

PACKAGE LEAFLET: INFORMATION FOR THE USER

TRUSOPT

20 mg/ml eye drops, solution

DORZOLAMIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What TRUSOPT is and what it is used for
2. Before you take TRUSOPT
3. How to take TRUSOPT
4. Possible side effects
5. How to store TRUSOPT
6. Further information

1. WHAT TRUSOPT IS AND WHAT IS IT USED FOR

TRUSOPT contains dorzolamide which belongs to a group of medicines called "carbonic anhydrase inhibitors."

This medicine is prescribed to lower raised pressure in the eye and to treat glaucoma. This medicine can be used alone or in addition to other medicines which lower the pressure in the eye (so-called beta-blockers).

2. BEFORE YOU TAKE TRUSOPT

Do not use TRUSOPT:

- if you are allergic to dorzolamide hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney impairment or problems, or a prior history of kidney stones.

Warnings and precautions

Talk to your doctor or pharmacists before using TRUSOPT.

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

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 suspect that TRUSOPT is causing an allergic reaction (for example, skin rash, severe skin reaction, or itching), stop using this medicine and contact your doctor immediately.

Use in children

TRUSOPT 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, the effects of this medicine were similar in both elderly and younger patients.

Use in patients with liver impairment

Tell your doctor about any liver problems you now have or have suffered from in the past.

Other medicines and TRUSOPT

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines (including eye drops). This is particularly important if you are taking another carbonic anhydrase inhibitor such as acetazolamide, or a sulpha drug.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Use in pregnancy

You should not use this medicine during pregnancy. Tell your doctor if you are pregnant or intend to become pregnant.

Use in breast-feeding

If treatment with this medicine is required, breast-feeding is not recommended. Tell your doctor if you are breast-feeding or intend to breast-feed.

Driving and using machines

No studies on the effects on the ability to drive or use machines have been performed. There are side effects associated with TRUSOPT, such as dizziness and blurred vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until you feel well or your vision is clear.

TRUSOPT contains benzalkonium chloride

TRUSOPT contains the preservative benzalkonium chloride. This preservative may be deposited in soft contact lenses and may possibly discolor the lenses. If you wear contact lenses, you should consult your doctor before using this medicine.

3. HOW TO TAKE TRUSOPT

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The appropriate dosage and duration of treatment will be established by your doctor.

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

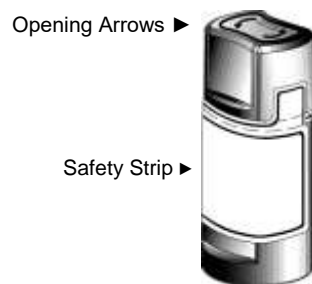
If your doctor has recommended you use this medicine with a beta-blocker eye drop to lower eye pressure, then the recommended dose is one drop of TRUSOPT in the affected eye(s) in the morning and in the evening.

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

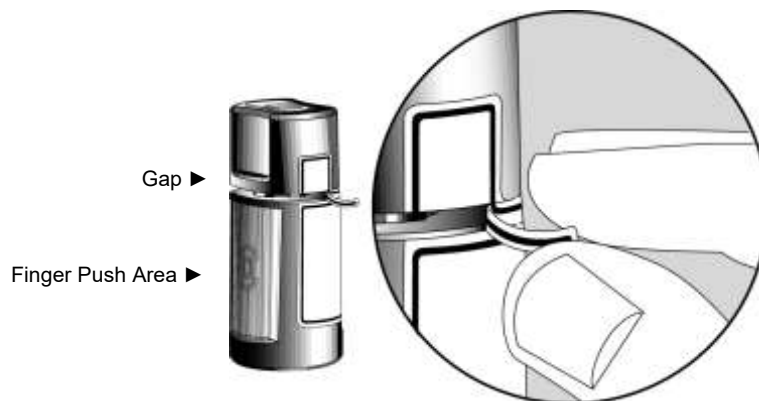
Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination, wash your hands before using this medicine and keep the tip of the container away from contact with any surface. 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.

Instructions for use:

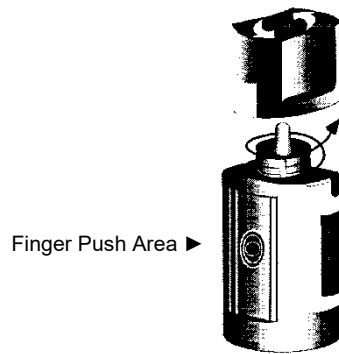
1. Before using the medication for the first time, be sure the Safety Strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.



