

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrAZOPT®

Brinzolamide Ophthalmic Suspension

Read this carefully before you start using **AZOPT®** 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 **AZOPT**.

What is AZOPT used for?

AZOPT is used to treat high pressure in the eye in adults with the following conditions:

- ocular hypertension
- open-angle glaucoma

How does AZOPT work?

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

What are the ingredients in AZOPT?

Medicinal ingredients: brinzolamide.

Non-medicinal ingredients: Benzalkonium chloride (preservative), carbomer 974P, edetate disodium, hydrochloric acid (to adjust pH), mannitol, purified water, sodium chloride, sodium hydroxide (to adjust pH), and tyloxapol.

AZOPT comes in the following dosage forms:

Ophthalmic suspension (eye drops): 1% w/v brinzolamide.

Do not use AZOPT if:

- you are allergic to brinzolamide or any other ingredients in AZOPT.
- you are allergic to sulfonamides, also known as “sulfa drugs” (used to treat bacterial infections).
- you have severe kidney problems.
- your blood is too acidic due to a condition called hyperchloremic acidosis.
- you are taking medicines called carbonic anhydrase inhibitors by mouth.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AZOPT. Talk about any health conditions or problems you may have, including if you:

- Have or have had mild to moderate kidney problems.
- Have liver problems.
- Have or have had diabetes or other blood sugar problems.
- Have certain eye problems like corneal defects or have had eye surgery in the past.
- Have a type of glaucoma known as acute angle-closure glaucoma.
- Are a woman, who is able to get pregnant and are not using an effective birth control method.

- Are pregnant, planning to become pregnant or think you may be pregnant.
- Are breastfeeding or planning to breast-feed.

Other warnings you should know about:

Contact lenses: If you wear contact lenses, consult your healthcare professional before using AZOPT. AZOPT contains the preservative benzalkonium chloride. It can deposit in soft contact lenses. This means that you must remove your contact lenses before you apply AZOPT. Wait 15 minutes before putting your contact lenses back in your eyes.

Driving and using machines: You may find your vision is blurred for a time just after you put AZOPT in your eye. Do not drive or use any tools or machines until your vision is clear.

Pregnancy:

- AZOPT is not recommended during pregnancy. It may harm an unborn baby. Your healthcare professional will discuss the potential risks with you.
- If you are a woman who is able to get pregnant, your healthcare professional may ask you to use a highly effective birth control method during your treatment with AZOPT.
- If you discover that you are pregnant during your treatment with AZOPT, contact your healthcare professional as soon as possible.

Breast-feeding:

- It is not known if AZOPT can pass into breast milk and harm a breast-fed baby. Therefore, AZOPT is not recommended during breast-feeding.
- Talk to your healthcare professional about the best way to feed your baby during your treatment with AZOPT.

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 AZOPT:

- other medicines (including eye drops) that you are using or plan to use
- carbonic anhydrase inhibitors taken by mouth (e.g., acetazolamide, methazolamide)
- medicines used to treat fungal infections (e.g., ketoconazole, itraconazole, clotrimazole)
- medicines used to treat bacterial infections (e.g., troleandomycin)
- medicines used to treat viral infections (e.g., ritonavir)
- salicylates, used to reduce fever and pain (e.g., acetylsalicylic acid)

How to take AZOPT:

- Take AZOPT exactly as your healthcare professional has told you to.
- If you are using AZOPT with another eye drop, the drops should be applied at least 10 minutes apart.
- Be careful not to touch your eye, the area around your eye, or any other surface with the tip of the container. It may become contaminated with bacteria. This can cause eye infections. This could lead to serious damage of the eye, including loss of vision. Keep the tip of the container away from contact with any surface. Contact your healthcare professional if you think the bottle might be contaminated or if you think you might have an eye infection.

- Do not use AZOPT if the bottle is cracked or damaged in any way.
- You may use a mirror to help you apply AZOPT. If you cannot apply AZOPT to yourself, a family member or caregiver may help you.

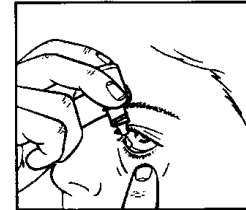
Instructions for use

Before using the medication for the first time, be sure the security snap collar on the bottle is unbroken. Hold the cap firmly and unscrew it to open the bottle. If the security snap collar is loose after removing the cap, remove the security snap collar before using AZOPT.

