

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S3

### Glaumide-Co 20 mg/ml + 5 mg/ml Ophthalmic Solution

Dorzolamide hydrochloride and Timolol maleate.

### Read all of this leaflet carefully before you start using GLAUMIDE-CO:

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

### 1. WHAT GLAUMIDE-CO IS AND WHAT IT IS USED FOR

GLAUMIDE-CO is used to treat high pressure inside the eye due to glaucoma (open-angle type) or other eye diseases (e.g. ocular hypertension). Lowering high pressure inside the eye helps to prevent blindness. GLAUMIDE-CO works by decreasing the amount of fluid in the eye.

Timolol is a non-selective beta-blocker and dorzolamide is a carbonic anhydrase inhibitor.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE GLAUMIDE-CO

### Do not use GLAUMIDE-CO:

- If you are hypersensitive (allergic) to dorzolamide hydrochloride, timolol maleate, benzalkonium chloride or any of the ingredients of GLAUMIDE-CO.
- If you have asthma or a history of asthma or lung disease.
- If you have a heart condition or irregular heartbeat.
- If you have had heart failure.
- If you are pregnant or breastfeeding your baby.

### Warnings and precautions:

#### Take special care with GLAUMIDE-CO:

- The safety and efficacy of GLAUMIDE-CO ophthalmic solution in children is not well known.
- In elderly patients, older than 65 years, greater sensitivity towards the effects of GLAUMIDE-CO cannot be ruled out.
- If you experience an allergic reaction to GLAUMIDE-CO seek immediate medical attention. Symptoms of a serious allergic reaction may include rash, itching/swelling (especially of the face/tongue/throat), dizziness and difficulty breathing.
- Dorzolamide hydrochloride in GLAUMIDE-CO is a sulphonamide and topical administration may result in absorption into the blood system. Therefore you may experience side effects pertaining to sulphonamides such as fever, body aches, flat red rash, blisters and peeling, signs of recurrent infections, fatigue and excessive bleeding. If you experience these side effects, stop using GLAUMIDE-CO and contact your doctor immediately.
- Timolol maleate in GLAUMIDE-CO is a beta-blocker and topical administration may result in absorption into the blood system. Therefore you may experience side effects pertaining to beta-blockers which may affect the respiratory system and normal functioning of your heart.
- If you are taking an oral carbonic anhydrase inhibitor or a beta-adrenergic blocker together with GLAUMIDE-CO, there is the potential for additive systemic effects.
- If you experience allergic-type reactions on the eye such as pink eye or lid reactions, stop using GLAUMIDE-CO and contact your doctor immediately.

- If you have eyesight disease and use GLAUMIDE-CO for an extended period of time, you should exercise caution and have regular eye examinations.
- You should not use GLAUMIDE-CO if you have liver or kidney function impairment as safety has not been established.

**Other medicines and GLAUMIDE-CO:**

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

Consult your doctor or pharmacist before using GLAUMIDE-CO with oral carbonic anhydrase inhibitors (e.g. acetazolamide), oral beta-blockers (e.g. propranolol, atenolol), aspirin or related salicylates, or other anti-glaucoma eye drops.

**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 of GLAUMIDE-CO during pregnancy and breastfeeding is not known.

Do not use GLAUMIDE-CO if you are pregnant or breastfeeding your baby.

**Driving and using machines:**

Your vision may be temporarily blurred or unstable after applying GLAUMIDE-CO.

Do not drive, use machinery, or do any activity that requires clear vision until you are sure you can perform such activities safely.

**GLAUMIDE-CO contains benzalkonium chloride:**

The preservative used in GLAUMIDE-CO (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses. Remove your lenses just before you use GLAUMIDE-CO and wait at least 15 minutes before you reinsert your lenses.

**3. HOW TO USE GLAUMIDE-CO**

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

Contact lenses should be removed before using GLAUMIDE-CO and reinserted 15 minutes after a dose of GLAUMIDE-CO.

The dose is one drop of GLAUMIDE-CO in the affected eye(s) two times a day.

If you have the impression that the effect of GLAUMIDE-CO is too strong or too weak talk to your doctor or pharmacist.

If more than one topical ophthalmic medication is being used, the medicines should be administered at least 10 minutes apart.

