

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTRUSOPT®

PrTRUSOPT® Preservative-free

Dorzolamide hydrochloride ophthalmic solution

Read this carefully before you start taking **TRUSOPT or TRUSOPT Preservative-free** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TRUSOPT or TRUSOPT Preservative-free**.

What is TRUSOPT and TRUSOPT Preservative-free used for?

TRUSOPT and TRUSOPT Preservative-free lower the pressure in the eye for conditions such as ocular hypertension or open-angle glaucoma.

TRUSOPT Preservative-free does not contain a preservative. This may be prescribed to you if you are sensitive to a preservative.

How does TRUSOPT and TRUSOPT Preservative-free work?

TRUSOPT and TRUSOPT Preservative-free belong to a group of medicines called carbonic anhydrase inhibitors. TRUSOPT and TRUSOPT Preservative-free work by reducing the production of liquid in the eye. This helps lower the pressure in the eye.

What are the ingredients in TRUSOPT and TRUSOPT Preservative-free?

Medicinal ingredients: dorzolamide (present as the hydrochloride salt)

Non-medicinal ingredients: Hydroxyethyl cellulose, mannitol, sodium citrate dihydrate, sodium hydroxide (to adjust pH) and water for injection.

Benzalkonium chloride is only added as a preservative to TRUSOPT. TRUSOPT Preservative-free does not contain benzalkonium chloride.

TRUSOPT and TRUSOPT Preservative-free come in the following dosage forms:

Solution: 2% dorzolamide (dorzolamide hydrochloride)

Do not use TRUSOPT or TRUSOPT Preservative-free if:

- You are allergic to any of its components (see: What are the ingredients in TRUSOPT and TRUSOPT and TRUSOPT Preservative-free).

- You have severe kidney problems.
- You are taking oral carbonic anhydrase inhibitors.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRUSOPT or TRUSOPT Preservative-free. Talk about any health conditions or problems you may have, including if you:

- Have any medical problems now or have had any in the past, including eye (corneal) problems, or previous eye surgery;
- Have any allergies to any medications;
- TRUSOPT contains the preservative benzalkonium chloride. If you wear contact lenses, you should consult your healthcare professional before using TRUSOPT. Do not use TRUSOPT while wearing (soft) contact lenses. Remove lenses before application and reinsert no earlier than 15 minutes after use. TRUSOPT Preservative-free does not contain the preservative benzalkonium chloride;
- Are pregnant or intend to become pregnant;
- Are breast feeding or intend to breast feed;
- Have now or have had in the past liver problems;
- Have now or have had in the past kidney problems.

Other warnings you should know about:

You may find that your vision is blurred for a time just after you put TRUSOPT or TRUSOPT Preservative-free in your eye. Do not drive or use any tools or machines until your vision is clear.

TRUSOPT and TRUSOPT Preservative-free are not recommended for children under 18 years of age.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TRUSOPT or TRUSOPT Preservative-free:

- Other drugs (including eye drops) that you are using or plan to use;
- Other drugs obtained without a prescription;
- Other carbonic anhydrase inhibitors;
- Large dose of ASA (acetylsalicylic acid);
- A group of drugs known as “sulfa drugs”.

How to take TRUSOPT or TRUSOPT Preservative-free:

- Do not start taking any other medicines unless you have discussed the matter with your healthcare professional.
- If you use other eye drops, they should be used at least ten minutes apart.
- If you use TRUSOPT or TRUSOPT Preservative-free with a beta-blocker eye drop, then the dose is one drop of TRUSOPT or TRUSOPT Preservative-free in the affected eye(s) in the morning and in the evening.
- Do not change how you take this drug without talking to your healthcare professional. If you must stop taking this drug, contact your healthcare professional immediately.

TRUSOPT

1. Before using this drug 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.

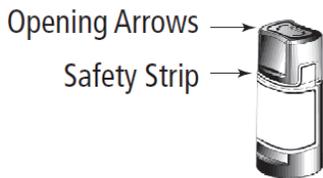


Figure A

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

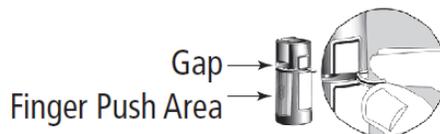
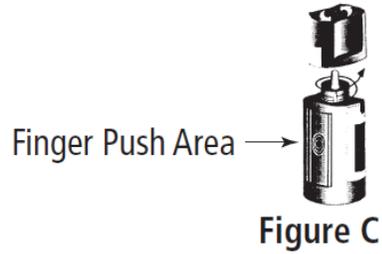


Figure B

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.