1. Before each use, wash your hands thoroughly and shake the bottle well.
2. Remove the cap from the bottle.

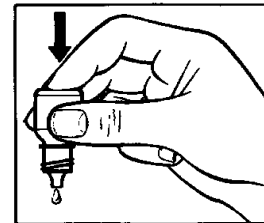
Do not touch the bottle tip with your fingers.

3. Tilt your head back and with the index and finger of your other hand, pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.



Do not allow the bottle tip to touch your eye or any area around your eye.

4. Hold the bottle dropper vertically, pointing down, above your eye and gently press on the base of the bottle until a single drop is dispensed into the eye as directed by your healthcare professional.



Do not squeeze the bottle. It is designed so that a gentle press on the bottom of the bottle is all that it needs.

If you miss, wipe up and try again.

5. After using AZOPT, close your eye and press a finger into the inner corner of your eye near your nose (as shown) for 2 minutes. This helps to keep AZOPT in your eye and prevents it from being absorbed into your body.



6. Repeat steps 3 to 5 with the other eye if instructed to do so by your healthcare professional.
7. Close the bottle cap firmly immediately after use.

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

Usual dose:

- The usual dose is one drop in the affected eye(s) twice a day.
- If needed after 4 weeks of treatment, your doctor may increase your dose to one drop in the affected eye(s) three times a day. Always follow your healthcare professional's instructions carefully.

Overdose:

If you use more AZOPT than you should, rinse your eye(s) with warm water. Do not apply any more drops until it is time for your next regular dose.

If you think you, or a person you are caring for, have used too much or accidentally swallowed AZOPT, 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 AZOPT as prescribed by your healthcare professional. If you miss a dose, apply a single drop 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 apply a double dose.

What are possible side effects from using AZOPT?

These are not all the possible side effects you may feel when using AZOPT. If you experience any side effects not listed here, tell your healthcare professional.

You may experience eye symptoms such as:

- blurry, double, abnormal or reduced vision
- burning, stinging, itching or redness of the eye
- a feeling that something is in the eye
- dry or watery eyes
- discharge, crusting of the eyelids
- a sticky feeling
- eye strain, fatigue or pain
- swelling of the eye or around the eye
- damage to the surface of the eye (cornea)
- numbness
- sensitivity to light
- flashes of light

Other side effects may include:

- altered sense of taste including a bitter taste
- dry mouth
- indigestion
- nausea
- abdominal discomfort
- diarrhea

- headache
- dizziness
- lack of energy or feeling tired
- feeling jittery or irritable
- burning or prickling sensation of the skin
- shortness of breath
- sore throat
- stuffy, runny or dry nose
- sinus congestion
- hair loss
- chest pain
- ringing in the ears
- memory loss
- feeling sleepy
- trouble falling and/or staying asleep
- cough
- chest cold (bronchitis)
- nosebleed
- itchy skin or hives
- loss of appetite
- joint pain

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Hepatic necrosis (death of liver cells): abdominal pain and dark urine, fever, light-colored stool, and jaundice (a yellow appearance of the skin and white portion of the eyes).			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide. If you have a history of depression, your depression may become worse.	✓		
RARE			
Angina pectoris (not enough oxygen to the heart muscle): discomfort in the shoulder, arm, back, throat, jaw or teeth; pain or pressure in the chest.			✓
Allergic reactions: rash, hives, swelling of the mouth, throat and lips, difficulty breathing, blue skin, shock, loss of consciousness, low blood pressure.			✓
UNKNOWN			
Agranulocytosis (decrease in white blood cells): frequent infection with fever, chills, sore throat.			✓
Aplastic anemia (when cells meant to develop into mature blood cells are damaged): fatigue, weakness, pale skin.			✓
Heart problems: irregular heartbeat, 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.			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Toxic epidermal necrolysis (severe skin reaction): redness, blistering and/or peeling of large areas of the skin.			✓

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 4°C - 30°C. Keep bottle tightly closed when not using.
- Do not use this medicine after the date shown on the bottle.
- Keep out of reach and sight of children.

If you want more information about AZOPT:

- 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 <http://www.novartis.ca>, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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