CONSUMER INFORMATION

Pr Sandoz Travoprost / Timolol PQ ophthalmic solution
travoprost and timolol ophthalmic solution
with POLYQUAD* as preservative

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Sandoz Travoprost / Timolol PQ. 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:**

Increased pressure in the eye(s) is found in patients who have open-angle glaucoma or high pressure in the eyes (ocular hypertension). If left untreated, the increased pressure can lead to nerve damage within the eye, ultimately affecting eyesight.

Sandoz Travoprost / Timolol PQ is a fixed combination of two drugs, travoprost and timolol, that are used to lower raised pressure in the eye(s) in adults with open-angle glaucoma or ocular hypertension.

**What it does:**

Sandoz Travoprost / Timolol PQ lowers the pressure in your eye(s) through the action of:

- **travoprost** (a prostaglandin analogue) – works by increasing the flow of fluid out of the eye.
- **timolol** (a beta-blocker) – works by decreasing the amount of fluid produced by the eye.

**When it should not be used:**

**Do not use Sandoz Travoprost / Timolol PQ if you:**

- ...have, or have ever had, an unusual or allergic reaction to travoprost, timolol or any other ingredient in Sandoz Travoprost / Timolol PQ (See **What the important nonmedicinal ingredients are**).
- ...are pregnant or planning to become pregnant.
- ...have, or have had, a lung condition, such as asthma or chronic obstructive pulmonary disease (COPD).
- ...have certain types of a heart condition, heart disease, or heart problems, such as sick sinus syndrome, sino-atrial block, heart failure or low heart rate (*bradycardia*).

* POLYQUAD is a trademark of Novartis AG.
What the medicinal ingredients are:
Sandoz Travoprost / Timolol PQ contains 0.04 mg/mL of travoprost and 5 mg/mL of timolol (as timolol maleate).

What the important nonmedicinal ingredients are:
Preservative: POLYQUAD* (polyquaternium-1)
Others: mannitol, polyoxyethylene hydrogenated castor oil 40, propylene glycol, boric acid, sodium chloride, and purified water. Tiny amounts of sodium hydroxide or hydrochloric acid are added to keep acidity levels (pH levels) normal.

What dosage form it comes in:
Sandoz Travoprost / Timolol PQ is a sterile eye drop supplied as a 2.5 mL solution in a 4 mL bottle or 5 mL solution in a 7.5 mL bottle.

WARNINGS AND PRECAUTIONS

BEFORE you use Sandoz Travoprost / Timolol PQ talk to your doctor or pharmacist if you:
- have diabetes, low blood sugar (hypoglycemia), a thyroid condition (thyrotoxicosis) or kidney problems.
- have muscle weakness or have been diagnosed with myasthenia gravis (a condition causing abnormal weakness in some muscles), have heart disease, low blood pressure, circulation problems or problems with blood circulation to the brain, are breastfeeding or planning to breast-feed, are planning to have surgery.
- have had a severe allergic (anaphylactic) reaction.
- have had cataract surgery, an eye injury or eye inflammation, are using other beta-blockers or prostaglandin analogues.

STOP taking Sandoz Travoprost / Timolol PQ if you develop an allergic reaction.

While using Sandoz Travoprost / Timolol PQ
Talk to your doctor if the following occurs while taking Sandoz Travoprost / Timolol PQ:
- you develop an eye or eyelid infection.
- you injure your eye(s).
- you plan to have surgery on your eye(s).

Pressure in your eye(s)
Your doctor should check the pressure in your eye(s) regularly.

Eye color and eyelash changes
Using Sandoz Travoprost / Timolol PQ may cause your eye color to become more brown or cause your eyelashes to become thicker, longer and darker. These changes may be permanent. If

* POLYQUAD is a trademark of Novartis AG.
you are using Sandoz Travoprost / Timolol PQ in only one eye, your two eyes may look different. Your doctor should examine you regularly to make sure your medication is working and look for changes in eye colour. Your doctor may stop treatment if needed.

Contact lens wear
Do not wear contact lenses while using Sandoz Travoprost / Timolol PQ. Remove your contact lenses before applying Sandoz Travoprost / Timolol PQ and wait at least 15 minutes before putting them back in.

Skin contact
Sandoz Travoprost / Timolol PQ contains propylene glycol and polyoxyethylene hydrogenated castor oil, which can cause skin reactions. Avoid accidental contact with skin, eyes and mucous membranes. Wipe up any spills and rinse the contacted areas with water.

Driving and using machines
Sandoz Travoprost / Timolol PQ may cause you to become drowsy or your vision to become temporarily blurry. If any of these effects happen to you, wait until they go away before driving or using machines.

Not recommended to individuals under 18 years of age.

