Information for the patient: Sandoz Travoprost (travoprost) Ophthalmic Solution.

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again. If you still have questions after reading it, please ask your doctor or your pharmacist.

The active substance is travoprost 0.040 mg/mL.

Other ingredients: Preservative: solZia® preservative system (boric acid, propylene glycol, sorbitol, zinc chloride), polyoxyl 40 hydrogenated castor oil, and purified water. Tiny amounts of hydrochloric acid or sodium hydroxide are added to maintain proper pH balance.

1. WHAT SANDOZ TRAVOPROST OPHTHALMIC SOLUTION DOES
Sandoz Travoprost ophthalmic solution is used to treat high pressure in the eye. This pressure can lead to an illness called glaucoma.

High pressure in the eye. Your eyeballs contain a clear, watery liquid which feeds the inside of the eye. Liquid is always emptying out of the eye, and more liquid is always being produced. If the eye fills up faster than it empties, the pressure inside the eye builds up. If it gets too high, it can damage your sight.

Sandoz Travoprost ophthalmic solution is one of a group of medicines for glaucoma which contain prostaglandin analogues. It works by increasing the outflow of liquid, which lowers the pressure in the eye. It may be used on its own or with other glaucoma eye drops, which also reduce pressure.

Sandoz Travoprost ophthalmic solution is a liquid (a colorless to light yellow solution) supplied in a 5 mL plastic bottle with a screw cap.

2. BEFORE YOU USE SANDOZ TRAVOPROST OPHTHALMIC SOLUTION
Do not use Sandoz Travoprost ophthalmic solution...

• If you are allergic to prostaglandin analogues or any of the other ingredients (see Other ingredients):
• If you are pregnant, or trying to become pregnant.

Ask your doctor for advice.

Take special care using Sandoz Travoprost ophthalmic solution...

• If you wear soft contact lenses. Don’t use the drops with your lenses already in place. Wait 15 minutes after using the drops before putting your lenses back in.
• If you are breast-feeding, Sandoz Travoprost ophthalmic solution may get into your breast milk. Ask your doctor for advice.
• Sandoz Travoprost ophthalmic solution is not to be used by people under 18 years of age.
• Sandoz Travoprost ophthalmic solution may increase the length, thickness, color and/or number of your eyelashes.
• Sandoz Travoprost ophthalmic solution may change the color of your eye. It may make your iris (the colored part of your eye) more brown.
• If you use Sandoz Travoprost ophthalmic solution in one eye only, the possible change in color in your iris, the skin around the eye or the change in the eyelashes may appear in the treated eye only.
• These changes in pigmentation and lash growth may be permanent.

If the product comes into contact with the skin then it should be washed off straight away.

Tell your doctor if you will be having eye surgery.

Tell your doctor immediately if you develop an eye infection, irritation or suffer any damage to your eye while taking Sandoz Travoprost ophthalmic solution.

Driving or using machines
You may find that your vision is blurred for a short time just after you use Sandoz Travoprost ophthalmic solution.

Do not drive or use machines until your vision is clear.

Please tell your doctor or pharmacist if you are taking (or recently took) any other medicines.

Also mention those medicines that you bought without prescription.

3. HOW TO USE SANDOZ TRAVOPROST OPHTHALMIC SOLUTION

The usual dose
Adults: 1 drop in the eye or eyes, once a day. Evening is the best time to take your medication.

Only use Sandoz Travoprost ophthalmic solution in both eyes if your doctor told you to. Take it for as long as your doctor told you to.

Only use Sandoz Travoprost ophthalmic solution in your eyes.

How to use
• Get the Sandoz Travoprost ophthalmic solution bottle and a mirror (if needed).
• Wash your hands.
• Twist-off the cap.
• Hold the bottle, pointing down, between your thumb and fingers.
• Tilt your head back. Pull down your eyelid with a clean finger, until there is a ‘pocket’ between the eyelid and your eye. The drop will go in here (picture 1).
• Bring the bottle tip close to the eye. Use the mirror if it helps.
• Don’t touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could get germs on the dropper tip.
• Gently squeeze the bottle to release one drop of Sandoz Travoprost ophthalmic solution at a time (picture 2).
• If you take drops in both eyes, repeat the steps for your other eye.
• Put the bottle cap back on tightly after use.

If a drop misses your eye, wipe it off with a tissue and try again.

If you forget to use Sandoz Travoprost ophthalmic solution, take your next scheduled dose. Do not use a double dose to make up.

If you are using other eye drops, wait at least 5 minutes between putting in Sandoz Travoprost ophthalmic solution and the other drops.

Overdosage:

In case of drug overdose, particularly accidental oral ingestion, contact your doctor, hospital emergency department, or regional Poison Control Centre, even if there are no symptoms.

If you accidentally use too many drops, just go back to your regular once a day dosing the next day. If you have any concerns, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Some people who use Sandoz Travoprost Ophthalmic Solution may have side effects. They can be unpleasant, but most of them soon pass.

You can usually carry on taking the drops, unless the effects are serious. If you’re worried, talk to your doctor or pharmacist.
Common side effects
The following may affect approximately 1 in every 3 people: Redness of the eye. Approximately 80 to 90% of the redness reported in clinical trials was mild and lessened over time without treatment.

One or more of these may affect approximately 5 in every 100 people:
- Burning or stinging upon instillation.
- Itchy eye.
- Change of color of the iris.
- Dry eye.
- Foreign body sensation.
- Itchiness of the eyelids.
- Pain in the eye.
- Blurred vision.
- Decreased vision.
- Sensitivity to light.
- Headache.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- 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 0701E
    Ottawa, (Ontario) K1A 0K9

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

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

5. STORING SANDOZ TRAVOPROST OPHTHALMIC SOLUTION
Keep the drops in a safe place where children can’t see or reach them.

This medicine has been prescribed for you personally. You must not pass it on to other people. It may harm them even if they have the same illness as you.

Store at 2-25°C. No refrigeration required.

Don’t use the drops after the expiry date (marked “Exp”) on the bottle and the box.

If you have any other questions about your medicines you should ask a doctor or pharmacist.

6. MORE INFORMATION
This document, plus the full Product Monograph prepared for health professionals, can be obtained by contacting the sponsor, Sandoz Canada Inc., at:

1-800-361-3062

or by written request at:

145, Jules-Léger
Boucherville, (QC), Canada
J4B 7K8

or by e-mail at: medinfo@sandoz.com

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