

AZARGA® Eye Drops

Brinzolamide 10 mg/mL and timolol 5 mg/mL

Consumer Medicine Information

What Is In This Leaflet

Please read this leaflet carefully before you use any AZARGA Eye drops.

This leaflet answers some common questions about AZARGA. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist. The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet in Australia from www.novartis.com.au and in New Zealand from www.medsafe.govt.nz.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you using AZARGA against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What AZARGA is used for

AZARGA is used to lower pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure.

Glaucoma is usually caused by a build-up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist. If glaucoma is not treated, it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

AZARGA combines two ingredients, brinzolamide and timolol. 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. Although AZARGA helps control your glaucoma, it does not cure it.

For more information about glaucoma, contact Glaucoma Australia on 1800 500 880 or Glaucoma New Zealand on 09 373 8779.

Your doctor may have prescribed AZARGA for another reason. Ask your doctor if you

have any questions about why AZARGA has been prescribed for you.

There is no evidence that AZARGA is addictive.

Use in Children

There is not enough information to recommend the use of this medicine in children under the age of 18 years.

Before you use AZARGA

When you must not use it

Do not use AZARGA if you have an allergy to:

- Brinzolamide
- Timolol or other beta blockers which are used to treat high blood pressure, heart problems, angina, migraine, anxiety and glaucoma
- Sulphonamides or sulpha-containing medicines
- Any of the other ingredients in AZARGA listed at the end of this leaflet.

If you think you may be allergic, ask your doctor or healthcare provider for advice.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use AZARGA if:

- the safety seal around the closure and neck area is broken
- the bottle/packaging is torn or shows signs of tampering
- the expiry date on the bottle/carton has passed.

If it has expired or is damaged, return it to your pharmacist for disposal. If you use this medicine after the expiry date has passed, it may not work.

Tell your doctor if you have or have had any medical conditions, particularly the following:

- **respiratory problems such as asthma, chronic obstructive lung disease (emphysema), bronchitis or other types of breathing problems**
- **bronchial hyper-reactivity seen in chronic asthma and obstructive lung disease**
- **heart and circulation conditions, such as a very slow heart rate, an irregular heartbeat, heart failure, chest pain or low blood pressure**
- **a condition called hyperchloraemic acidosis (too much acidity in your blood)**
- **severe kidney impairment**
- **severe allergic rhinitis or hayfever.**

If you are not sure whether you should start using AZARGA, talk to your doctor.

Before you start to use it

Tell your doctor if you have had an allergy to any other medicines or any other

substances, such as foods, preservatives or dyes.

Tell your doctor if:

You are pregnant or plan to become pregnant.

Your doctor will discuss the possible risks and benefits of using AZARGA during pregnancy.

You are breast-feeding or intend to breast-feed.

Your doctor will discuss the possible risks and benefits of using AZARGA when you are breast feeding.

You have or have had any medical conditions such as:

- **problems with your kidneys**
- **diabetes mellitus as timolol may mask signs and symptoms of low blood sugar**
- **Raynaud's disease**
- **severe heart disease**
- **Prinzmetal angina, blood circulation problems or low blood pressure**
- **impaired corneas which can occur in diabetes mellitus**
- **problems with your corneas such as low endothelial cell counts or corneal dystrophies**
- **narrow angle glaucoma**
- **thyrotoxicosis, a condition where there is too much thyroid in the body as timolol may mask signs and symptoms of thyroid disease**
- **muscle weakness consistent with certain myasthenic symptoms.**

If you are unsure if you have any of these conditions ask your doctor.

If you have not told your doctor about any of the above, tell them before you use AZARGA.

Do not put AZARGA Eye Drops into your eye(s) while you are wearing contact lenses.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.

The preservative in AZARGA (benzalkonium chloride) may be deposited in soft contact lenses.

You can put your soft contact lenses back into your eyes 15 minutes after you have used AZARGA.

Using other medicines

Tell your doctor if you are taking or using any other medicines, including other eye drops or ointments, and any other medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and AZARGA may interfere with each other or add to the effects of AZARGA. These include:

- medicines for high blood pressure or heart conditions, including a group of medicines called beta-blockers and calcium channel blockers
- digoxin, a medicine used to treat heart failure
- medicines such as quinidine or amiodarone used to treat slow or irregular heart beat

- clonidine, a medicine used to treat high blood pressure and migraines
- other medicines or eye drops for glaucoma
- medicines used to treat diabetes
- carbonic anhydrase inhibitors such as acetazolamide or medicines that are nonsteroidal anti-inflammatory drugs (NSAIDs) or salicylates
- medicines such as cimetidine used to treat stomach or bowel ulcers
- medicines such as ketoconazole, itraconazole, clotrimazole and ritonavir
- parasympathomimetics.

