PART III: CONSUMER INFORMATION

PrAZARGA®
brinzolamide and timolol
ophthalmic suspension

This leaflet is part III of a three-part "Product Monograph" published when AZARGA® suspension was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AZARGA suspension. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
AZARGA suspension is used to treat high pressure in the eye. This pressure can lead to an illness called glaucoma.

What it does:
AZARGA suspension is a combination of treatments to reduce pressure in the eye for conditions such as glaucoma. It contains two ingredients which work together to reduce pressure within the eye. Brinzolamide is a carbonic anhydrase inhibitor and timolol is a beta-blocker. Both brinzolamide and timolol work by reducing the production of fluid within the eye.

When it should not be used:
- **if you are allergic to brinzolamide, timolol or any other of the ingredients of AZARGA suspension (see What the important nonmedicinal ingredients are).**
- **if you are allergic to medications called sulfonamides (medicines used to treat diabetes and infections).**
- **if you are allergic to beta blockers (medicines used to treat heart disease or lower blood pressure).**
- **if you have respiratory problems such as asthma, bronchitis, severe chronic obstructive pulmonary disease (COPD) or other types of breathing problems.**
- **if you have heart problems, such as a slow heartbeat, heart failure or disorders of heart rhythm.**
- **if you have too much acidity in your blood (a condition called hyperchloraemic acidosis).**
- **if you have severe kidney problems.**

What the medicinal ingredients are:
The medicinal ingredients are brinzolamide and timolol maleate. One mL of suspension contains 10 mg of brinzolamide and 5 mg of timolol (as timolol maleate).

What the important nonmedicinal ingredients are:
Preservative: benzalkonium chloride. The other ingredients are carbomer 974P, disodium edetate, mannitol, purified water, sodium chloride and tyloxapol. Tiny amounts of hydrochloric acid and/or sodium hydroxide are added to keep acidity levels (pH levels) normal.

What dosage forms it comes in:
AZARGA suspension contains tiny white particles suspended in a clear liquid. It is supplied as 5 mL of suspension in an 8 mL plastic DROP-TAINER® dispenser bottle with a screw cap.

WARNINGS AND PRECAUTIONS

BEFORE you use AZARGA suspension, talk to your doctor or pharmacist if you have or have had:
- **angina (chest pains), heart disease (symptoms can include chest pain or tightness, breathlessness or choking), circulation problems or low blood pressure.** AZARGA suspension may make any of these worse.
- **diabetes.** AZARGA suspension can mask the symptoms of low blood sugar (hypoglycaemia) such as shakiness and dizziness, so you need to use it with care.
- **liver problems.**
- **thyroid problems.**
- **cornea problems or glaucoma.**
- **chronic muscle weakness (a condition called myasthenia gravis).**
- **history of severe allergic reactions or tendency to develop severe allergic reactions.**

BEFORE taking AZARGA suspension, tell your doctor if you are taking or planning to take other carbonic anhydrase inhibitors or beta-blockers. Do not take AZARGA suspension while taking another carbonic anhydrase inhibitor or beta-blocker.

While you are using AZARGA suspension, talk to your doctor immediately if you:
- develop an eye infection, swelling, redness or irritation of the eyelid.
- suffer any eye injury or have eye surgery.

Pregnancy or breast-feeding
If you are pregnant, or might get pregnant, breastfeeding or planning to breastfeed, talk to your doctor before you use AZARGA suspension. Do not use AZARGA suspension when you are pregnant unless your doctor tells you otherwise. AZARGA is not recommended for nursing women.

Surgery
Before having surgery, tell your doctor that you are taking AZARGA suspension as it may change the effect of some medicines used during anesthesia.

Driving and using machines
AZARGA suspension may reduce coordination and mental alertness and cause blurred vision. Do not drive or use machinery until these symptoms go away.

If you wear contact lenses
There is a preservative in AZARGA suspension (benzalkonium chloride) that can discolour soft contact lenses and may cause eye irritation. Do not wear contact lenses while using AZARGA suspension. Wait 15 minutes after using AZARGA suspension before putting your lenses back in.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all drugs, including eye drops, that you are using or plan to use, including those without a prescription.

