PATIENT INFORMATION LEAFLET GLAUTIDOR

SCHEDULING STATUS: S3

GLAUTIDOR 20 mg/mL + 5 mg/mL eye drops.

Dorzolamide and Timolol

Read all of this leaflet carefully before you start using GLAUTIDOR.

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

1. What GLAUTIDOR is and what it is used for

GLAUTIDOR contains two medicines: dorzolamide and timolol.

- Dorzolamide belongs to a group of medicines called “carbonic anhydrase inhibitors”.
- Timolol belongs to a group of medicines called “beta blockers”.

These medicines lower the pressure in the eye in different ways.

GLAUTIDOR is prescribed to lower raised pressure in the eye in the treatment of glaucoma and ocular hypertension.

Elevated pressure in the eye may damage the optic nerve resulting in deterioration of vision and possible blindness. There generally are few symptoms that you can feel to tell you whether you have elevated pressure within your eye. Your doctor's examination is needed to determine this.

If you have raised pressure in your eye, regular eye examinations and measurements of the pressure within your eyes will be necessary.

2. What you need to know before you use GLAUTIDOR

Do not use GLAUTIDOR:

- If you are hypersensitive (allergic) to dorzolamide and/or timolol or any of the other ingredients of GLAUTIDOR (see section 6).
- If you have or ever had respiratory problems, such as asthma or severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- If you have a slow heartbeat, heart failure or disorders of heart rhythm (irregular heart beats).

If you are not sure whether you should use GLAUTIDOR, contact your doctor or pharmacist.

Warnings and Precautions

Tell your doctor:

- About any medical problems you have now or have had in the past, especially asthma and other lung problems or heart problems, and about any allergies to any medications.
- If you have or ever had coronary heart disease (symptoms can include chest pain or tightness, breathlessness, or choking), heart failure, low blood pressure.
- If you have disturbances of heart rate such as slow heartbeat.

- If you have breathing problems, asthma or chronic obstructive pulmonary disease.
- If you have poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome).
- About any allergies or allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing. If you suspect that GLAUTIDOR is causing an allergic reaction (e.g. skin rash, or redness and itching of the eye), stop its use and contact your doctor immediately.
- If you have kidney or liver problems, or if you have a history of kidney stones.
- If you have diabetes as timolol may mask signs and symptoms of low blood sugar.
- If you have overactivity of the thyroid gland as timolol may mask signs and symptoms.
- If you have a serious condition that can cause clouding, distortion, scarring and eventually blindness (Corneal disease), since GLAUTIDOR may cause dryness of the eyes.
- Before you have an operation that you are using GLAUTIDOR as timolol may change effects of some medicines used during anaesthesia.
- If you have muscle weakness or have been diagnosed as having myasthenia gravis.
- If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately.
- If you wear soft contact lenses, you should consult your doctor before using GLAUTIDOR.

Children and adolescents

GLAUTIDOR should not be used in children less than 2 years of age.

There is limited experience with GLAUTIDOR in children between 2 and 6 years of age.

However, safety and efficacy data with this solution are insufficient to recommend a safe and effective dose.

Other medicines and GLAUTIDOR

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

GLAUTIDOR can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are:

- Taking medicine to lower blood pressure or to treat heart disease or irregular heartbeat (such as calcium channel blockers, beta-blockers or digoxin).
- Taking large doses of aspirin.
- Using another eye drop that contains a beta-blocker.
- Taking another carbonic anhydrase inhibitor such as acetazolamide.
- Taking monoamine oxidase inhibitors (MAOIs) which are used to treat depression.
- Taking medicines to treat diabetes.
- Taking antidepressants known as fluoxetine and paroxetine.
- Taking quinidine (used to treat heart conditions and some types of malaria).

Pregnancy, breastfeeding and fertility

Do not use GLAUTIDOR if you are pregnant or 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 health care provider for advice before using this medicine.

Driving and using machines

There are possible side effects associated with GLAUTIDOR (such as blurred vision) which may affect your ability to drive and/or operate machinery (see section 4).

