

PATIENT INFORMATION LEAFLET: BRIMOCT

SCHEDULING STATUS S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BRIMOCT® 2,0 mg/ml Ophthalmic Solution

Brimonidine tartrate

Read all of this leaflet carefully before you start using BRIMOCT:

- Keep this leaflet. You may need to read it again.
- If you have any further questions please ask your doctor, pharmacist, nurse or other healthcare provider.
- BRIMOCT 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 BRIMOCT is and what it is used for
2. What you need to know before you use BRIMOCT
3. How to use BRIMOCT
4. Possible side effects
5. How to store BRIMOCT
6. Contents of the pack and other information

1. WHAT BRIMOCT IS AND WHAT IT IS USED FOR

BRIMOCT is an eye drop that is used to treat open-angle glaucoma or high fluid pressure in the eye. It does this by helping fluid flow out of the eye chamber and by reducing the amount of fluid produced by the eye.

Lowering high fluid pressure in the eye reduces the risk of vision loss, nerve damage or blindness.

BRIMOCT may be used together with other topical ophthalmic medicinal products to lower ocular pressure. The topical ophthalmic products should be administered at least 5 minutes apart if more

than one is being used.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BRIMOCT:

Do not use BRIMOCT:

- If you are hypersensitive (allergic) to brimonidine tartrate, benzalkonium chloride or any other ingredient of BRIMOCT.
- If you are being treated with monoamine oxidase (MAO) inhibitors.
- BRIMOCT should not be given to children under the age of two years, due to an increased risk of serious side effects such as very slowed breathing.

Warnings and precautions:

Take special care with BRIMOCT:

- If you suffer from dry eye syndrome, BRIMOCT may worsen this condition.
- If you have any diseases that affect the liver and kidney.
- If you have any diseases associated with the heart.
- If you suffer from depression, Raynaud's Syndrome, reduced mental capacity, reduced blood supply to the brain, or have very low blood pressure.
- If you have extensive eye surface disease and you use BRIMOCT for a long period of time, regular eye examinations are recommended.
- If you wear contact lenses. It is not recommended that you use BRIMOCT while wearing contact lenses. Wait at least 15 minutes after instilling BRIMOCT ophthalmic solution to insert soft contact lenses.
- When used for a prolonged period of time. It is recommended that you go for regular eye examinations due to the risk of developing corneal side effects due to the preservative benzalkonium chloride.
- It is also recommended that you check your eye pressure regularly.
- BRIMOCT may cause fatigue and drowsiness (sleepiness). It is recommended that you exercise caution when engaging in hazardous activities due to the potential for reduced mental alertness.

Other medicines and BRIMOCT:

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

- Tell your doctor if you are using medicines for the heart, high blood pressure medication or medicine for depression.
- Also tell your doctor or pharmacist if you are taking any medication that may cause drowsiness such as: medicines for allergies that cause drowsiness, calming medication, medication for convulsions (fits), sleep inducing medicines, muscle relaxing medicines, narcotic pain relievers, psychiatric medicines or tranquilizers.
- Check the labels on all your medicines (e.g. cough-and-cold products) because they may contain drowsiness-causing ingredients.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

The safety and efficacy of BRIMOCT in pregnant women have not been established. It has not been established whether BRIMOCT is excreted in human milk. A decision should be made with your doctor, on whether to discontinue BRIMOCT or discontinue breastfeeding.

Driving and using machinery:

BRIMOCT may make you feel drowsy or sleepy. Be careful when driving a car or operating machinery until you know how BRIMOCT affects you.

BRIMOCT contains benzalkonium chloride:

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

3. HOW TO USE BRIMOCT

Always use BRIMOCT exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

You must not use the eye drops if the tamper-proof seal on the bottle neck is broken before you first use it.

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

If you are using other eye medications (e.g. drops or ointments) in addition to BRIMOCT, you should wait at least 5 minutes before applying the other medication.

Use eye drops before eye ointments in order to allow the eye drops to enter the eye.

Your doctor will tell you how long your treatment with BRIMOCT will last. Do not stop using BRIMOCT even if you feel well unless instructed to do so by your doctor.

Use this eye drop regularly in order to get the most benefit from it. Remember to use it at the same times each day.