Drugs that may interact with AZARGA suspension include:

- heart or blood pressure medications such as beta-blockers, calcium channel blockers, digitalis, guanethidine, amiodarone and other beta-adrenergic blocking agents.
- quinidine (medicine used to treat heart conditions and malaria).
- cimetidine (medicine used to treat ulcers and acid reflux)
- antivirals, antifungals and antibiotics such as ketoconazole, itraconazole, clotrimazole, ritonavir and troleandomycin.
- salicylates such as acetylsalicylic acid (ASA).
- antidepressants such as fluoxetine, paroxetine.
- adrenaline (epinephrine).
- medicines belonging to class of drugs known as carbonic anhydrase inhibitors.

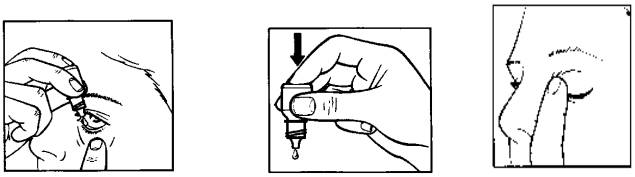
PROPER USE OF THIS MEDICATION

Always use AZARGA suspension exactly as your doctor has told you.

Usual adult dose:
One drop in the eye or eyes, twice a day - morning and night.

Only use AZARGA suspension in both eyes if your doctor told you to. Take it for as long as your doctor told you to.

How to Use:



1 2 3

- Get the AZARGA suspension bottle and a mirror.
- Wash your hands.
- Shake well before use.
- Twist off the bottle cap. If the security snap collar is loose after moving the cap, remove the snap collar before using AZARGA suspension.
- 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.
- **Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could contaminate the drops, cause an eye infection and damage the eyes.
- Gently press on the base of the bottle to release one drop of AZARGA suspension at a time
- Do not squeeze the bottle: it is designed so that a gentle press on the bottom is all that it needs (picture 2).
- After using AZARGA suspension, press a finger into the corner of your eye, by the nose for 2 minutes (picture 3). This helps to stop AZARGA suspension getting into the rest of the body.
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Use up one bottle before opening the next bottle.

Do not use the suspension if the bottle is cracked or damaged.

If a drop misses your eye, try again.

If you are using other eye drops, wait at least 5 minutes between using AZARGA suspension and the other drops.

Overdose:
If you use more AZARGA suspension than you should, rinse your eye with warm water. Do not put in any more drops until it is time for your next regular dose.

> In case of overdose, particularly oral ingestion, contact your doctor, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If you forget to use AZARGA suspension, continue with the next dose as planned. Do not use a double dose to make up for the missed dose. Do not use more than one drop in the affected eye(s) twice daily.

If you stop using AZARGA suspension without speaking to your doctor, the pressure in your eye will not be controlled which could lead to a loss of sight.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, AZARGA suspension can cause side effects although not everybody gets them.

You can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to your doctor or pharmacist.

The most common side effects in the eye include blurred vision, eye irritation, eye pain, and abnormal eye sensation. The most common side effect in other areas of body includes bad taste.

Less common side effects include redness of the eye, decreased pressure in eye, itchy eye, eye surface inflammation with surface damage, dry eye, eye discharge, allergic conjunctivitis (eye allergy), corneal disorder (problems with the cornea, such as damage, inflammation and swelling), eyelid abnormality, irritation, itching, redness, pain, swelling, or crusting, increased

tear production, inflammation inside the eye, sensitivity to light, tired eyes and corneal staining.

Less common side effects in other areas of body include abdominal discomfort, decreased blood pressure, abnormal increase in heart rate, blood in urine, body weakness, chronic lung disease, cough, bronchospasm (constriction of the airways with difficulty in breathing), asthma, difficulty sleeping, hair disorder, decrease in white blood cell count, runny nose, skin inflammation, redness, or itching, abnormal skin sensation, ringing in ears and throat irritation and/or pain.

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Slow heartbeat			✓
Rare	Heart effects such as irregular heartbeat, low blood pressure			✓
	Allergic reactions with symptoms such as swelling of the mouth and throat, shortness of breath, hives, severe itching and rash			✓

This is not a complete list of side effects. For any unexpected effects while taking AZARGA suspension, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach and sight of children.

Do not use AZARGA suspension after the expiry date which is stated on the bottle and the carton after EXP. The expiry date refers to the last day of that month.

Store at 2°C to 30°C. Discard 60 days after opening.

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 https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html
- call toll-free at 1-866-234-2345
- complete a Canada Vigilance Reporting Form and:
  - fax toll-free to 1-866-678-6789
  - mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html.

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 found on the Health Canada website or by contacting the sponsor Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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