Important information about some of the ingredients of GLAUTIDOR

GLAUTIDOR contains the preservative benzalkonium chloride. This preservative may be absorbed by soft contact lenses and may change the colour of the contact lenses. If you wear contact lenses, consult your doctor before using GLAUTIDOR. 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. Your doctor will monitor you closely in case of prolonged use.

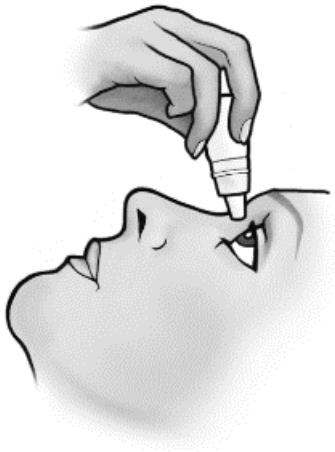
3. How to use GLAUTIDOR

Do not share medicines prescribed for you with any other person. Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

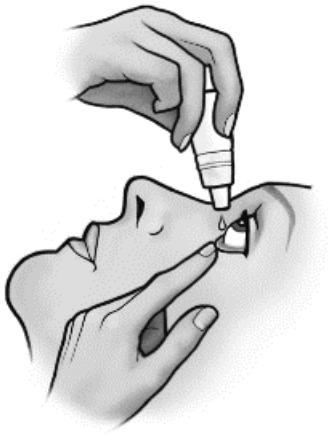
The appropriate dosage and duration of treatment will be established by your doctor.
The usual dose is one drop in the affected eye(s) in the morning and in the evening.
If you are using GLAUTIDOR with another eye drop, the drops should be instilled at least 10 minutes apart.
Do not change the dose of the medicine without consulting your doctor. If you must stop the treatment, contact your doctor immediately.

Instructions on how to use GLAUTIDOR

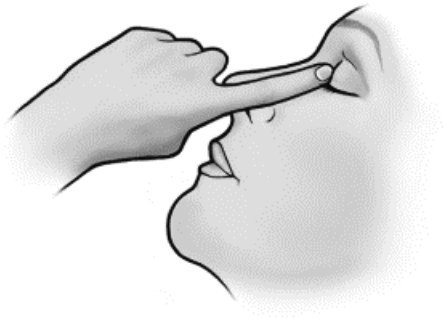
1. Wash your hands.
2. Open the container. Take special care that the tip of the dropper bottle does not touch your eye, the skin around your eye or your fingers.
3. Tilt your head backwards and hold the bottle upside down over the eye.



4. Pull the lower eyelid downwards and look up. Hold and gently squeeze on the sides of the bottle and let one drop fall into the space between the lower eyelid and the eye.



5. Press a finger into the corner of your eye, by the nose, or close your eyelids for 2 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.

If you have the impression that the effect of GLAUTIDOR is too strong or too weak, tell your doctor or pharmacist.

If you use more GLAUTIDOR than you should

If you put too many drops in your eye or swallow any of the contents of the bottle, among other effects, you may become light-headed, have difficulty breathing, or feel that your heart rate has slowed. Contact your doctor immediately.

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 GLAUTIDOR

Always use GLAUTIDOR as prescribed. If you have missed a dose, use it as soon as you remember. Do not take a double dose of GLAUTIDOR to make up for forgotten individual doses.

If you stop using GLAUTIDOR

Do not stop using GLAUTIDOR unless your doctor tells you to.

4. Possible side effects

GLAUTIDOR can have side effects.

Not all side effects reported for GLAUTIDOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using GLAUTIDOR, please consult your health care provider for advice.

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to GLAUTIDOR. 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:

- Systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs, which can affect the joints, skin, kidneys, blood cells, brain, heart and lungs).
- Stroke which may include having trouble walking, speaking and understanding, as well as paralysis or numbness of the face, arm or leg.
- Changes in the way your heart beats for example, if you notice it beating faster, slower or irregular, chest pain, heart failure, heart attack, blockage in an artery that limits the delivery of oxygen-rich blood to the brain, resulting in damage to brain tissue.
- Respiratory failure.
- Severe skin disorders, which can sometimes be life-threatening, causing swelling of

the lips, eyes and mouth, wheezing, or severe skin reactions (Stevens Johnson syndrome, toxic epidermal necrolysis).

