PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

TRUSOPT® 2 % Ophthalmic Solution

Active substance(s)

Dorzolamide

Read all of this leaflet carefully before you start using

TRUSOPT 2 %®

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

1. What TRUSOPT® 2 % is and what it is used for

TRUSOPT® 2 % is a sterile eyedrop.

TRUSOPT® 2 % contains 2 % dorzolamide hydrochloride, a sulphonamide related compound as the active ingredient.

TRUSOPT® 2 % is prescribed to lower raised pressure in the eye in the treatment of glaucoma.

2. What you need to know before you use TRUSOPT® 2 %

Do not use TRUSOPT® 2 %:

- if you are hypersensitive (allergic) to dorzolamide or any of the other ingredients of TRUSOPT® 2 % (listed in section 6),
- if you have moderate to severe 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 have liver problems now, or in the past, tell your doctor.

Warnings and precautions

Tell your doctor about any medical problems you have now or have had in the past, and about any allergies to any medications.

Take special care with TRUSOPT® 2 %

- If you suspect that TRUSOPT® 2 % 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 TRUSOPT® 2 %.

Children and adolescents

TRUSOPT® 2 % 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.

Use in elderly

In studies with TRUSOPT® 2 %, the effects of TRUSOPT® 2 % were similar in both elderly and younger patients.

Other medicines and TRUSOPT® 2 %

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

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 health care provider for advice before taking this medicine.

Pregnancy

Your doctor will decide if you should use TRUSOPT® 2 %. The safety of this medicine in pregnant and lactating women has not been established.

Breastfeeding

Do not use TRUSOPT® 2 % while breastfeeding. If you intend to breastfeed, consult your doctor.

Driving and using machines

There are side effects associated with TRUSOPT® 2 % that may affect your ability to drive and/or operate machinery (see “Possible side effects”).

TRUSOPT® 2 % contains the preservative benzalkonium chloride.

This preservative may be deposited in soft contact lenses. If you wear contact lenses consult your doctor before using TRUSOPT® 2 %.

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 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.

3. How to use TRUSOPT® 2 %

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

Always use TRUSOPT® 2 % exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will establish the appropriate dose and duration of treatment.

The usual dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening, when TRUSOPT® 2 % is used alone.

If your doctor has recommended you use TRUSOPT® 2 % with a beta-blocker eye drop to lower eye pressure, then the dose is one drop of TRUSOPT® 2 % in the affected eye(s) in the morning and in the evening.

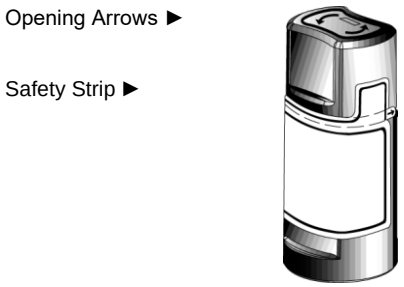
If you are using TRUSOPT® 2 % with another eye drop, the drops should be instilled at least 10 minutes apart.

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

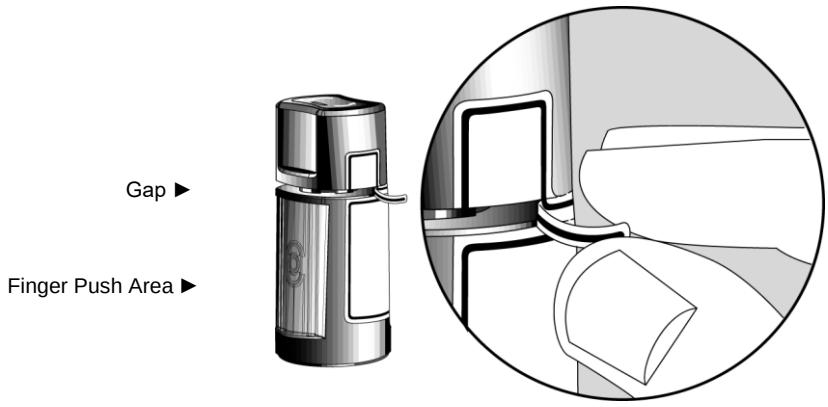
Do not change the dosage of the medicine without consulting your doctor. If you must stop treatment, contact your doctor immediately.
If you have the impression that the effect of TRUSOPT® 2 % is too strong or too weak, talk to your doctor or pharmacist.

Instructions for use

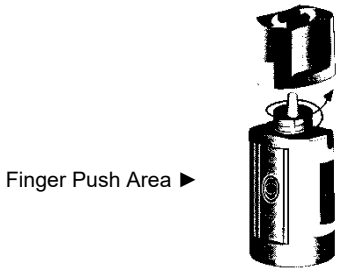
1. Before using the medication for the first time, be sure the Safety Strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.



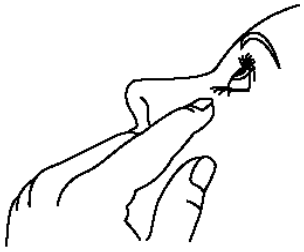
2. Tear off the Safety Strip to break the seal.