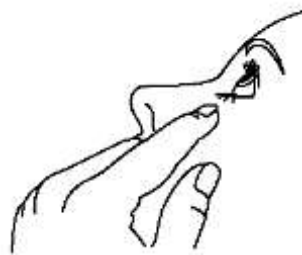
2. First wash your hands, then tear off the Safety Strip to break the seal.



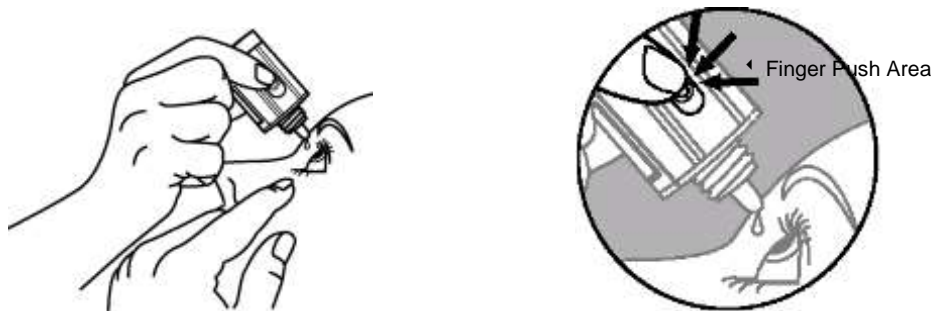
3. To open the bottle, unscrew the cap by turning as indicated by the arrows on the top of the cap. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.



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.

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 directions as indicated by the arrows on the top of the cap.
7. Repeat steps 4 & 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 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 medicine left in the bottle. You should not be concerned since an extra amount of medicine has been added and you will get the full amount of medicine that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

If you use more TRUSOPT than you should

If you put too many drops in your eye or swallow any of the contents of the container, you should contact your doctor immediately.

If you forget to use TRUSOPT

It is important to take this medicine as prescribed by your doctor. If you miss a dose, take 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.

Do not take a double dose to make up for the forgotten dose.

If you stop using TRUSOPT

If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you develop allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, you should stop using this medicine and seek immediate medical advice.

The following side effects have been reported with TRUSOPT either during clinical trials or during post-marketing experience:

Very Common side effects: (affects more than 1 user in 10)

Burning and stinging of the eyes.

Common side effects: (affects 1 to 10 users in 100)

Disease of the cornea with sore eye and blurred vision (superficial punctate keratitis), discharge with itching of the eyes (conjunctivitis), irritation/inflammation of the eyelid, blurred vision, headache, nausea, bitter taste, and fatigue.

Uncommon side effects: (affects 1 to 10 users in 1,000)

Inflammation of the iris.

Rare side effects: (affects 1 to 10 user in 10,000)

Tingling or numbness of the hands or feet, temporary shortsightedness which may resolve when treatment is stopped, development of fluid under the retina (choroidal detachment, following filtration surgery), eye pain, eyelid crusting, low pressure in the eye, swelling of the cornea (with symptoms of visual disturbances), eye irritation including redness, kidney stones, dizziness, nose bleed, throat irritation, dry mouth, localized skin rash (contact dermatitis), severe skin reactions, allergic type reactions such as rash, hives, itching, in rare cases possible swelling of the lips, eyes and mouth, shortness of breath, and more rarely wheezing.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRUSOPT

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated by the six numbers following EX (or EXP) on the bottle and outer carton. The first two numbers indicate the month; the last four numbers indicate the year. The expiry date refers to the last day of the month.

TRUSOPT should be used within 28 days after the bottle is opened.

This medicinal product does not require any special temperature storage conditions.
Store bottle in outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What TRUSOPT contains

The active substance is dorzolamide.

Each ml contains 22.26 mg of dorzolamide hydrochloride equivalent to 20 mg of dorzolamide.

The other ingredients are hydroxyethyl cellulose, mannitol, sodium citrate, sodium hydroxide, and water for injections. Benzalkonium chloride is added as a preservative.

What TRUSOPT looks like and contents of the pack

TRUSOPT is a clear, colourless to nearly colourless slightly viscous solution. The OCUMETER Plus Ophthalmic Dispenser consists of a translucent high-density polyethylene container containing 5 ml of solution. Tamper evidence is provided by a safety strip on the container label.

Pack sizes:

1 x 5.0 ml (single 5 ml container)

3 x 5.0 ml (three 5 ml containers)

6 x 5.0 ml (six 5 ml containers)

Not all pack sizes may be marketed.