- Generalised allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airways which may cause difficulty swallowing, shortness of breath, hives or itchy rash, localised and generalised rash, itchiness, severe sudden life-threatening allergic reaction (anaphylaxis).

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

Tell your doctor if you notice any of the following:

The following side effect have been reported when using GLAUTIDOR:

Frequent side effects:

- Burning, stinging, enlargement of conjunctival vessels.
- Inflammation or swelling of the tissue lining the sinuses (sinusitis).

Less frequent side effects:

- Inflammation and swelling of the mucous membrane of the nose, characterised by a runny nose and stuffiness (rhinitis).
- Skin rash caused by contact with a certain substance.
- Kidney stones.

The following side effects have been reported when using dorzolamide, timolol or GLAUTIDOR:

Frequent side effects:

- Headache.
- Blurred vision, corneal erosion (when the outer layer of the cornea wears away, eye itching, tearing, eye inflammation, eye irritation, death of small groups of cells on the surface of the cornea causing the eyes to become red, watery, and sensitive to light,

inflammation of the eyelids, inflammation of the cornea, decreased sensitivity of the cornea, dry eyes, inflammation or infection of the outer membrane of the eyeball and the inner eyelid.

- Changes in taste, nausea (feeling sick).
- Asthenia (weakness), fatigue (tiredness).

Less frequent side effects:

- Depression.
- Dizziness, tingling or prickling, “pins-and-needles” sensation; usually temporary, often occurs in the arms, hands, legs or feet, memory loss, increase in signs and symptoms of muscle weakness (myasthenia gravis).
- Inflammation of the iris (the coloured part of the eye), eyelid crusting, short sightedness which may resolve when treatment is stopped, detachment of the layer below the retina that contains blood vessels following surgery to reduce eye pressure, eyelid reactions, redness and irritation, pain, swelling of the cornea, low pressure in the eye, visual disturbances, eye drooping, double vision.
- Ringing or buzzing noise in one or both ears (tinnitus).
- Fainting, fluid retention (oedema).
- Low blood pressure (hypotension), pain caused by too little blood flow to your legs or arms, areas of the body feel numb and cool (Raynaud's phenomenon), cold hands and feet.
- Shortness of breath, spasm of the airways which makes it hard to breathe and causes wheezing, nosebleeds, coughing.
- Dry mouth, throat irritation, indigestion, diarrhoea.
- Rash, hair loss, itchy and dry patches on skin (psoriasis).
- Scar tissue inside the penis that causes curved, painful erections, decreased libido.

Frequency unknown:

- Low blood sugar (hypoglycaemia).
- Seeing or hearing something that wasn't actually there (hallucination), insomnia, nightmares.
- Foreign body sensation in eye (feeling that there is something in your eye).
- Abdominal pain, vomiting.
- Itchy skin, skin rash.
- Muscle pain.
- Sexual dysfunction.

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 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 GLAUTIDOR.

5. How to store GLAUTIDOR

Store all medicines out of reach of children.

Store at or below 25 ºC.

Keep the bottle in the outer carton in order to protect from light.

Do not use after the expiry date stated on the package.

GLAUTIDOR should not be used longer than 28 days after first opening the bottle.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What GLAUTIDOR contains:

The active substances are dorzolamide and timolol.

Each mL contains 22,3 mg dorzolamide hydrochloride equivalent to 20 mg dorzolamide and 6,8 mg timolol maleate equivalent to 5 mg timolol.

The other ingredients are hydroxypropyl methylcellulose, mannitol, sodium citrate dihydrate, sodium hydroxide and/or hydrochloric acid (for pH adjustment) and water for injections. Benzalkonium chloride is added as a preservative.

What GLAUTIDOR looks like and contents of the pack

Clear, colourless to nearly colourless, slightly viscous solution free from visible particulate matter.

A 5 mL translucent LDPE bottle with LDPE nozzle, containing 5 mL solution, closed with a HDPE cap, packed in an outer carton.

Pack size: 1 x bottle (5 mL or 10 mL) containing 5 mL solution.

Holder of certificate of registration

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