

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Azarga?

Azarga contains the active ingredient Brinzolamide and timolol maleate. Azarga is used to treat certain types of eye conditions such as high pressure inside your eye and open angle glaucoma (an eye condition caused by fluid buildup that damages the optic nerve).

For more information, see Section [1. Why am I using Azarga?](#) in the full CMI.

2. What should I know before I use Azarga?

Do not use if you have ever had an allergic reaction to Azarga or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Azarga?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Azarga and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Azarga?

- Follow the instructions provided and use Azarga until your doctor tells you to stop.
- Put one drop of Azarga in the conjunctival sac of the affected eye(s) twice daily.

More instructions can be found in Section [4. How do I use Azarga?](#) in the full CMI.

5. What should I know while using Azarga?

Things you should do	• Remind any doctor, dentist, pharmacist or specialist you visit that you are using Azarga. • Remove soft contact lenses before using Azarga. • Tell your doctor immediately if you develop any signs of an allergic reaction.
Things you should not do	• Do not stop using this medicine suddenly. • Do not give Azarga to anyone else, even if they seem to have the same condition as you. • Do not use Azarga in children.
Driving or using machines	• Azarga may impair the ability to perform tasks requiring mental alertness and/or physical coordination or can cause temporary blurred vision or other visual problems in some people. • Be careful before you drive or use any machines or tools until you know how Azarga affects you.
Looking after your medicine	• Store below 25 °C • Do not freeze.

For more information, see Section [5. What should I know while using Azarga?](#) in the full CMI.

6. Are there any side effects?

Common side effects include temporary blurred vision, eye pain, bitter or unusual taste in the mouth after using Azarga, dry eye, eye irritation, vision problems, eyelid swelling.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Azarga. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Azarga.**

Where to find information in this leaflet:

1. [Why am I using Azarga?](#)
2. [What should I know before I use Azarga?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Azarga?](#)
5. [What should I know while using Azarga?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Azarga?

Azarga contains the active ingredients Brinzolamide and timolol maleate. Brinzolamide belongs to class of drugs called carbonic anhydrase inhibitors and timolol maleate belongs to class of drugs called beta-blockers.

Azarga is used to treat certain types of eye conditions such as high pressure inside your eye and open angle glaucoma (an eye condition caused by fluid buildup that damages the optic nerve).

The active ingredients of Azarga eye drops help in reducing the production of fluid within the eye.

2. What should I know before I use Azarga?

Warnings

Do not use Azarga:

- If you are allergic to Brinzolamide and other sulphonamides, timolol maleate, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.

- In children under 18 years old.
- If you suffer from any respiratory problems such as asthma (symptoms such as wheezing, coughing, shortness of breath) or a history of asthma, or shortness of breath, persistent cough or any symptoms such as runny nose, sneezing, itchy, watery eyes.
- If you have any heart problems such as problems with your heart beat, problems with heart function, any history of heart attack or any other heart diseases.

- If you are allergic to any other drugs similar to timolol maleate (other beta blockers).
- If you suffer from symptoms such as headache, lack of energy, vomiting and feeling sick.
- If you have any kidney problems.

Check with your doctor if you:

- take any medicines for any other condition
- have any skin rash, problems with your skin
- have any problems with your blood vessels, having symptoms such as skin colour changes, affected part feels cold or numb, skin ulcers.
- have diabetes or problems with low blood sugar levels (symptoms like sweating, confusion, shakiness)
- suffer from problems with your thyroid gland
- have any problems with your blood circulation or if you have low blood pressure, symptoms include dizziness, blurred vision, fatigue
- have a history of allergic problems (symptoms such as hives, shortness of breath, difficulty in breathing)
- have any other type of Glaucoma
- have any problems with your cornea.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will advise you regarding the possible risks and benefits of using Azarga during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will advise you regarding the possible risks and benefits of using Azarga during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Azarga and affect how it works.

Tell your doctor if you use any of the following medicines:

- Drugs used to treat high blood pressure or heart problems, e.g. beta-blockers (Metoprolol), calcium channel blockers or digitalis glycosides or Pilocarpine (parasympathomimetics)
- Digoxin, a medicine used to treat heart failure

- Medicines used to treat an irregular heartbeat e.g. amiodarone and quinidine
- Nonsteroidal anti-inflammatory drugs (NSAIDs) eg Ibuprofen, Aspirin and salicylates or carbonic anhydrase inhibitors such as acetazolamide
- Antifungal medicines such as ketoconazole, itraconazole, clotrimazole
- Ritonavir, a medicine used to treat HIV
- Cimetidine, a medicine used to treat stomach or intestine ulcers
- Clonidine, a medicine used to treat high blood pressure and migraines
- Any other medicines or eye drops used for treatment of glaucoma
- Medicine used to treat severe allergic reaction e.g. adrenaline
- Medicines used to treat high blood sugar.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Azarga.

4. How do I use Azarga?

How much to use

- Follow the instructions provided and use Azarga until your doctor tells you to stop.
- Put one drop of Azarga in the conjunctival sac of the affected eye(s) twice daily.
- Do not exceed the dose of one drop in the affected eye(s) twice daily.

When to use Azarga

- Use Azarga eye drops at about the same time each day, unless your doctor tells you otherwise.

