

CONSUMER INFORMATION

Pr **TRUSOPT**[®]

dorzolamide hydrochloride ophthalmic solution

This leaflet is part III of a three-part "Product Monograph" published when TRUSOPT[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TRUSOPT[®]. Contact your physician or pharmacist if you have any questions about the drug.

Read the following information carefully. **If you need any explanations, or further information, ask your physician or pharmacist.**

ABOUT THIS MEDICATION

What the medication is used for:

TRUSOPT[®] is the brandname for the medication dorzolamide hydrochloride available **only on prescription** through your physician. TRUSOPT[®] is an ophthalmic carbonic anhydrase inhibitor. TRUSOPT[®] is prescribed to lower the raised pressure in your eye(s) because you have increased pressure in your eye(s) or glaucoma.

TRUSOPT[®] preservative-free formulation is indicated in patients who may be sensitive to a preservative, or for whom the use of a preservative-free formulation is otherwise advisable.

What it does:

TRUSOPT[®] inhibits the enzyme carbonic anhydrase to reduce production of the watery secretion of the eye, which helps reduce the pressure in your eye.

Remember - This medicine is prescribed for the particular condition that you have. Do not give this medicine to other people, nor use it for any other condition.

When it should not be used:

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

Do not use TRUSOPT[®] if you:

- are allergic to any of its components (see: What the important nonmedicinal ingredients are).
- have severe kidney problems.
- are taking oral carbonic anhydrase inhibitors.

What the medicinal ingredient is:

2% dorzolamide present as the hydrochloride salt, a sulfonamide-related compound.

What the important nonmedicinal ingredients are:

hydroxyethyl cellulose, mannitol, sodium citrate dihydrate, sodium hydroxide and water for injection. Benzalkonium

chloride is only added as a preservative to TRUSOPT[®] Ophthalmic Solution. TRUSOPT[®] preservative-free formulation does not contain benzalkonium chloride.

What dosage forms it comes in:

TRUSOPT[®] and TRUSOPT[®] preservative-free formulation ophthalmic solution 2% are sterile eye drops.

WARNINGS AND PRECAUTIONS

This medicine may not be suitable for some patients. So, tell your physician if you think **any** of the following applies to you:

- If you have any medical problems now or have had any in the past, including eye (corneal) defects, or previous eye surgery while using dorzolamide;
- If you are using any other medications (see INTERACTIONS WITH THIS MEDICATION);
- If you have any allergies to any medications;
- TRUSOPT[®] contains the preservative benzalkonium chloride. If you wear contact lenses, you should consult your physician before using TRUSOPT[®]. Do not administer while wearing (soft) contact lenses. Remove lenses before application and reinsert no earlier than 15 minutes after use. TRUSOPT[®] preservative-free formulation has not been studied in patients wearing contact lenses;
- If you are pregnant or intend to become pregnant;
- If you are breast feeding or intend to breast feed;
- If you have now or have had in the past kidney or liver problems.

If any of the following occur during treatment with TRUSOPT[®], consult your physician immediately:

- if you suspect that TRUSOPT[®] is causing an allergic reaction such as skin rash or itching or other reactions in the eye, such as conjunctivitis;
- if you develop any eye infection or any eye irritation or any new eye problem such as redness of the eye or swelling of the eyelids;
- if you have any eye surgery or suffer eye injury;
- if you have severe skin reactions with symptoms such as blisters, peeling skin, red/purple rash, skin lesions and sores, and associated fever, sore throat.

TRUSOPT® IS NOT RECOMMENDED FOR CHILDREN.

In studies with TRUSOPT®, the effect of TRUSOPT® was similar in both elderly and younger adult patients.

INTERACTIONS WITH THIS MEDICATION

Your physician also needs to know about drugs (including eye drops) that you are using or plan to use, including drugs obtained without a prescription, in particular, large doses of ASA (acetylsalicylic acid) or sulfa drugs.

PROPER USE OF THIS MEDICATION

- Do not start taking any other medicines unless you have discussed the matter with your physician.
- If more than one topical ophthalmic drug is being utilized, the drugs should be administered at least ten minutes apart.
- If your physician has recommended you use TRUSOPT® with a beta-blocker eye drop to lower eye pressure, then the dose is one drop of TRUSOPT® in the affected eye(s) in the morning and in the evening.
- Do not change the dosage of the drug without consulting your physician. If you must stop treatment, contact your physician immediately.
- 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 of the container, keep the tip of the container away from contact with any surface.

Usual Adult dose:

The appropriate dosage and duration of treatment will be established by your physician.

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

Missed Dose:

It is important to apply TRUSOPT® 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.

