Approved Patient Information Leaflet for Medicines for Human Use:

DORZOPRES FORTE

SCHEDULING STATUS: S3

DORZOPRES FORTE (2,0 + 0,5) % *w/v* Eye drops Solution

Dorzolamide (as hydrochloride) and Timolol (as maleate)

Contains Preservative: Benzalkonium chloride, 0,0075 % *(m/v)*

Read all of this leaflet carefully before you start using DORZOPRES FORTE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your health care provider.
- DORZOPRES FORTE 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 DORZOPRES FORTE is and what it is used for

DORZOPRES FORTE is a sterile eye drops solution.

The active substances are dorzolamide and timolol.

Dorzolamide belongs to a group of medicines called "carbonic anhydrase inhibitors" and Timolol belongs to a group of medicines called “Nonselective beta-adrenergic receptor blocking medicines”.

DORZOPRES FORTE 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 health care provider'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 DORZOPRES FORTE

Do not use DORZOPRES FORTE

- if you are hypersensitive (allergic) to dorzolamide and/or timolol or any of the other ingredients of DORZOPRES FORTE (listed in section 6).
- if you have asthma or have ever had asthma
- if you have chronic obstructive lung disease (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- if you have certain heart diseases (such as slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats)
- if you have kidney disease or problems, or a prior history of kidney stones
- if you have excess acidity of the blood caused by a build-up of chloride in the blood (hyperchloraemic acidosis).

If you are not sure whether you should use DORZOPRES FORTE, contact your health care provider.

Warnings and precautions

Take special care with DORZOPRES FORTE

Tell your doctor or health care provider about any medical problems you have now or have had in the past, especially:

- Breathing problems, asthma and other lung problems and about any allergies to any medications
- Coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure or low blood pressure.
- Poor blood circulation disease (called Raynaud's disease or Raynaud's syndrome).
- Diabetes as timolol may mask signs and symptoms of low blood sugar.
- Overactivity of the thyroid gland as timolol may mask signs and symptoms.
- Eye infection, receive an eye injury, have eye surgery, or develop a reaction including new or worsening symptoms.

If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your health care provider immediately.

If you suspect that DORZOPRES FORTE is causing an allergic reaction (e.g. skin rash, or redness and itching of the eye), stop its use and contact your health care provider immediately.

If you wear soft contact lenses, you should consult your health care provider before using DORZOPRES FORTE.

Use in patients with liver impairment

Tell your health care provider if you now have or have had in the past liver problems.

Children

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

There is limited experience with DORZOPRES FORTE 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 DORZOPRES FORTE

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

Tell your health care provider about all medicines, including other eye drops, that you are using or plan to use, including those obtained without a prescription.

Tell your doctor if you are taking:

- Medicines to lower blood pressure or to treat heart disease or to treat disturbed or irregular heartbeat (such as calcium channel blockers, beta-blockers or digoxin).
- Another eye drop that contains a beta-blocker.
- A medicine containing acetazolamide.
- Monoamine oxidase inhibitors (MAOIs) (used to treat depression).
- A parasympathomimetic medicine which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which is sometimes used to help restore normal movements through the bowel.

- Narcotics such as morphine used to treat moderate to severe pain.
- Medicines to treat diabetes.
- Antidepressants such as fluoxetine and paroxetine.
- Quinidine (medicines used to treat heart conditions and some types of malaria – (decreased heartrate has been reported with quinidine and timolol).
- Large doses of aspirin.

Pregnancy and breastfeeding

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

You should not use DORZOPRES FORTE if you are pregnant.

Driving and using machines

There are side effects associated with DORZOPRES FORTE that may affect your ability to drive and/or operate machinery (see section 4).

DORZOPRES FORTE contains Benzalkonium chloride

DORZOPRES FORTE contains benzalkonium chloride. Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

If you wear soft contact lenses

If you wear soft contact lenses, you should consult your doctor before using DORZOPRES FORTE as it contains benzalkonium chloride as preservative. Contact lenses should be removed prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses.

As the possibility of adverse effects on the corneal permeability, and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations cannot be excluded, regular ophthalmological examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

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 health care provider.

3. How to use DORZOPRES FORTE

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

Always use DORZOPRES FORTE exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Dose

When this medicine is used alone, the recommended dose is one drop in the affected eye(s) in the morning and in the evening.

If your health care provider has recommended you use this medicine with a beta-blocker eye drop to lower eye pressure, then the recommended dose is one drop of DORZOPRES FORTE in the affected eye(s) in the morning and in the evening.

Do not allow the tip of the container to touch the eye or areas around the eye. To avoid possible contamination, keep the tip of the container away from contact with any surface.

Do not change the dosage of DORZOPRES FORTE without consulting your doctor.

If you must stop treatment, contact your doctor immediately.

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

Instructions for use

1. Before using the medicine for the first time, be sure the Safety Strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.

2. First wash your hands, then tear off the Safety Strip to break the seal.

3. To open the bottle, unscrew the cap by turning it the left. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.

4. Tilt your head back and pull your lower eyelid down slightly to form a pouch between your eye and eyelid.

5. Invert the bottle and press lightly with the thumb or index finger until a single drop is dispensed into the eye as directed by your health care provider. **DO NOT LET YOUR EYE OR EYELID TOUCH THE DROPPER TIP.**

6. After using DORZOPRES FORTE 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.

7. Repeat steps 4 and 5 in the other eye if instructed to do so by your health care provider.

8. Replace the cap by turning until it is firmly touching the bottle. Do not overtighten or you may damage the bottle and cap.