How to use Azarga

- In a sitting or lying down position might make the process simpler.
- Remove contact lenses if you are wearing them before using the eye drops.
- Shake the bottle well prior to use.
- **Follow the steps below to use Azarga:**
- Wash your hands thoroughly with soap and water.
- Before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
- Remove the cap from the bottle.
- After the cap is removed, if tamper evident snap collar is loose, this should be removed before using the product.
- Mix the contents of the bottle by inverting 5 to 10 times.
- Hold the bottle upside down in one hand between your thumb and middle finger (refer diagram 1).

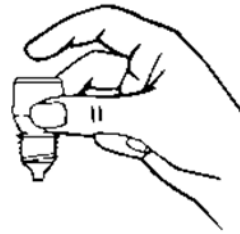


Diagram 1

- Tilt your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
- Place the tip of the bottle close to your eye. Do not touch the tip to your eye as this may cause injury to your eye.
- Do not touch the dropper tip to your eyelid or to surrounding areas or to any surface to avoid contamination of the dropper tip and solution.
- 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 (refer diagrams 2 and 3).



Diagram 2



Diagram 3

- Gently close your eye(s) for 2 minutes. Do not blink or rub your eye(s).
- When 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 prevent 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 and may result in less side effects.
- This will also help to prevent the unpleasant taste sensation that some people experience while using these eye drops.
- If necessary, repeat the above steps for the other eye.
- You may feel a slight burning sensation in the eye shortly after using Azarga. If it continues, or is uncomfortable, contact your doctor or pharmacist.
- If you want to use any other eye drops wait at least 5 minutes after using Azarga.

- It is normal for a small amount of eye drops to spill onto your cheek since your eyelids can only hold less than one drop at a time. Wipe away any spillage with a tissue.
- Replace the cap on the bottle and close it tightly.
- Always keep the bottle tightly closed when not in use.
- Wash your hands again with soap and water to remove any residue.
- Wait for 15 minutes before putting your contact lenses in.
- Discard Azarga eye drops 4 weeks after opening.

If you forget to use Azarga

Azarga should be used regularly at the same time each day. If you miss your dose at the usual time, treatment should be continued with the next dose as planned.

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

Do not take a double dose to make up for the dose you missed.

If you use too much Azarga

If you think that you have used too much Azarga, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you accidentally put several Azarga Eye Drops in your eyes, immediately wash your eyes with warm tap water.

5. What should I know while using Azarga?

Things you should do

- Tell your doctor immediately if you are going to have any surgery.
- Use Azarga for eye use only.
- Remove soft contact lenses before putting in Azarga eye drops. Benzalkonium chloride one of the ingredients in Azarga may cause eye irritation and is known to discolour soft contact lenses.
- Put your lenses back in 15 minutes after using the eye drops.

Call your doctor straight away if you:

- develop any signs of allergic reaction.
- become pregnant, are planning to become pregnant or if you are breast feeding while using Azarga.
- suffer from any heart or breathing problems.
- develop a skin rash, hives or other skin problems while on treatment with Azarga.

Remind any doctor, dentist, pharmacist or specialist you visit that you are using Azarga.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not use Azarga in children.
- Do not give Azarga to anyone else, even if they seem to have the same condition as you.
- Do not touch the dropper tip to any surface.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Azarga affects you.

Azarga may impair the ability to perform tasks requiring mental alertness and/or physical coordination. It may also cause temporary blurred vision or other visual problems in some people.

If blurred vision occurs when you use Azarga, wait until your vision clears before driving or using machinery.

Looking after your medicine

- Store below 25 °C
- Do not freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard Azarga 4 weeks after opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Eye Problems: • Temporary blurred vision lasting from a few seconds to a few minutes. • Bitter or unusual taste in the mouth after using Azarga • Eye pain • Eye irritation	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
- Feeling that something is in your eye(s) - Dry eye(s) - Eye discharge - Itching of the eye(s) - Increased sensitivity to light - Excessive secretion of tears from the eye(s) - Lack of sleep - Watery or sticky discharge from eye(s), itching or discomfort, red or pink eye(s) - Reddening of eye(s) - Vision problems - Eyelid swelling - Itching or burning sensation, blurred vision, eyelid swelling General problems: - Cough - Generally feeling unwell - Dizziness - Tingling or numbness of the hands or feet - Headache - Dry mouth - Feeling sick - Fatigue - Aching muscles, not caused by exercise Other problems: - Dizziness, lightheadedness - Severe headache, dizziness, vision problems	

Serious side effects

Serious side effects	What to do
Eye Problems: - Light sensitivity, discomfort or pain in the eyes General problems: - Symptoms of allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives Ear and nose problems: - Bleeding from nostrils, feeling weak	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears Skin problems: - Severe blisters and bleeding in the lips, eyes, mouth, nose - Redness of the skin - Rash Other problems: - Slow, fast or irregular heartbeat	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Azarga contains

Active ingredient (main ingredient)	Brinzolamide and timolol maleate.
Other ingredients (inactive ingredients)	Mannitol, carbomer 974P, sodium chloride, tyloxapol, disodium edetate, sodium hydroxide and/or hydrochloric acid (for pH adjustment) purified water and benzalkonium chloride.
Potential allergens	Benzoates, sulfites and hydroxybenzoates.

Do not take this medicine if you are allergic to any of these ingredients.

What Azarga looks like

Azarga eye drops is a white to off-white uniform suspension and is presented in an 8 mL round opaque low density polyethylene bottle dispenser containing 5 mL suspension.

Australian registration number

AUST R 156500.

Who distributes Azarga

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

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Free Phone: 0800 354 335.

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