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

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 to release the drop into the eye.
- Avoid touching the eye, eyelids or 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.

GLAUMIDE-CO is intended to be instilled into the eye only. Do not swallow.

**If you use more GLAUMIDE-CO than you should:**

In the event of overdosage or if GLAUMIDE-CO 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 the eye(s) with clean water.

**If you forget to use GLAUMIDE-CO:**

Apply 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 apply the drops as you were supposed to.

Do not apply 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**

GLAUMIDE-CO can have side effects. Not all side effects reported for GLAUMIDE-CO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using GLAUMIDE-CO, please consult your healthcare provider for advice.

If any of the following happens, stop using GLAUMIDE-CO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the skin, including face, tongue or throat, difficulty breathing or swallowing,

wheezing.

- Skin rash or itchiness of the skin.
- Joint pain, chest pain, fever, fatigue and general discomfort.
- Pink eye.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Irregular heartbeat and rhythm, fast heartbeat, slow heartbeat, stroke.
- Fainting, cold hands and feet, discolouration of fingers and toes, pain in the lower leg.
- Pain in back, chest or abdomen.
- Blood in the urine.
- Unusual tiredness or weakness.
- Persistent dizziness.
- Persistent discharge from the eye.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Blurred vision, tearing, eyelid irritation.
- Burning, stinging, itching or redness of the eye, inflammation of the eyelid, dry eyes, decreased sensitivity of the eye.
- Headache.
- Nausea.
- Inflammation of the conjunctiva of the eye (transparent mucous membrane covering the eyeball).
- Inflammation or irritation of the eyelid.
- Fatigue.
- Bitter taste.

Less frequent side effects:

- Inflammation of the iris (the coloured part of the eye), temporary short-sightedness, eyelid oedema, double vision.
- Ringing in the ears.
- Dizziness, tingling, tickling and burning sensation of the skin, depression, nightmares, sleeplessness, memory loss, increase in signs and symptoms of muscle weakness, decreased sex drive.
- Respiratory failure, nosebleed, shortness of breath, cough.
- Dry mouth, diarrhoea (runny tummy), skin rash, exacerbation of psoriasis (skin condition causing itchiness), hair loss.
- Kidney stones, manifested as blood in the urine, pain in the abdomen and groin.
- Abnormally bent penis.

**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 or pharmacist.

You can report side effects to Gen-Eye (Pty) Ltd via email: [pharmacovigilance@gen-eye.co.za](mailto: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’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

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

#### **5. HOW TO STORE GLAUMIDE-CO**

Keep all medicines out of reach of children.

Store at or below 25 °C in a well closed container. Protect from light.

Do not remove the container from the carton until required for use.

Do not use more than 28 days after opening.

Return all unused medicines to your pharmacist.

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

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

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What GLAUMIDE-CO contains:**

The active substances are dorzolamide and timolol.

1 ml of solution contains 22,26 mg dorzolamide hydrochloride equivalent to 20 mg dorzolamide base and 6,83 mg timolol maleate equivalent to 5,0 mg timolol base.

The other ingredients are: benzalkonium chloride 0,0075 % *m/v* (preservative), hydroxyethylcellulose, mannitol, sodium citrate dihydrate and water for injection.

### **What GLAUMIDE-CO looks like and contents of the pack:**

GLAUMIDE-CO is a slightly opalescent, nearly colourless, slightly viscous solution.

GLAUMIDE-CO is supplied in a sterile, white, 10 ml, low density polyethylene container with a sterile, white low density polyethylene under-cap dropper and a sterile, white high density polyethylene cap.

Each container contains 5 ml of GLAUMIDE-CO ophthalmic solution.

The container is contained in an outer cardboard carton.

### **Holder of Certificate of Registration:**

Gen-Eye (Pty) Ltd<sup>1</sup>

Unit 7, Royal Palm Business Estate

646 Washington Street

Halfway House, Midrand, 1685

Gauteng, South Africa

### **This leaflet was last revised in:**

Date of the most recently revised patient information leaflet as approved by SAHPRA: 11 October 2022



**Registration number:**

46/15.4/0684

**Access to the corresponding professional information**

The corresponding Professional Information is available electronically on [www.gen-eye.co.za](http://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](mailto:info@gen-eye.co.za).

<sup>1</sup> Company Registration number: 2009/009360/07