PART III: CONSUMER INFORMATION

Sandoz® Dorzolamide/Timolol
2% Dorzolamide (as Dorzolamide Hydrochloride USP) and 0.5% Timolol (as Timolol Maleate USP)

This leaflet is part III of a three-part “Product Monograph” published when Sandoz Dorzolamide/Timolol was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about Sandoz Dorzolamide/Timolol. Contact your physician or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Sandoz Dorzolamide/Timolol is the brandname for the medication dorzolamide hydrochloride and timolol maleate available on prescription through your doctor. Sandoz Dorzolamide/Timolol is a combination of an ophthalmic carbonic anhydrase inhibiting drug and an ophthalmic beta-blocking drug, both of which lower the pressure in the eye in different ways.

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 Sandoz Dorzolamide/Timolol if you:
- are allergic to any of its components (see: “What the nonmedicinal ingredients are”),
- have now or have had in the past certain serious breathing problems such as asthma,
- have chronic obstructive lung disease,
- have certain heart diseases or conditions (such as slow or irregular heartbeats),
- have severe kidney problems,
- are taking oral carbonic anhydrase inhibitors,
- are breast feeding or intend to breast feed.

What the medicinal ingredients are:
Each mL contains 20 mg dorzolamide (as 22.3 mg of dorzolamide hydrochloride USP) and 5 mg timolol (as 6.83 mg of timolol maleate USP).

What the nonmedicinal ingredients are:
Benzalkonium chloride (as a preservative), hydroxyethylcellulose, mannitol, sodium hydroxide, sodium citrate dihydrate and water for injection.

What dosage forms it comes in:
Sandoz Dorzolamide/Timolol are sterile eye drops supplied in a white LDPE plastic DROP-TAINER® bottle, a white dropper tip and a blue polypropylene cap.

WARNINGS AND PRECAUTIONS

This medicine may not be suitable for some patients. So, tell your doctor if you think any of the following applies to you:
- If you have any medical problems now or have had any in the past, lung or breathing (such as asthma or chronic obstructive lung disease) problems or heart problems (such as coronary heart disease, heart failure or low blood pressure).
- If you have any allergies to any medications.
- Sandoz Dorzolamide/Timolol contains the preservative benzalkonium chloride. If you wear contact lenses, you should consult your doctor before using Sandoz Dorzolamide/Timolol. Do not administer while wearing (soft) contact lenses. Remove lenses before application and reinsert no earlier than 15 minutes after use.
- 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 problems.
- If you have now or have had liver or thyroid problems.
- If you have now or have had diabetes or other blood sugar problems.
- If you have now or have had in the past poor blood circulation problems (such as Raynaud’s syndrome).
- If you have now or have had in the past diabetes or other blood sugar problems.
- If you have certain eye problems (i.e., corneal defects) or history of eye surgery.
- If you are planning major surgery, including eye surgery, as Sandoz Dorzolamide/Timolol may change the effects of some medicines during anesthesia.
- If you are taking any other medications (see INTERACTIONS WITH THIS MEDICATION).

If the following occur during treatment, consult your doctor immediately:
- allergic reaction such as skin rash or itching.
- develop any eye infection, swelling of the eyelid, redness or irritation.
- you have any eye surgery or suffer eye injury.
- severe skin reactions with symptoms such as blisters, peeling skin, red/purple rash, skin lesions and sores, and associated fever, sore throat.

This medication can be used in children. In studies with dorzolamide hydrochloride and timolol maleate, its effect was similar in both elderly and younger adult patients.

INTERACTIONS WITH THIS MEDICATION

Your doctor also needs to know about drugs (including eye drops) that you are using or plan to use, including drugs obtained without a prescription. This is particularly important if you are taking medicine to lower blood pressure (i.e., calcium channel blockers, clonidine), or to treat heart disease (i.e., quinidine, beta blockers), diabetes, or depression (i.e., selective serotonin reuptake inhibitors, SSRIs). Also tell your doctor if you are taking large doses of acetylsalicylic acid or sulfa drugs.

