suffer or have suffered from depression, reduced mental capacity, reduced blood supply to the brain, Raynaud's phenomenon (a condition resulting in painful discolouration of the fingers and/or the toes after exposure to changes in temperature or emotional events), or have very low blood pressure.
- If you are scheduled to have surgery using a general anaesthetic.
- If you are being treated with monoamine oxidase (MAO) inhibitors.

Pregnancy and breastfeeding

Safety and/or efficacy for ALPHAGAN® Purite® use during pregnancy and breastfeeding have not been established.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before using ALPHAGAN® Purite®.

Driving and using machinery

Be careful driving a car or operating machinery until you know how ALPHAGAN® Purite® ophthalmic solution affects you. It may make you drowsy. ALPHAGAN® Purite® may also cause blurred vision or visual disturbance. You should wait until these symptoms have cleared before driving or using machinery.

Using other medicines with ALPHAGAN® Purite®

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The following medicine should be used with caution:

- Medicines used in the treatment of high blood pressure;
- Digoxin, used in the treatment of congestive heart failure and cardiac dysrhythmia;
- Beta-blockers (ophthalmic and systemic) e.g. atenolol, sotalol, timolol;
- Tricyclic antidepressants e.g. amitriptyline, imipramine etc.;
- Monoamine oxidase (MAO) inhibitors used in the treatment of depression e.g. moclobemide, selegiline etc.;
- Alcohol, nervous system depressants, opiates, sedatives, or anaesthetics.

4. HOW TO USE ALPHAGAN® PURITE®

Do not share medicines prescribed for you with any other person.

Always use ALPHAGAN® Purite® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one drop in the eye(s) every twelve hours.

Helpful hints:

- Open the eye(s) needing the drops, tilt your head back and look upward
- Gently pull down the lower eyelid
- Bring the eye drops near the eye and squeeze one drop into the eye
- Avoid touching the eye, eyelids or lashes with the dropper
- Close your eyes and blink; this helps distribute the drops in the eye chamber
- While your eyes are closed, gently press your fingers on the inner corner(s) of your eye(s)
- Wipe any excess away with a clean tissue
- Replace cap on the dropper bottle

Your doctor will tell you how long your treatment with ALPHAGAN® Purite® will last. Do not stop using ALPHAGAN® Purite® ophthalmic solution even if you feel well unless instructed by your doctor.

If you are under the impression that the effect of ALPHAGAN® Purite® is too strong or too weak for you, tell your doctor or pharmacist.

Method of administration if you are using other medicines with ALPHAGAN® Purite®

- If you have glaucoma which is difficult to control, certain other medicines or drops may be added to the existing treatment with ALPHAGAN® Purite® ophthalmic solution.
- The length of treatment with these eye drops depends on your condition, and will be determined by your doctor.
- The dose of the eye drops may be changed by your doctor to best treat your condition.
- If you use ALPHAGAN® Purite® ophthalmic solution with another eye medicine, apply ALPHAGAN® Purite® ophthalmic solution first and wait five minutes before applying the second eye medicine.

Use in children

ALPHAGAN® Purite® should not be used in children below the age of 2 years.
Children 2 years of age and above or weighing ≤ 20 kg should be treated with caution.

Things to be careful of

- Keep enough eye drops to last weekends and holidays.
- If not handled properly, eye drops can become contaminated by germs which can cause eye infections. This may cause serious damage to your eye and loss of vision. To help prevent infections, do not let the tip of the bottle touch your eye or anything else. Put the cap back on and close the bottle straight after you have used it. Do not use if the solution changes colour or becomes cloudy. Do not use after the expiry date marked on the bottle.
- Tell your doctor immediately if you develop an eye infection, if you hurt your eye, or if you have to go for an eye operation.

If you use more ALPHAGAN® Purite® than you should

The eye(s) should be flushed with water. If you have questions or concerns, or are not sure about something, please consult your doctor or pharmacist.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use ALPHAGAN® Purite®

Use the eye drops as soon as you remember, and then go back to using them as you would normally. If it is almost time for your next dose, ignore the dose you missed and put the drops in when you are meant to.

Do not take a double dose to make up for the dose that you missed. If you have missed several doses, consult your doctor. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

Effects when treatment with ALPHAGAN® Purite® is stopped

ALPHAGAN® Purite® lowers pressure in your eye for the treatment of high pressure in the eye in glaucoma or ocular hypertension and if treatment is interrupted or stopped early your condition may return and have serious adverse effect.

5. POSSIBLE SIDE EFFECTS

ALPHAGAN® Purite® can have side effects. Not all side effects reported for ALPHAGAN® Purite® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ALPHAGAN® Purite®, please consult your doctor, pharmacist or other health care professional for advice.

Frequent side effects

- High levels of cholesterol in the blood
- Allergic reaction
- Dizziness, headache
- Eye allergy, red eye, itchy eyes, itchy eyelids, burning sensation (eyes), small bumps inside the eyelid, eye swelling, eye surface bleeding, eye surface inflammation, watery eyes, sticky eyes, dry eyes, eye irritation, eye pain, small bumps on the eye surface, a feeling that something in is your eye, light sensitivity, stinging, visual disturbance, abnormalities in the field of view, eye floaters, eye sight worsening, eyelid and eye surface irritations, blurred vision, cloudy lens inside the eye, inflammation of the central front part of the eye, eyelid abnormalities, tearing, separation of gel tissue in the eye, abnormal gel tissue in the eye
- High blood pressure, low blood pressure
- Cough, shortness of breath
- Indigestion, dryness of the mouth, digestive disorder
- Bronchitis, flu syndrome, pharyngitis (sore throat), runny nose, sinus infection, sinusitis, colds and respiratory infections
- Feeling weak, tiredness

Less frequent side effects

- Difficulty in sleeping, feeling drowsy
- Distorted or abnormal sense of taste
- Superficial damage to the front part of the eye, styes
- Dryness of the nose

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

You can report side effect to SAHPRA via “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publication:
https://www.sahpra.org.za/Publications/Index/8
By reporting side effects, you can help provide more information on the safety of ALPHAGAN® Purite®.

You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.com

6. STORING AND DISPOSING OF ALPHAGAN® PURITE®

- Store at or below 25 °C and protect from light.
- Store all medicines out of reach of children.
- The EXPIRY date is marked on the bottle. Do not use the ophthalmic solution beyond the expiry date. Throw out any unused drops 30 days after opening the bottle.
- Store in the original eye drop bottle.
- To avoid contamination of the solution, keep container tightly closed and do not touch dropper tip to any surface.
- Contents are sterile if seal is intact.
- Do not put the eye drops in the freezer.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ALPHAGAN® PURITE®

ALPHAGAN® Purite® ophthalmic solution is supplied sterile in opaque teal plastic bottles and tips with purple caps, containing 5 ml of solution.

8. IDENTIFICATION OF ALPHAGAN® PURITE®

ALPHAGAN® Purite® is a clear green-yellow solution, essentially free of any visible particulate matter.

9. REGISTRATION NUMBER

A39/15.4/0202

10. NAME AND ADDRESS OF REGISTRATION HOLDER

AbbVie (Pty) Ltd
Building 7, Waterfall Corporate Campus
74 Waterfall Drive
Waterfall City
Midrand, 1685
South Africa
Tel: +27 (0) 11 031 1600

11. DATE OF PUBLICATION

Date of registration: 05 October 2007

Date of most recent patient information leaflet as approved by Council: 21 April 2023

For the professional information, please email medicalinfo.za@abbvie.com

CCDS v2.0