Figure D

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 healthcare professional.

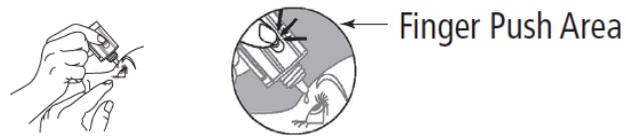


Figure E

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

Eye droppers can become contaminated with bacteria from touching the eye or around the eye area. This can cause eye infections leading to serious damage of the eye, even loss of vision. If you think your bottle may be contaminated, or if you develop an eye infection, contact your healthcare professional 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). Then, remove by turning the cap in the opposite direction as indicated by the arrows on top of the cap.

7. Repeat steps 4 & 5 with the other eye if instructed to do so by your healthcare professional.
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 TRUSOPT left in the bottle. You should not be concerned since an extra amount of TRUSOPT has been added and you will get the full amount of TRUSOPT that your doctor prescribed. Do not attempt to remove excess medicine from the bottle.

TRUSOPT Preservative-free

Use the individual pipette of TRUSOPT preservative-free immediately after opening. Discard any remaining solution immediately after use.

Usage Instructions

1. Open the foil pouch which contains 15 individual unit dose pipettes. There are three strips of 5 pipettes each in the pouch.
2. Break off one pipette from the strip and twist open the top of the pipette as shown in Figure F.

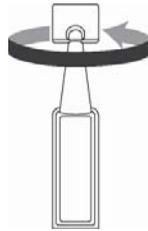


Figure F

3. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and eye as shown in Figure G.

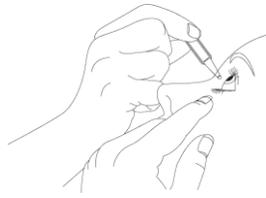


Figure G

4. Apply one drop in the affected eye(s) as directed by your healthcare professional. Each pipette contains enough solution for both eyes.
5. After application, discard the used pipette even if there is solution remaining.
6. Store the remaining pipettes in the foil pouch; the remaining pipettes must be used within 15 days.

Usual dose:

Your doctor will tell you the right dose and length of time to use TRUSOPT or TRUSOPT Preservative-free.

When TRUSOPT or TRUSOPT Preservative-free is used alone, the dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.

Overdose:

If you think you, or a person you are caring for, have taken too much TRUSOPT or TRUSOPT Preservative-free, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is important to apply TRUSOPT or TRUSOPT Preservative-free as prescribed by your physician. If you miss a dose, apply 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.

What are possible side effects from using TRUSOPT or TRUSOPT Preservative-free?

These are not all the possible side effects you may have when taking TRUSOPT or TRUSOPT Preservative-free. If you experience any side effects not listed here, tell your healthcare professional.

You may experience eye symptoms such as:

- Burning and stinging
- Blurred vision
- Itching
- Tearing
- Redness of the eye(s)
- Eye pain
- Swelling of the eyelids
- Crusting of the eyelids
- Eyelid irritation
- Sensitivity to light
- A feeling of something in the eye

Other side effects may include:

- Bitter taste after putting in your eye drops
- Headache
- Nosebleed
- Dry mouth
- Throat irritation
- Nausea
- Tiredness
- Dizziness
- Numbness or tingling of the skin
- Itchy skin

If the contents of the container are swallowed, you should contact your healthcare professional immediately.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Allergic Reaction: rash, hives, swelling of the mouth, throat, and lips, difficulty breathing, blue skin, shock, loss of consciousness, low blood pressure			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Stevens-Johnson syndrome (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			✓
Toxic Epidermal Necrolysis (severe skin reaction): redness, blistering and/or peeling of large areas of the skin			✓
Urolithiasis (Kidney stones): pain when urinating, severe pain in the side and back, below the ribs			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:**TRUSOPT:**

Store at 15°-25°C. Protect from light.

TRUSOPT Preservative-free:

Store at 15°-25°C. Protect from light. Store in protective foil pouch.

Do not use this medicine after the date shown on the container.

Keep out of reach and sight of children.

If you want more information about TRUSOPT or TRUSOPT Preservative-free:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.elvium.ca, or by calling 1-833-744-0005.

This leaflet was prepared by Elvium Life Sciences.

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