

Azopt

Eye Drops 1%®

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 Azopt?

Azopt contains the active ingredient brinzolamide. Azopt is used to treat ocular hypertension (high pressure in eye) and open-angle glaucoma (an eye disorder that causes damage to the optic nerve of the eye).

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

2. What should I know before I use Azopt?

Do not use if you have ever had an allergic reaction to Azopt 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 Azopt?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Azopt 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 Azopt?

- Put one drop of AZOPT eye drop in affected eye or eyes twice daily.
- If you do not understand how to use your eye drops, consult your doctor for advice.

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

5. What should I know while using Azopt?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are using Azopt.</p> <ul style="list-style-type: none"> ● Contact your doctor immediately if you notice any signs of allergic reactions such as skin rash, redness of skin or fever ● Remove contact lenses if you are wearing them before instilling the eye drops.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine suddenly. ● Do not use Azopt eye drops to treat other problems unless your doctor or pharmacist tells you to. ● Do not leave the top off the bottle for any time to avoid any contamination.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Azopt may cause blurred vision or other visual disturbances in some people after putting eye drops in. ● Wait until vision clears before driving or using machinery.

	<ul style="list-style-type: none"> • Precaution should be taken before driving and using any machinery as Azopt may also cause nervous system problems.
Looking after your medicine	<ul style="list-style-type: none"> • Store below 25°C. • Do not freeze the eye drops

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

6. Are there any side effects?

Common side effects include blurred vision, double vision, dry or itchy eye(s), discomfort, discharge from eye(s), hives, headache, nervousness, keratitis (an eye disease of the cornea)

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.

Azopt

EYE DROPS 1%®

Active ingredient(s): *brinzolamide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Azopt. **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 Azopt.**

Where to find information in this leaflet:

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

1. Why am I using Azopt?

Azopt contains the active ingredient brinzolamide. Azopt belongs to class of drugs called "Carbonic anhydrase inhibitors".

Azopt is used to treat ocular hypertension (high pressure in eye) and open-angle glaucoma (an eye disorder that causes damage to the optic nerve). It is either used alone or in combination with other eye drops/medicines. Azopt helps to lower the eye pressure by reducing the production of fluid that the eye naturally produces.

2. What should I know before I use Azopt?

Warnings

Do not use Azopt if:

- you are allergic to brinzolamide, or any of the ingredients listed at the end of this leaflet.
- you have problems with your kidney's or hyperchloraemic acidosis (a condition in which there are high levels of chloride in your blood)
- you are allergic to sulfonamides medications.
Symptoms of allergic reactions may include:
Stevens-Johnson syndrome (SJS) [A skin disease having symptoms such as blisters and sores on skin, eyes, nose, genitals, mouth, skin pain, rash, fever] and toxic epidermal necrolysis (TEN) [severe form of SJS having symptoms such as peeling and blistering of skin, including mouth, eyes and genitals]
If you think you may be allergic, ask your doctor for advice.

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

Check with your doctor if you:

- have acute angle-closure glaucoma (eye disorder)
- have diabetes mellitus or problems with your cornea, corneal dystrophies (a group of rare hereditary eye disorders that affect cornea)
- have liver or kidney disease.

Do not put Azopt eye drops in your eyes if you are wearing contact lenses as it may cause irritation to your eyes and discolor soft contact lenses.

Remove your contact lenses before putting Azopt eye drops in and wait at least 15 minutes before you reinsert your contact lenses into your eyes.

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 potential possible risks and benefits of using Azopt during pregnancy.

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

Your doctor will advise you regarding the potential possible risks and benefits of using Azopt during breast feeding.

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 Azopt and affect how it works. They may include:

High doses of salicylate-containing medicines which act as pain killers.

Other medicines known as "oral carbonic anhydrase inhibitors"

Nonsteroidal anti-inflammatory drugs (NSAIDs)

If you are taking any of the above medications, consult your doctor for advice.

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

4. How do I use Azopt?

How much to use

- Put one drop of AZOPT eye drop in affected eye(s) twice daily.
- Follow the instructions provided and use Azopt until your doctor tells you to stop.
- In case you are using other topical eye drop medications, administer Azopt with an interval of at least five minutes. If you are using any eye ointments, administer them last.
- **If you do not understand how to use your eye drops, consult your doctor for advice.**
- If you are being advised to change your eye drops to Azopt, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

When to use Azopt

- Instill Azopt eye drops in the conjunctival sac of affected eye(s) twice daily.

How to use Azopt

- Sitting or lying down might make administration of your eye drops process simpler.
- Remove contact lenses if you are wearing them before instilling the eye drops.
- Shake the bottle well prior to use.

Follow below steps to use Azopt Eye Drops:

- 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.
- Mix the contents of the bottle by inverting 5 to 10 times.
- Remove the cap from the bottle.
- Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

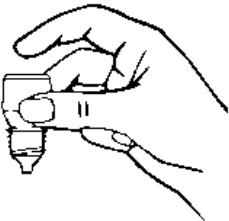


Diagram 1

- 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 the eye
- **Do not touch the dropper tip to any surface to avoid contamination.**
- 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).

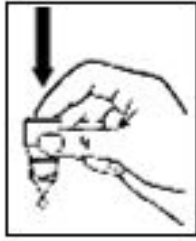


Diagram 2



Diagram 3

- Close your eye. Do not blink or rub your eye.
- 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 may result in a decrease in systemic side effects and an increase in local activity.
- This will also help to reduce the unpleasant taste sensation that some people experience when using these drops.
- If necessary, repeat the above steps for the other eye.
- It is normal for a small amount of the eye drop 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, closing it tightly.
- Always keep the bottle tightly closed when not in use.

