

Patient Information Leaflet

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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PATIENT INFORMATION LEAFLET

AGOBRIM EYE DROPS

(Brimonidine tartrate 0,2 % w/v)

Read all this leaflet carefully before you start taking AGOBRIM EYE DROPS

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- AGOBRIM EYE DROPS 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.

What is in this leaflet:

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

1. What AGOBRIM EYE DROPS is and what it is used for.

AGOBRIM EYE DROPS is used to reduce pressure within the eye. The active ingredient in AGOBRIM EYE DROPS 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, in the treatment of open angle glaucoma or ocular hypertension.

2. What you need to know before you take AGOBRIM EYE DROPS

Do not use AGOBRIM EYE DROPS:

- If you are allergic (hypersensitive) to brimonidine tartrate, benzalkonium chloride 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 medicine.
- In infants/babies (from birth until 2 years).

Warnings and precautions

Take special care with AGOBRIM EYE DROPS

Talk to your doctor before taking AGOBRIM EYE DROPS if you have now or have had in the past.

- 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

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

The preservative in AGOBRIM EYE DROPS, benzalkonium chloride, may cause eye irritation, symptoms of dry eyes, and may affect the tear film and corneal surface. Patients should remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses. Patients should avoid contact with soft contact lenses.

Other medicines and AGOBRIM EYE DROPS:

Always tell your health care provider if you are taking any other medicines (This includes all complementary or traditional medicines).

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

- Pain killers, sedatives, opiates, barbiturates or are regularly consuming alcohol.
- Anaesthetics.
- Medicines to treat a heart condition or to lower blood pressure.
- Medicines that can change the way your body works to break down AGOBRIM EYE DROPS, like chlorpromazine, methylphenidate and reserpine.
- Medicines which work the same way as AGOBRIM EYE DROPS, for example isoprenaline and prazosin, medicines called beta-blockers,

antihypertensives.

- 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 AGOBRIM EYE DROPS.

Pregnancy, breast feeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other healthcare professional for advice before AGOBRIM EYE DROPS is administered to you.

Use in pregnancy.

Do not use AGOBRIM EYE DROPS if you are pregnant

Use in breast-feeding.

Do not use AGOBRIM EYE DROPS if you are breast-feeding.

Driving and using machines

AGOBRIM EYE DROPS may cause blurred or abnormal vision. This effect may seem worse at night or in reduced lighting.

AGOBRIM EYE DROPS 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.

AGOBRIM EYE DROPS contains benzalkonium chloride.

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 AGOBRIM EYE DROPS 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 take AGOBRIM EYE DROPS

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

Always take AGOBRIM EYE DROPS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose for lowering eye pressure is one drop into the affected eye(s) every 12 hours.

Do not change your usual dose without talking to your doctor.

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Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infection leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from contact with any surface.

Instructions for use

Do not use the bottle if the plastic safety strip around the neck is missing or broken. When opening the bottle for the first time, tear off the plastic safety strip.

Every time you use AGOBRIM EYE DROPS:

1. Wash your hands.
2. Open the bottle. Take special care that the tip of the dropper bottle does not touch your eye, the skin around your eye or your fingers.
3. Tilt your head backwards and hold the bottle upside down over the eye.
4. Tilt your head backwards and hold the bottle upside down over the eye.
5. Press a finger into the corner of your eye, by the nose, or close your eyelids for 1 minutes. This helps to stop the medicine from getting into the rest of the body.
6. Repeat steps 3 to 5 with the other eye if instructed to do so by your doctor.
7. Put the cap back on and close the bottle tightly.

Ophthalmic medications, if handled improperly, can become contaminated by common bacteria known to cause infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated ophthalmic medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

Use in children and adolescents.

AGOBRIM EYE DROPS should not be used in children below the age of 2 years. Children 2 years of age and above or weighing $\leq 20\text{kg}$ should be treated with caution.