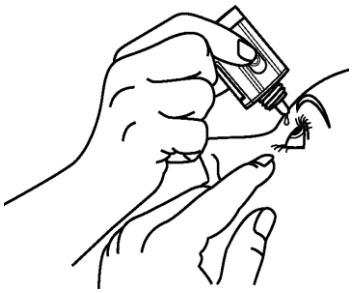
3. To open the bottle, unscrew the cap by turning as indicated by the arrows on the top of the cap. Do not pull the cap back directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.

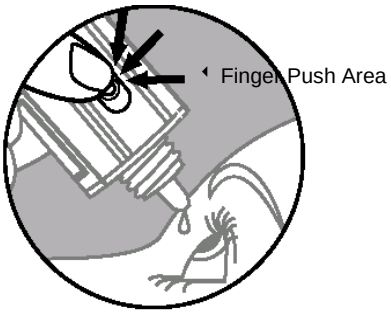


4. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.



5. Invert the bottle and press lightly with the thumb or index finger over the “Finger Push Area” (as shown) until a single drop is dispensed into the eye as directed by your doctor.





DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP.

Ophthalmic medications, if handled improperly, can become contaminated by common bacteria known to cause eye infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated ophthalmic medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

6. If drop dispensing is difficult after opening for the first time, replace the cap on the bottle and tighten (DO NOT OVERTIGHTEN) and then remove by turning the cap in the opposite direction as indicated by the arrows on top of the cap.
7. Repeat steps 4 and 5 with the other eye if instructed to do so by your doctor.
8. Replace the cap by turning until it is firmly touching the bottle. The arrow on the left side of the cap must be aligned with the arrow on the left side of the bottle label for proper closure. Do not over-tighten 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 TRUSOPT® 2 % left in the bottle. You should not be concerned since an extra amount of TRUSOPT® 2 % has been added and you will get the full amount of TRUSOPT® 2 % that your doctor prescribed. Do not attempt to remove excess medicine from the bottle

If you use more TRUSOPT® 2 % than you should

If the contents of the bottle are swallowed, you should 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 TRUSOPT® 2 %

It is important to use TRUSOPT® 2 % 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 TRUSOPT® 2 %

If you want to stop using this medicine talk to your doctor first.

4. Possible side effects

TRUSOPT® can have side effects.

Not all side effects reported for TRUSOPT® are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

Although not all these side effects may occur, if they do occur, you may need medical attention.

Serious side effects:

If any of the following happens, stop using TRUSOPT® 2 % and contact your doctor or go to the casualty department at your nearest hospital.

- 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRUSOPT® 2 %. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- bitter taste after putting in your eye drops,
- disease of the cornea with sore eye and blurred vision (superficial punctate keratitis),
- burning and stinging of the eyes, blurred vision, itching, tearing, redness of the eye(s), swelling and/or irritation of the eyelids,
- headache,
- nausea,
- tiredness.

Less frequent side effects:

- development of fluid under the retina (choroidal detachment, following filtration surgery),
- eye pain or crusting of the eyelids, swelling of the cornea (with symptoms of visual disturbances),
- allergic type reactions such as rash, hives, itching, in rare cases possible swelling of the lips, eyes and mouth, wheezing, or severe skin reactions (Stevens Johnson syndrome, toxic epidermal necrolysis),
- kidney stones,
- dizziness, tingling sensation,
- dry mouth, throat irritation,
- nose bleed.

Frequency not known:

- forceful heartbeat that may be rapid or irregular (palpitations),
- shortness of breath, feeling out of breath,
- feeling of having something in the eye

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 or nurse. 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 TRUSOPT® 2 %. Alternatively report to the following e-mail address: ZADrugsafety@mundipharma.co.za

5. How to store TRUSOPT® 2 %

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light.
- Do not use this medicine after the month and year of Expiry on the container.
- Do not use more than 30 days after opening.
- 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 TRUSOPT® 2 % contains

- TRUSOPT® 2 % is a sterile eye drop.
- The active substance is dorzolamide hydrochloride, a sulphonamide related compound.
- Each ml of TRUSOPT® 2 % contains 20 mg dorzolamide.
- The other ingredients are benzalkonium chloride (0,0075 % *m/v*), hydroxyethyl cellulose, mannitol, sodium citrate (dihydrate), sodium hydroxide and water for injection. Benzalkonium chloride is added as a preservative.

What TRUSOPT® 2 % looks like and contents of the pack

TRUSOPT® 2 % is a clear, colourless to nearly colourless, slightly viscous solution.

TRUSOPT® 2 % Ophthalmic Solution is supplied in Ocumeter™ containers containing 5 ml solution.

Tamper evidence is provided by a safety strip on the container label.

Holder of Certificate of Registration

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Registration number

South Africa: S3

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Namibia: NS2

13/15.4/0014

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

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