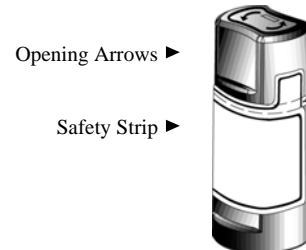
Overdose:

For management of a suspected drug overdose, particularly oral ingestion, contact your Regional Poison Control Centre even if there are no symptoms.

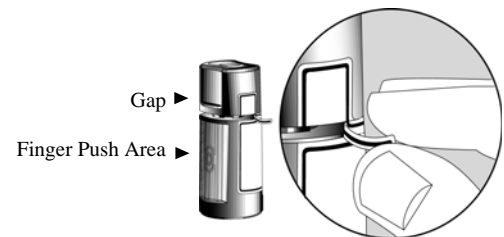
INSTRUCTIONS FOR USE

TRUSOPT® Ophthalmic Solution

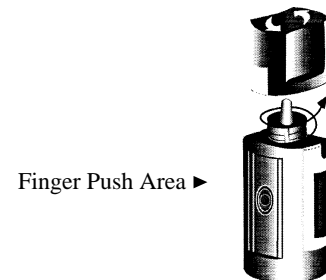
1. Before using the medication for the first time, be sure the Safety Strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.



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 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.



- 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.

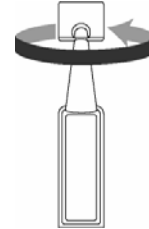
- If drop dispensing is difficult after opening for the first time, replace the cap on the bottle and tighten (DO NOT OVERTIGHTEN) and then remove by turning the cap in the opposite direction as indicated by the arrows on top of the cap.
- Repeat steps 4 & 5 with the other eye if instructed to do so by your doctor.
- Replace the cap by turning until it is firmly touching the bottle. Do not overtighten or you may damage the bottle and cap.
- The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.
- 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 Formulation Ophthalmic Solution

The solution from one individual unit dose pipette of TRUSOPT[®] preservative-free formulation is to be used immediately after opening for administration to the affected eye(s). Since sterility cannot be maintained after the individual unit dose pipette is opened, any remaining contents must be discarded immediately after administration.

Usage Instructions

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



- Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and eye as shown in Figure 2.



- Instill one drop in the affected eye(s) as directed by your physician. Each pipette contains enough solution for both eyes.
- After instillation, discard the used pipette even if there is solution remaining.
- Store the remaining pipettes in the foil pouch; the remaining pipettes must be used within 15 days.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Any medicine may have unintended or undesirable effects, so-called side effects.

You may experience eye symptoms such as burning and stinging, blurred vision, itching, tearing, redness of the eye (s), eye pain, or swelling or crusting of the eyelids. You may sense a bitter taste after putting in your eye drops.

Other side effects may include headache, nosebleed, dry mouth, nausea, tiredness, kidney stones and rarely, rash such as severe skin reactions. If you develop a severe skin reaction with symptoms such as blisters, peeling skin, red/purple rash, skin lesions and sores, and associated fever, sore throat, stop taking this medication immediately and contact your physician.

There have been post-marketing experience reports of allergic reactions to TRUSOPT[®] with symptoms such as tissue swelling, difficulty in breathing, itching, and urticaria (raised skin rash). If this occurs, stop taking this medication and contact your physician.

Your physician or pharmacist has a complete list of the possible side effects from this medication. Please tell your physician or pharmacist promptly about any unusual symptom.

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

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

This is not a complete list of side effects. For any unexpected effects while taking TRUSOPT[®], contact your physician or pharmacist.

HOW TO STORE IT

TRUSOPT[®] Ophthalmic Solution:

Store at 15°-25°C (59° - 77°F). Protect from light.

TRUSOPT[®] Preservative-free Formulation Ophthalmic Solution:

Store at 15°-25°C (59° - 77°F). Protect from light. Store in protective foil pouch.

Keep all medicines safely away from children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance program by one of the following 3 ways:

- Call toll-free at 1-866-234-2345
- Report online at:
www.healthcanada.gc.ca/medeffect
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789 or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reactions reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

or at Merck Frosst Canada Ltd. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-877-428-8675 or
 - Mail to: Merck Frosst Canada Ltd.
P.O. Box 100
Pointe-Claire - Dorval, QC
H9R 4P8

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program or Merck Frosst do not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.merckfrosst.com>
or by contacting the sponsor, Merck Frosst Canada Ltd., at: 1-800-567-2594.

This leaflet was prepared by Merck Frosst Canada Ltd.

Last revised: April 21, 2010

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