- Wash your hands again with soap and water to remove any residue.
- You may feel a slight burning sensation or discomfort in the eye shortly after using Azopt eye drops.
- Contact your doctor immediately if the discomfort persists for a long time.
- If you want to wear your contact lenses, wait 15 minutes after instillation of the dose before reinserting the contact lenses.
- Do not use the eye drops after 4 weeks from opening it.
- Discard any remaining solution after four weeks and open a new bottle every four weeks.

If you forget to use Azopt

Azopt should be used regularly at the same time each day. If you miss your dose at the usual time, use the eye drops as soon as you remember.

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 as it may cause undesirable side effects.

If you use too much Azopt

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

Symptoms of overdose may include:

Electrolyte imbalance

Development of an acidotic state

Nervous system problems.

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 instilled several drops in your eyes, immediately wash your eyes with warm tap water and consult your doctor.

5. What should I know while using Azopt?

Things you should do

Call your doctor straight away if you:

- feel any persisting discomfort in your eyes after putting eye drops in.
- become pregnant while using Azopt eye drops.
- notice any signs of allergic reactions such as skin rash, red skin, blistering of the lip's eyes or mouth, fever.

- develop an eye infection or have any eye injury or an eye surgery.

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

Keep the Azopt eye drops away from children.

Have your eye pressure checked regularly.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not use Azopt eye drops to treat other problems unless your doctor or pharmacist tells you to.

Do not give Azopt eye drops to anyone else, even if they seem to have the same condition as you.

Driving or using machines

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

Azopt may cause blurred vision or other visual disturbances in some people after putting eye drops in.

Wait until vision clears before driving or using machinery.

Azopt may also cause nervous system disorders. Precaution should be taken before driving and using any machinery.

Looking after your medicine

- Store below 25°C.
- Do not freeze the eye drops.
- Do not leave the top off the bottle for any time. Put the top back on the bottle immediately after use to avoid any contamination.

Follow the instructions in the carton on how to take care of your eye drops 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

Do not use the eye drops after 4 weeks from opening it. Discard any remaining solution after four weeks and open a new bottle every four weeks.

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
<p>Eye problems:</p> <ul style="list-style-type: none">• Blurred Vision• Dry eye(s)• Discomfort• Eye(s) discharge• Itchy eye(s)• Irritation in eye(s)• Foreign body sensation or feeling of something in the eye(s)• Pain in eye(s)• Double vision• Vision changes <p>General problems:</p> <ul style="list-style-type: none">• Headache	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Nausea ● Dry mouth ● Indigestion ● Dizziness ● Unusual weakness ● Fatigue ● Blood pressure decreased ● Decreased appetite ● Joint pain ● Diarrhoea <p>Respiratory problems:</p> <ul style="list-style-type: none"> ● Sore throat, irritation, coughing ● Runny or blocked nose, sneezing, facial pressure or pain (Rhinitis) ● Shortness of breath ● Asthma ● Bleeding nose <p>Skin problems:</p> <ul style="list-style-type: none"> ● Hives (Urticaria) ● Itching 	

Serious side effects

Serious side effects	What to do
<p>Eye problems:</p> <ul style="list-style-type: none">• Keratitis (a disease of the cornea)• Tearing• Discharge with itching of the eye(s) and crusty eyelids (Conjunctivitis)• Reduced vision (Visual acuity)• Uncomfortable sensitivity to light• Swelling around the eye(s) (Periorbital oedema)• Swollen eyelid (Blepharitis)• Swelling of cornea• Medication residue• Corneal erosion (An eye disorder of cornea in which its outer layer becomes damaged)• Excessive dilation of blood vessels of eye causing reddening of	<p>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.</p>

Serious side effects	What to do
<p>white portion of the eye (sclera) (ocular hyperaemia)</p> <ul style="list-style-type: none"> ● Eyelid disorder <p>General problems:</p> <ul style="list-style-type: none"> ● Chest pain <p>Skin problems:</p> <ul style="list-style-type: none"> ● Stevens-Johnson syndrome (SJS) (A skin disease having symptoms such as blisters and sores on skin, eyes, nose, genitals, mouth, skin pain, rash, fever) ● Toxic epidermal necrolysis (TEN) (severe form of SJS having symptoms such as peeling and blistering of skin, including mouth, eyes and genitals) ● Dermatitis (Skin disease) ● Unusual hair loss or thinning <p>Kidney problems:</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> • kidney pain • Impotence <p>Nervous system problems:</p> <ul style="list-style-type: none"> • Tingling or numbness of the hands or feet • Depression • Dream abnormality • Unusual muscle stiffness causing poor control of movement • Agitation • Loss of memory • Nervousness • Taste disturbance or loss of taste <p>Ear and problems:</p> <ul style="list-style-type: none"> • Tinnitus (ringing in the ears, even though no external sound is present) 	

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 Azopt contains

Active ingredient (main ingredient)	Brinzolamide
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.

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

What Azopt looks like

Azopt is a white to off-white, uniform suspension.

AZOPT Eye Drops 1.0% is available in LDPE bottle dispenser. Pack sizes: 1 x 5 mL and 1 x 10 mL

Not all pack sizes may be marketed.

Australian registration number

AUST R 72750.

Who distributes Azopt

Azopt 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

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