

Approved Patient Information Leaflet for Medicines for Human Use:

DORZOPRES

SCHEDULING STATUS: S3

DORZOPRES, 20 mg/mL Eye Drops Solution

Dorzolamide (as hydrochloride)

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

Read all of this leaflet carefully before you start using DORZOPRES

- 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.
- DORZOPRES 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.
- If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What DORZOPRES is and what it is used for

DORZOPRES is a sterile eye drops solution.

The active substance is dorzolamide. Dorzolamide belongs to a group of medicines called "carbonic anhydrase inhibitors".

DORZOPRES is used to lower raised pressure in the eye and to treat glaucoma. DORZOPRES can be used alone or in addition to other medicines which lower the pressure in the eye.

2. What you need to know before you use DORZOPRES

Do not use DORZOPRES

- if you are hypersensitive (allergic) to dorzolamide hydrochloride or any of the other ingredients of DORZOPRES (listed in section 6).
- if you have severe kidney problems, or have had a condition called "kidney stones".
- if you wear contact lenses.

Warnings and precautions

Take special care with DORZOPRES

- Tell your doctor about any medical problems you currently have or have had in the past, and about any allergies to any medications.
- If you suspect that DORZOPRES is causing an allergic reaction (e.g. skin rash or itching), stop its use and contact your doctor at once.
- 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 contact lenses, you should consult your doctor before using DORZOPRES.
- Tell your doctor if you have liver problems now or have had liver problems.

- Tell your doctor if you have problems with the cornea in your eye, or if you have had eye surgery. The cornea in your eye might get swollen (a condition called “corneal oedema”) or even dehydration of the cornea in your eye (irreversible corneal decomposition) which can affect your sight.

Children and adolescents

DORZOPRES has been studied in infants and children less than 6 years of age who have raised pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

Other medicines and DORZOPRES

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

Pregnancy, breastfeeding and fertility

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 taking this medicine. Your doctor will decide if you should use DORZOPRES.

Safety during pregnancy and breastfeeding has not been established.

Driving and using machines

Possible side effects associated with DORZOPRES such as dizziness and visual disturbances may affect the ability to drive and use machines.

It is not always possible to predict to what extent DORZOPRES may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DORZOPRES affects them.

DORZOPRES contains Benzalkonium chloride

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back in 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 health care provider.

3. How to use DORZOPRES

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

Always use DORZOPRES exactly as your doctor has instructed you. Check with your doctor if you are not sure.

Dose

When DORZOPRES is used alone, the dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.

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

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

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 the drug without consulting your doctor. If you must stop treatment, contact your doctor immediately.

If you have the impression that the effect of DORZOPRES 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 doctor. **DO NOT LET YOUR EYE OR EYELID TOUCH THE DROPPER TIP.**



6. After using DORZOPRES 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 doctor.
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 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 that your doctor 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 with another eye drop, the drops should be instilled at least 10 minutes apart.

If you are use more DORZOPRES than you should

In the event of overdose, 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

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

It is important to use DORZOPRES as prescribed by your doctor.

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

DORZOPRES should be used every day to work properly. If you stop using DORZOPRES 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 can have side effects.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Burning and stinging, superficial punctate keratitis, tearing, conjunctivitis, eyelid inflammation, eye itching, eyelid irritation, blurred vision
- Nausea, bitter taste
- Asthenia/fatigue

Less frequent side effects:

- Dizziness, paraesthesia
- Iridocyclitis, irritation including redness, pain, eyelid crusting, transient myopia (which resolved upon discontinuation of therapy), corneal oedema, ocular hypotony, choroidal detachment following filtration surgery.

- Epistaxis
- Throat irritation, dry mouth
- contact dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis
- urolithiasis
- Hypersensitivity: signs and symptoms of local reactions (palpebral reactions) and systemic allergic reactions, including angioedema, urticaria and pruritus, rash, shortness of breath, rarely bronchospasm

Side effects with frequency unknown:

- Foreign body sensation in eye
- palpitations
- Dyspnoea

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 DORZOPRES.

5. How to store DORZOPRES

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.

Austell Pharmaceuticals (Pty) Ltd, 550345-6, DORZOPRES Eye Drops Solution, 20 mg/mL

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.

6. Contents of the pack and other information

What DORZOPRES contains

- The active substance is dorzolamide.
- The other ingredients are: Mannitol, Sodium Citrate Dihydrate, Hydroxyethyl Cellulose, Benzalkonium Chloride, Sodium Hydroxide solution 1 N.

What DORZOPRES looks like and contents of the pack

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

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

Each bottle contains 5 mL of DORZOPRES.

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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