PROPER USE OF THIS MEDICATION

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

- Do not start taking any other medicines unless you have discussed the matter with your doctor.
- If you are using Sandoz Dorzolamide/Timolol with another eyedrop, the drops should be instilled at least 10 minutes apart.
- Do not change the dosage of the drug without consulting your doctor. If you must stop treatment, contact your doctor 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 doctor.

The usual dose is one drop in the affected eye(s) in the morning and in the evening.

Missed Dose:
It is important to apply Sandoz Dorzolamide/Timolol as prescribed by your doctor. 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. Do not double dose.
**Overdose:**

In case of drug overdose, particularly oral ingestion, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you feel you have taken too much of Sandoz Dorzolamide/Timolol and symptoms may include shortness of breath, low heartbeat, dizziness, headache, etc., seek medical help.

**How to use the DROP-TAINER® BOTTLE**

The DROP-TAINER® bottle is designed to assure the delivery of a precise dose of medication. Before using your DROP-TAINER® bottle, read the complete instructions carefully.

1. If you use other topically applied ophthalmic medications, they should be administered at least 10 minutes before or after Sandoz Dorzolamide/Timolol.
2. Wash hands before each use.
3. Before using the medication for the first time, be sure the Safety Seal on the bottle is unbroken.
4. Tear off the Safety Seal to break the seal.
5. Before each use, shake once and remove the screw cap.

6. Invert the bottle and hold the bottle between your thumb and middle finger, with the tips of the fingers pointing towards you.
7. Tilt your head back and position the bottle above the affected eye.
8. With the opposite hand, place a finger under the eye. Gently pull down until a “V” pocket is made between your eye and lower lid. DO NOT TOUCH THE EYE WITH THE DROPPER TIP.
9. With the hand holding the bottle, place your index finger on the bottom of the bottle. Push the bottom of the bottle to dispense one drop of medication. DO NOT SQUEEZE THE SIDES OF THE BOTTLE.
10. Repeat 6, 7, 8, & 9 with other eye if instructed to do so.

**KEEP YOUR HEAD TILTED BACKWARD AND CLOSE YOUR EYE TO ALLOW ABSORPTION OF THE MEDICATION INTO THE EYE.**

After using Sandoz Dorzolamide/Timolol, press a finger into the corner of your eye, by the nose (as shown) for 2 minutes. This helps keep Sandoz Dorzolamide/Timolol in your eye.

11. Replace screw cap by turning until firmly touching the bottle.

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 that your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

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 Sandoz Dorzolamide/Timolol ophthalmic solution left in the bottle. You should not be concerned since an extra amount of Sandoz Dorzolamide/Timolol ophthalmic solution has been added and you will get the full amount of Sandoz Dorzolamide/Timolol ophthalmic solution that your doctor prescribed. Do not attempt to remove excess medicine from the bottle.

**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).
- You may sense a bitter taste after putting in your eye drops. Kidney stones and rarely, rash may also occur.
- Also, other side effects that have been observed with dorzolamide hydrochloride or timolol maleate separately, include muscle pain, abdominal pain, headache, nosebleed, dry mouth, nausea, tiredness, swelling or crusting of the eyelids.

Other side effects may also occur rarely, and some of these may be serious. These may include shortness of breath, severe skin reactions, visual changes, an irregular heartbeat and a slowing of your heart rate. 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.

- Your doctor or pharmacist has a complete list of the possible side effects from this medication. Please tell your doctor 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 doctor immediately.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

<table>
<thead>
<tr>
<th>Symptoms/Effects</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and seek immediate emergency medical attention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncommon</td>
<td>Heart effects such as irregular heartbeat, heart block, low blood pressure</td>
<td>Only if severe</td>
</tr>
<tr>
<td>Rare</td>
<td>Allergic reactions with symptoms such as swelling of mouth and throat, shortness of breath, hives, severe itching and rash</td>
<td>Only if severe</td>
</tr>
</tbody>
</table>

This is not a complete list of side effects. For any unexpected effects while taking Sandoz Dorzolamide/Timolol, contact your doctor or pharmacist.

**HOW TO STORE IT**

Store Sandoz Dorzolamide/Timolol at 2–25°C. Protect from light.

KEEP ALL MEDICINES OUT OF REACH OF 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:

- 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.

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

This leaflet was prepared by Sandoz Canada Inc.