Before you or your child starts to take AGOBRIM EYE DROPS, your doctor or your child's doctor will have carried out a detailed medical examination and decided whether this medicine is suitable. You or your child should be closely monitored for one to two hours after the first dose and carefully monitored for any signs of side effects until surgery is carried out.

If you use AGOBRIM EYE DROPS with another eye medicine, apply AGOBRIM EYE DROPS first and wait five

minutes before applying the second eye medicine.

Duration of treatment:

Your doctor will tell you how long your treatment with AGOBRIM EYE DROPS Will last. You should not take AGOBRIM EYE DROPS for longer than necessary.

If you use more AGOBRIM EYE DROPS than you should

In the event of overdosage or if AGOBRIM EYE DROPS is accidentally swallowed consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. If you have placed too many drops in your eye(s), wash your eye(s) with clean water.

If you forget to use AGOBRIM EYE DROPS

It is important to take AGOBRIM EYE DROPS as prescribed by your doctor.

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 AGOBRIM EYE DROPS

To be effective AGOBRIM EYE DROPS must be used every day. Do not stop using AGOBRIM EYE DROPS 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

AGOBRIM EYE DROPS can have side effects.

Not all side effects reported for AGOBRIM EYE DROPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AGOBRIM EYE DROPS, please consult your doctor, pharmacist, or other healthcare professional for advice.

The following side effects may occur when using AGOBRIM EYE DROPS:

If any of the following happens, stop using AGOBRIM EYE DROPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Itching or watery eyes
- Rash
- Swelling around the eyeball or eyelid
- Inflammation/redness of the white part of the eye and the eyelids
- Pink eyes

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These are all very serious side effects. If you have them, you may have had a serious reaction to AGOBRIM EYE DROPS. You may need urgent medical attention or hospitalisation

Tell your doctor immediately or go to the nearest casualty department if you notice changes in the way your heart beats, for example if you notice it beating faster or slower. This side effect occurs less frequently but is serious.

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

- Flu like symptoms or other infections
- Changes in breathing
- Follicles or pimples on the conjunctiva
- Eye discharge
- Changes to the surface of the eye
- High or low blood pressure

Tell your doctor if you notice any of the following:

Frequent side effects:

- Burning and stinging
- Foreign body sensation
- Blurred vision
- Dryness in the eyes
- Ache or pain in the eye
- Eye sensitivity to bright light
- Headaches
- Dizziness/drowsiness/tiredness
- Cough
- Mouth dryness
- Stomach upset/burning

Less frequent side effects:

- Abnormal taste
- Insomnia or sleepiness
- Depression

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- Anxiety
- Dry nose

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via the “6.04 Adverse Drug reaction Reporting Form” found online under SAHPRA’s publications: <https://www.sahpra.org.za/publications/Index/8>. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store AGOBRIM EYE DROPS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 30°C.
- Protect from light.
- You can use AGOBRIM EYE DROPS for 28 days after first opening the bottle.

Do not use AGOBRIM EYE DROPS after the expiry date which is stated on the carton and the bottle after Expiry. The expiry date refers to the last day of that month. Make sure the container is properly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What AGOBRIM EYE DROPS 5 mL contains

The active substance is Brimonidine tartrate.

Polyvinyl Alcohol.

Citric acid.

Sodium citrate Dihydrate.

Sodium chloride.

Benzalkonium chloride.

Sodium Hydroxide.

Water for injection.

WHAT AGOBRIM EYE DROPS LOOKS LIKE AND CONTENTS OF THE PACK

AGOBRIM EYE DROPS 0,2 % w/v is clear greenish yellow solution is filled in 5 mL clear translucent LDPE vial

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with white HIPS cap

One such vial is packed in a printed carton with Package insert.

NAME OF CERTIFICATE OF REGISTRATION

FDC SA (Pty) Ltd

Unit J3, The Willows Office Park,

Farm Road, The willows, Pretoria East,

Pretoria, 0081,

South Africa.

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Access to the corresponding Professional Information

Scan the QR code to access the corresponding professional Information (PI) and HCR details.