These medicines may be affected by AZARGA, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are unsure if you are taking or using any of these medicines ask your doctor or pharmacist.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using AZARGA.

How to use AZARGA

Carefully follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you are being changed from one medicine to another, follow your doctor's instructions carefully as to when to stop the medicine and when to start the new eye drops.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

How much to use

Use AZARGA only when prescribed by your doctor.

The usual dose of AZARGA is ONE DROP in the affected eye(s) TWICE DAILY. Usually, this means ONE DROP in the affected eye(s) first thing in the morning, and ONE DROP in the evening.

Your doctor will tell you how many drops you need to use each day.

These dosing instructions will be printed on the label your pharmacist adds.

How to use it

It is important to use AZARGA exactly as your doctor or pharmacist has told you. If you use the drops less often than prescribed, they may not work as well and the eye problem may not improve. Using the drops more often than prescribed may not improve the eye problem any faster and may cause increased side effects.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

Follow these steps to use the eye drops:

1. Wash your hands thoroughly with soap and water.
2. Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
3. Shake the bottle.
4. Remove the cap from the bottle.

5. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

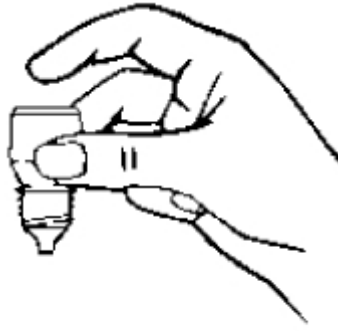


Diagram 1

6. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
7. Place the tip of the bottle close to your eye. Do not let it touch your eye. Do not squeeze the bottle.
8. Release ONE DROP into the pouch/pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger (see Diagrams 2 and 3).

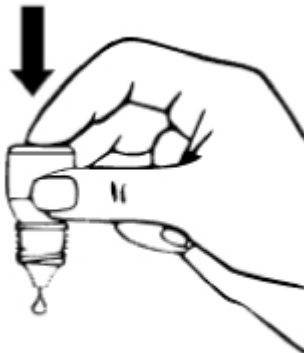


Diagram 2



Diagram 3

9. Close your eye. Do not blink or rub your eye.
10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from

where it can be absorbed into other parts of your body. This will also reduce the unpleasant taste sensation that some people experience when using these drops.

11. If necessary, repeat the above steps for the other eye.
12. Your eyelids can only hold less than one drop at a time, so it is normal for a small amount of the eye drop to spill onto your cheek. You should wipe away any spillage with a tissue.
13. Replace the cap on the bottle, closing it tightly.
14. Wash your hands again with soap and water to remove any residue.

You may feel a slight burning sensation in the eye shortly after using the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the dropper tip against your eye, eyelid or anything else. This will help prevent the drops becoming dirty or contaminated.

If you have trouble knowing whether you have placed your drops correctly, you may want to store them in the fridge. Some people find it easier to feel the drops in the eye if they are cold.

After using AZARGA, wait at least 5 minutes before putting any other eye drops in your eye(s).

Wait 15 minutes before replacing your contact lenses.

When to use it

Use AZARGA every day, at about the same times each day, unless your doctor tells you otherwise.

Using your eye drops at the same times each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

How long to use it

AZARGA helps control your condition but does not cure it. AZARGA must be used every day. Continue using AZARGA for as long as your doctor prescribes.

If you are unsure about when or how to stop using AZARGA, you should talk to your doctor or pharmacist.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

Do not use double the amount to make up for the dose that you missed.

Using multiple doses may cause unwanted side effects.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of AZARGA, immediately

telephone your doctor or the Poisons Information Centre on 13 1126 in Australia or the National Poisons Centre on 0800 POISON or 0800 764 766 in New Zealand for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using AZARGA

Things you must do

Keep all your doctor's appointments so that your progress can be checked.