9. The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.

10. After you have used all doses, there will be some DORZOPRES FORTE left in the bottle. You should not be concerned since an extra amount of this medicine has been added and you will get the full amount of DORZOPRES FORTE that

your health care provider prescribed. Do not attempt to remove the excess medicine from the bottle.

If you wear soft contact lenses

Do not use the drops with your soft contact lenses in. After using the drops wait 15 minutes before putting your lenses back in.

If you are using other eye drops

If you are using DORZOPRES FORTE with another eye drop, the drops should be instilled at least 10 minutes apart.

If you use more DORZOPRES FORTE than you should

In the event of overdosage, consult your health care provider. If not available, contact the nearest hospital or poison centre.

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 health care provider immediately.

If you forget to use DORZOPRES FORTE

Do not use a double dose to make up for forgotten individual doses.

It is important to use DORZOPRES FORTE as prescribed by your health care provider. If you miss a dose, use it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule.

If you stop using DORZOPRES FORTE

DORZOPRES FORTE should be used every day to work properly. If you stop using DORZOPRES FORTE the pressure inside your eye may go up, therefore talk to your health care provider before stopping this treatment.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

DORZOPRES FORTE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing or shortness of breath, wheezing, or severe skin reactions (Stevens Johnson syndrome, toxic epidermal necrolysis)
- rash or itching
- fainting.

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

- Chest pain, changes in the way your heart beats (beating slower than normal, beating faster than normal)
- Difficulty breathing, constriction of the airways, feeling out of breath, shortness of breath
- Congestive heart failure (heart disease with shortness of breath and swelling of feet and legs due to fluid build-up), oedema (fluid build-up), cerebral ischaemia (reduced blood supply to the brain), chest pain, forceful heartbeat that may be rapid or irregular (palpitations), heart attack.

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:

- Headache
- Burning and stinging of the eyes, blurred vision, itchy eyes, tearing, redness of the eye(s), corneal erosion (damage to the front layer of the eyeball), swelling and/or irritation in and around the eye(s), feeling of having something in the eye(s), decreased corneal sensitivity (not realizing of getting something in the eye(s) and not feeling pain), pain in the eye(s), dry eye(s)
- Bitter taste in the mouth
- Painful, watery eyes, eyes sensitive to bright light, and bloodshot, and vision may be slightly blurred (Superficial punctuate keratitis)
- Sinusitis (feeling of tension and fullness in the nose)
- Nausea
- Feeling tired or weak, fatigue.

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Less frequent side effects:

- Slowing of your heart rate
- Shortness of breath
- Visual changes
- Dizziness, memory loss, not being able to fall asleep, having bad dreams, feeling depressed, burning or prickling sensation that is usually felt in the hands, arms, legs, or feet, but can also occur in other parts of the body
- An increase in signs and symptoms of myasthenia gravis (muscle disorder)
- Decreased sex drive
- Detachment of the layer below the retina that contains blood vessels following from filtration surgery which may cause visual disturbances
- Eyelid crusting, swelling of the cornea
- Ringing noises in the ears
- Low blood pressure
- Raynaud's phenomenon, swelling or coldness of your hands and feet and reduced circulation in your arms and legs
- Cold hands and feet
- Runny nose, nose bleed
- Irritated and/or sore throat, dry mouth, difficulty breathing, coughing
- Diarrhoea
- contact dermatitis, skin rash with white silvery coloured appearance (psoriasiform rash)
- Hair loss
- Peyronie’s disease (which may cause a curvature of the penis).

Side effects with frequency unknown:

- Irregular heartbeat, heart failure

- Having hallucinations
- Low blood sugar levels
- Stomach pain, vomiting
- Muscle pain not caused by exercise
- Foreign body sensation in the eye(s) (feeling like there is something in the eye).

If you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your health care provider. 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 DORZOPRES FORTE.

5. How to store DORZOPRES FORTE

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not use more than 28 days after opening. Once opened, solutions may become contaminated, which can cause eye infections. Therefore, you must throw away the bottle 4 weeks (28 days) after you first opened it, even if some solution is left. To help you remember, write down the date that you opened it in the space on the carton.

Do not use this medicine after the expiry date which is printed on the carton and bottle after EXP. The expiry date refers to the last day of that month.

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6. Contents of the pack and other information

What DORZOPRES FORTE contains

- The active substances are dorzolamide and timolol.
- The other ingredients are Benzalkonium chloride, Hydroxyethyl Cellulose, Mannitol, Sodium Citrate Dihydrate, Sodium Hydroxide solution 1N.

What DORZOPRES FORTE looks like and contents of the pack

DORZOPRES FORTE Eye drops solution is a colourless solution that is practically clear and practically free of particles.

DORZOPRES FORTE is available in a 10 mL LDPE bottle with dropper and seal.

Each bottle contains 5 mL of DORZOPRES FORTE.

The following pack sizes are available: cartons containing 1 or 3's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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