

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **PrSANDOZ DORZOLAMIDE**

#### **Dorzolamide Hydrochloride Ophthalmic Solution**

Read this carefully before you start taking **Sandoz Dorzolamide** 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 **Sandoz Dorzolamide**.

#### **What is Sandoz Dorzolamide used for?**

Sandoz Dorzolamide lowers the pressure in the eye for conditions such as ocular hypertension or open-angle glaucoma.

#### **How does Sandoz Dorzolamide work?**

Sandoz Dorzolamide belongs to a group of medicines called carbonic anhydrase inhibitors. Sandoz Dorzolamide works by reducing the production of liquid in the eye. This helps lower the pressure in the eye.

#### **What are the ingredients in Sandoz Dorzolamide?**

Medicinal ingredient: dorzolamide (present as the hydrochloride salt)

Non-medicinal ingredients: benzalkonium chloride (as a preservative), hydroxyethyl cellulose, mannitol, sodium citrate dihydrate, sodium hydroxide (to adjust pH) and water for injection.

#### **Sandoz Dorzolamide comes in the following dosage forms:**

Solution; 2% w/v dorzolamide (as dorzolamide hydrochloride)

#### **Do not use Sandoz Dorzolamide if:**

- You are allergic to any of its components (see: What are the ingredients in Sandoz Dorzolamide?).
- 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 Sandoz Dorzolamide. 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;

- Sandoz Dorzolamide contains the preservative benzalkonium chloride. If you wear contact lenses, you should consult your healthcare professional before using Sandoz Dorzolamide. Do not use Sandoz Dorzolamide while wearing (soft) contact lenses. Remove lenses before application and reinsert no earlier than 15 minutes after use.
- 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 Sandoz Dorzolamide in your eye. Do not drive or use any tools or machines until your vision is clear.

Sandoz Dorzolamide is 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 Sandoz Dorzolamide:**

- 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 Sandoz Dorzolamide:**

- 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 Sandoz Dorzolamide with a beta-blocker eye drop, then the dose is one drop of Sandoz Dorzolamide 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.

<b>How to Use the DROP-TAINER®* BOTTLE</b>
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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.
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 YOUR EYE OR EYELID 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.

Keep your head tilted back, close your eye and press the inner corner of the eye with your finger for about two minutes. This helps to stop the medicine from getting into the rest of the body.

10. Repeat 6, 7, 8 and 9 with the other eye if instructed to do so.
11. Replace screw cap by turning until firmly touching the bottle.

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.

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 left in the bottle. You should not be concerned since an extra amount of Sandoz Dorzolamide has been added and you

will get the full amount of Sandoz Dorzolamide that your doctor prescribed. Do not attempt to remove excess medicine from the bottle.

**Usual dose:**

Your doctor will tell you the right dose and length of time to use Sandoz Dorzolamide.

When Sandoz Dorzolamide 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 Sandoz Dorzolamide, 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 Sandoz Dorzolamide 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 Sandoz Dorzolamide?**

These are not all the possible side effects you may have when taking Sandoz Dorzolamide. 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.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>UNKNOWN</b>			
Allergic Reaction: rash, hives, swelling of the mouth, throat, and lips, difficulty breathing, blue skin, shock, loss of consciousness, low blood pressure			√
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			√
Increased heart rate		√	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, racing pulse or heart palpitations.			√

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/adverse-reaction-reporting.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:**

Store at 2°C - 25°C. Protect from light.

Keep out of reach and sight of children.

### **If you want more information about Sandoz Dorzolamide:**

- 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.sandoz.ca](http://www.sandoz.ca), or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

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