If you notice signs of serious reactions or hypersensitivity including severe skin reaction such as skin rash, red skin, blistering of the lips, eyes or mouth, skin peeling and fever (signs of Stevens-Johnson syndrome or toxic epidermal necrolysis) discontinue the use of this product and seek medical attention immediately.

Your eye specialist will check your eye pressure to make sure AZARGA is working.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using AZARGA.

Tell all the doctors, dentists and pharmacists who are treating you that you are using AZARGA.

Tell your doctor if, for any reason, you have not used AZARGA exactly as prescribed. Otherwise your doctor may think that the eye drops were not effective and change the treatment unnecessarily.

If you become pregnant or decide to breastfeed while using AZARGA, tell your doctor immediately.

Things you must not do

Do not use AZARGA to treat other complaints unless your doctor tells you to.

Do not give AZARGA to anyone else, even if they have the same condition as you.

Do not stop using AZARGA without first talking to your doctor. If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving, operating machinery or performing tasks requiring mental alertness and/or physical coordination until you know how AZARGA affects you and your vision.

As with any eye medicine, temporary blurred vision or other visual disturbances may affect the ability to drive or use machinery in some people. If blurred vision occurs when you use your drops, wait until your vision is clear before driving or operating machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using AZARGA.

AZARGA helps most people with high eye pressure and glaucoma, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following effects in the eye(s) and the eye area, and they worry you:

- blurred vision
- eye pain
- eye irritation
- feeling of having something in the eye.

These are the more common side effects of your medicine. They are usually mild and short-lived.

Additional side effects that are noticed more rarely include:

- corneal erosion (pain, feeling of having something in the eye, sensitivity to bright light, excessive tears)
- eye surface inflammation with surface damage
- dry eye
- eye discharge
- itchy eye
- redness of the eye and/or eyelids
- allergic conjunctivitis (eye allergy)
- corneal disorder
- inflammation inside the eye
- eyelid margin crusting
- tired eyes
- inflammation of the eyelids
- problems seeing clearly.

Occasionally some people notice unwanted effects in the rest of their body as a result of using AZARGA. These effects may include:

- bad taste in the mouth
- dry mouth
- lung disease
- throat irritation and soreness
- cough
- asthma
- increased or decreased blood pressure
- decreased heart rate
- changes to heart rhythm
- chest pain
- fatigue
- dizziness
- headache
- difficulty sleeping
- abdominal pain or discomfort
- diarrhoea
- nausea
- skin inflammation, redness or itching
- tingling or prickling sensation of the skin
- decreased white blood cells
- runny nose
- nose bleed
- ringing or buzzing in the ears
- hair disorder
- muscular pain
- depression
- feeling or hearing things that are not there (hallucination)
- blood in the urine.

Some of the above possible side effects (for example change in blood pressure) can only be found when your doctor does tests to check your progress.

If any of the following happen, stop using AZARGA and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- skin rash, red skin, skin peeling, blistering of the lips, eyes or mouth, fever or any combination of these (Stevens-Johnson syndrome / toxic epidermal necrolysis)
- swelling of the face, hands or feet
- wheezing, difficulty in breathing
- shortness of breath
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash

These hypersensitivity reactions can be very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may also occur in some people.

After using AZARGA

Storage

Store AZARGA in a cool dry place where the temperature stays below 25°C. It is not necessary to store AZARGA in the refrigerator, but it is acceptable if you prefer to instil cold drops. Do not freeze.

Do not store AZARGA or any other medicine in the car, in the bathroom or in other warm, damp places.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave the top off the bottle for any length of time, to avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should then be used.

If your doctor tells you to stop using AZARGA or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

AZARGA is a liquid (white to off-white uniform suspension) supplied in a pack containing 5 mL in an 8 mL dropper bottle with screw cap.

Tamper evidence is provided with a safety seal around the neck area of the bottle.

Ingredients

Active ingredient(s):

- brinzolamide 10 mg in 1 mL
- timolol maleate 5 mg in 1 mL

Inactive ingredients:

- mannitol
- carboxymethylcellulose sodium salt 974P

- sodium chloride
- tyloxapol
- disodium edetate
- sodium hydroxide and/or hydrochloric acid are added to adjust pH
- purified water
- benzalkonium chloride as a preservative.

Allergens:

May contain traces of benzoates, sulfites and hydroxybenzoates.

Supplier

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1-800-671-203

Web site: www.novartis.com.au

This product is supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

New Zealand

Free Phone: 0800 354 335.

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