PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrAZARGA®

brinzolamide and timolol ophthalmic suspension

Read this carefully before you start taking **AZARGA®** 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 **AZARGA.**

What is AZARGA used for?

AZARGA is used to treat high pressure in the eye. It is used in adults with eye conditions called open-angle glaucoma or ocular hypertension. It is used when treatment with a single medicine does not work to lower high pressure in the eye.

How does AZARGA work?

AZARGA contains two medicinal ingredients, brinzolamide and timolol maleate. These work together to reduce pressure in the eye.

What are the ingredients in AZARGA?

Medicinal ingredients: brinzolamide and timolol maleate.

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

AZARGA comes in the following dosage forms:

As a suspension containing 1 % w/v brinzolamide and 0.5 % w/v timolol (as timolol maleate).

Do not use AZARGA if you:

- are allergic to brinzolamide, timolol or any other of the ingredients in AZARGA suspension (see What are the ingredients in AZARGA).
- are allergic to medicines called sulfonamides used to treat diabetes and infections.
- are allergic to medicines called beta blockers used to treat heart disease or lower blood pressure.
- have or have had breathing problems such as asthma, or have severe chronic obstructive pulmonary disease (COPD).
- have severe allergic rhinitis
- have a condition called bronchial hyper-reactivity
- have heart problems, such as a slow heartbeat, heart failure or disorders of heart rhythm.
- have a condition called hyperchloraemic acidosis.
- have severe kidney problems.

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

- have liver problems.
- have kidney problems.
- have thyroid problems.
- have cornea problems or glaucoma.
- have a condition called myasthenia gravis which causes chronic muscle weakness.
- have or have had heart problems.
- have low blood pressure.
- have or have had circulatory disturbances/disorders (Raynaud's disease or Raynaud's syndrome).
- are taking other medicines called carbonic anhydrase inhibitors such as acetazolamide or dorzolamide.
- are taking other medicines called beta blockers.
- have had severe allergic reactions in the past.

Other warnings you should know about:

While you are using AZARGA suspension, talk to your healthcare professional immediately if you:

- develop an eye infection, swelling, redness or irritation of the eyelid.
- suffer any eye injury or have eye surgery.

Diabetes:

Before you use AZARGA, tell your healthcare professional if you have diabetes. AZARGA might mask the symptoms of low blood sugar such as shakiness and dizziness. Talk to your healthcare professional about how to safely take AZARGA if you have diabetes.

Pregnancy

Before you use AZARGA, tell your healthcare professional if you are pregnant or not using any contraceptives to plan your pregnancy. You should not use AZARGA while you are pregnant unless your healthcare professional advises that you can.

Breastfeeding

Before you use AZARGA tell your healthcare professional if you are breastfeeding or are planning to breastfeed. You should not breastfeed while you are using AZARGA.

Surgery

Before having surgery, tell your healthcare professional 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 co-ordination and alertness and cause blurred vision. Do not drive or use machinery until these symptoms go away.

Contact Lenses

Before you use AZARGA, tell your healthcare professional if you wear contact lenses. AZARGA contains a preservative (benzalkonium chloride) that can discolour soft contact lenses and may cause eye irritation. Do not administer AZARGA while you wear contact lenses. Remove your contact lenses before applying AZARGA. Wait for 15 minutes before you put your contact lenses back in. This medicine may also cause eye irritation and cornea problems. If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your healthcare professional.

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 AZARGA:

- heart or blood pressure medications such as beta-blockers, calcium channel blockers, digitalis, clonidine, guanethidine, amiodarone and other beta-adrenergic blocking agents.
- quinidine, a medicine used to treat heart conditions and malaria.
- cimetidine, a medicine used to treat ulcers and acid reflux.
- antiviral, antifungal and antibiotic medicines such as ketoconazole, itraconazole, clotrimazole, ritonavir and troleandomycin.
- acetylsalicylic acid (ASA) used to treat pain and fever.
- antidepressant medicines such as fluoxetine, paroxetine.
- epinephrine used to treat severe allergic reactions.
- medicines belonging to class of drugs known as carbonic anhydrase inhibitors such as acetazolamide or dorzolamide.

How to take AZARGA:

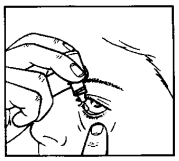
Always use AZARGA exactly as your healthcare professional has told you.

Usual Adult Dose:

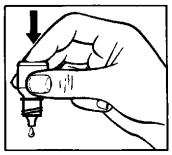
One drop in the affected eye(s) twice a day.

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

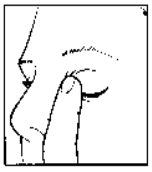
How to Use:



1



2



3

- Get the AZARGA bottle and a mirror.
- Wash your hands.
- Shake the bottle 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 your 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.

Do not use AZARGA 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.

If you think you, or a person you are caring for, have taken too much AZARGA, particularly oral ingestion, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of AZARGA, take it as soon as you remember, before your next planned dose. Then, take the next dose at the regular time. Never take a double dose to make up for a missed dose.

Do not use more than one drop in the affected eye(s) twice daily.

What are possible side effects from using AZARGA?

These are not all the possible side effects you may have when taking AZARGA. If you experience any side effects not listed here, tell your healthcare professional.

The side effects in the eye include:

- blurred vision
- eye irritation
- eye pain
- abnormal eye sensation

- redness of the eye
- decreased pressure in eye
- itchy eye
- eye surface swelling with surface damage
- dry eye
- eye discharge
- eye allergy
- problems with the cornea such as damage, inflammation and swelling
- eyelid changes
- irritation
- itching, redness, pain, swelling
- crusting, increased tear production
- swelling inside the eye
- sensitivity to light, tired eyes
- corneal staining

The side effects in other areas of body includes:

- bad taste
- abdominal discomfort
- decreased blood pressure, abnormal increase in heart rate
- blood in urine
- body weakness
- difficulty sleeping
- hair disorder
- decrease in white blood cell count
- runny nose
- skin swelling
- redness or itching
- abnormal skin sensation
- ringing in ears
- throat irritation and/or pain

Contact your healthcare professional if you experience any of these symptoms.

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**	
COMMON			
Slow heartbeat			✓
UNCOMMON			
Cough			✓
RARE			
Heart effects such as irregular heartbeat, low blood pressure			✓
Allergic reactions: swelling of the mouth and throat, shortness of breath, hives, itching and rash			✓
UNKNOWN			
Choroidal detachment (Severe eye pain): disturbance of vision, pain in eye		✓	
Punctate keratopathy and/or Toxic ulcerative keratopathy (swelling of cornea): pain in eye, tearing, sensitivity to light		✓	
Seeing, feeling or hearing things that are not there (hallucination) and depression		✓	
Shortness of breath/ difficulty in breathing			✓
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			✓

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.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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of the reach and sight of children.

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

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.

If you want more information about AZARGA:

- 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.

Last Revised DEC 23, 2022

AZARGA is a registered trademark.

Novartis Version JUL 07, 2023