INTERACTIONS WITH THIS MEDICATION

No specific drug interaction studies were done using Sandoz Travoprost / Timolol PQ.

Tell your doctor about all the drugs you are taking, recently took or are planning to take, including any prescription or non-prescription drugs.

Drugs that may interact with Sandoz Travoprost / Timolol PQ include:

• ...Digitalis (used to treat congestive heart failure and heart rhythm problems).
• ...Calcium antagonists.
• ...Catecholamide-depleting drugs, e.g. reserpine (used to treat high blood pressure).
• ...Quinidine (an antiarrhythmic).
• ...Injectable epinephrine (used to treat severe allergic reactions).
• ...Central nervous system depressants.
• ...Tricyclic antidepressants.
• ...Other beta-blocking drugs.

PROPER USE OF THIS MEDICATION

Usual Adult Dose:
Use one drop of Sandoz Travoprost / Timolol PQ in the affected eye(s) once daily, either morning or evening.
**How to Use:**

- Get the Sandoz Travoprost / Timolol PQ bottle and a mirror.
- Wash your hands.
- If you wear contact lenses, remove them before using your eye drops.
- Open the bottle being careful not to touch the dropper tip. 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 there (see 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 bottle tip. It could contaminate the drops.
- Gently squeeze the bottle to release one drop of Sandoz Travoprost / Timolol PQ (see picture 2). After using Sandoz Travoprost / Timolol PQ, press a finger into the corner of your eye, by the nose (see picture 3). This helps to stop Sandoz Travoprost / Timolol PQ from getting into the rest of the body.
- If a drop misses your eye, wipe with a tissue and try again.
- If you take drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Wash your hands after use.

If you are using more than one eye drop, wait at least 5 minutes between using Sandoz Travoprost / Timolol PQ and the other drop(s).

Avoid unnecessary contact with the skin.

**Missed Dose:**

If you miss a dose, wait until it is time for your next dose. Do not double dose to make up for a missed dose.
Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional poison control centre, even if there are no symptoms.

If you use more Sandoz Travoprost / Timolol PQ than you should, rinse it all out with warm tap water. Using too many drops may cause your eyes to become red and irritated. Do not put in any more drops until it's time for your next regular dose.

If you accidentally ingest Sandoz Travoprost / Timolol PQ, contact your doctor or pharmacist for advice.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, Sandoz Travoprost / Timolol PQ may cause side effects, although not everybody gets them. They can be unpleasant, but most of them soon pass. You can usually keep taking the drops, unless the effects are serious. If you're worried, talk to your doctor or pharmacist.

Side effects in the eye(s) include: redness, itching, dryness, pain, sensitivity to light, abnormal sensation in eye or other eye irritations, blurred vision, temporary reduction of vision, tearing, growth of eyelashes and eyebrows hair, abnormally positioned eyelashes, eye swelling, discomfort (burning and stinging), changes in vision, itching, swollen, heavy, painful or irritated eyelids, inflammation of the eyelid glands, increased eye pressure, and eyelid crusting, sunken eyes (eyes appear more inset), changes in the color of the iris (colored part of the eye), skin darkening (around the eye).

Side effects in other areas of the body include: headache, postnasal drip, thirst, cough or throat pain or irritation, a change in blood pressure or heart rate, disturbance in attention, dizziness, nervousness, skin infection or irritation, skin reaction, skin redness, ear infections, pain in arms or legs, shortness of breath, difficulty breathing, fatigue, discomfort inside the nose, a change in urine color, bad taste in the mouth, strained talking or swelling in the limbs, rash.

<table>
<thead>
<tr>
<th>Symptom / effect</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and call your doctor or pharmacist</th>
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<tbody>
<tr>
<td><strong>Unknown</strong></td>
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<td>Allergic reaction</td>
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<td>Symptoms include swelling or inflammation of the eye, trouble breathing</td>
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**Serious side effects and what to do about them**

- **Unknown**
  - Allergic reaction
  - Symptoms include swelling or inflammation of the eye, trouble breathing

- **Talk with your doctor or pharmacist**
  - Only if severe
  - In all cases

- **Stop taking drug and call your doctor or pharmacist**
This is not a complete list of side effects. For any unexpected effects while taking Sandoz Travoprost / Timolol PQ, contact your doctor or pharmacist.

HOW TO STORE IT

Keep these eye drops in a safe place out of the reach and sight of children. Store between 2ºC and 25ºC. No refrigeration is required. Do not use this medicine after the expiry date on the bottle or carton. Discard 120 days after first opening.

REPORTING SUSPECTED SIDE EFFECTS

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:
- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
            Health Canada, Postal Locator 0701E
            Ottawa, ON
            K1A 0K9

  Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.sandoz.ca or 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

This leaflet was prepared by Sandoz Canada Inc.