Apply your eye drops in the following way:

Wash your hands. Tilt your head back and look upward. Gently pull the lower eyelid down. Bring the eye drops near the eye, turn the bottle upside down and squeeze it gently to release a drop into the eye. Avoid touching the eye, eyelids or eye lashes with the dropper as this can cause a bacterial infection. Let go of the lower lid, and close your eye for 30 seconds. While your eyes are closed, gently press your fingers on the inner corner(s) of your eye(s). This will prevent the eye drops from draining out of the eye. If a drop misses your eye, try again.

Wipe away any excess with a clean tissue. Replace and tighten the cap straight after use to avoid contamination.

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

Keep to the dosage stated in this patient information leaflet or as your doctor has instructed you. You should always check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of BRIMOCT is too strong or too weak, talk to your doctor or pharmacist.

BRIMOCT is intended to be instilled into the eye only. Do not swallow.

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

If you use more BRIMOCT than you should:

In the event of overdosage or if BRIMOCT 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 BRIMOCT:

Apply the eye drops as soon as you remember, and then go back to using them as you would normally.

If it's almost time for your next dose, ignore the dose you missed and apply the drops as you were supposed to.

Do not use a double dose to make up for a missed dose.

If you have missed several doses, consult your doctor.

If you seem to always have trouble remembering when to use your medicines, ask your pharmacist for some helpful hints.

4. POSSIBLE SIDE EFFECTS

BRIMOCT can have side effects. Not all side effects reported for BRIMOCT are included in this leaflet. Should your general health worsen while using BRIMOCT, please consult your doctor, pharmacist or other healthcare provider for advice.

The following side effects may occur when using BRIMOCT:

If any of the following should happen, stop using BRIMOCT and tell your doctor immediately.

- 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

These are all very serious side effects. If you have them, you may have had an allergic reaction to BRIMOCT.

These are very common side effects.

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 common 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:

- 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

These are all mild side effects of BRIMOCT and are frequent.

You may also experience:

- Abnormal taste
- Insomnia or sleepiness
- Depression
- Anxiety
- Dry nose

These are all mild side effects of BRIMOCT and are less frequent.

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

Reporting of side effects:

If you experience side effects, talk to your doctor or pharmacist.

You can report side effects to Gen-Eye (Pty) Ltd via email: pharmacovigilance@gen-eye.co.za or telephonically on 011 312 3812.

You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form” found online under SAHPRA publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BRIMOCT.

5. HOW TO STORE BRIMOCT:

Store at or below 25 °C. Keep well closed. Protect from light. Do not refrigerate.

Store in a cool dry place in the original container. Keep the container in the outer carton.

Store all medicines out of reach of children.

Do not use BRIMOCT after the expiry date stated on the bottle and carton.

Do not use more than 30 days after opening.

To protect the solution from contamination, keep the container tightly closed and do not touch the dropper tip to any surface.

Do not use BRIMOCT if you notice visible signs of deterioration.

Do not use BRIMOCT if you notice the tamper-proof seal on the bottle is broken. Contents are sterile if seal is intact.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BRIMOCT contains:

The active substance is brimonidine tartrate. Each ml of BRIMOCT contains 2,0 mg of brimonidine tartrate. The other ingredients are: benzalkonium chloride 0,005 % *m/v* (preservative), citric acid monohydrate, polyvinyl alcohol, purified water, sodium chloride, sodium citrate dihydrate, sodium hydroxide.

What BRIMOCT looks like and contents of the pack:

BRIMOCT ophthalmic solution is a clear, transparent, yellowish solution without suspending particles.

BRIMOCT is supplied in an opaque, white, sterile dropper bottle with a white capillary plug and a purple sterile cap, containing 5 ml solution.

The dropper bottle is contained in an outer cardboard carton.

Holder of Certificate of Registration:

Gen-Eye (Pty) Ltd¹

Royal Palm Business Estate

Unit 7, 646 Washington Street

Halfway House, Midrand, 1685

Gauteng, South Africa

This leaflet was last revised in:

To be allocated

Registration number:

45/15.4/0688

Access to the corresponding Professional Information:

The corresponding Professional Information is available electronically on www.gen-eye.co.za.

Alternatively, to obtain this Professional Information please contact Gen-Eye (Pty) Ltd on 011-312 3812 or email info@gen-eye.co.za.

¹ Company Registration number: 2009/009360/07

Namibia:

Registration number: 15/15.4/0164

Scheduling status: NS2