

AZOPT

EYE DROPS 1%®

Brinzolamide

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you start to use Azopt Eye Drops.

This leaflet answers some common questions about Azopt. 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 from www.novartis.com.au

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 Azopt 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 Azopt is used for

Azopt Eye Drops contain the active ingredient brinzolamide, which belongs to a class of medicines known as "carbonic anhydrase inhibitors".

Azopt Eye Drops are used, either alone or in combination with other eye drops/medicines, to lower high pressure inside the eye(s) and to treat open-angle glaucoma or hypertension (high pressure) in the eye.

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 the 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 or optometrist. 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.

Azopt Eye Drops lower the pressure within the eye by reducing the production of fluid.

Although Azopt Eye Drops help to control your glaucoma, they do not cure it.

For more information about glaucoma, contact Glaucoma Australia Inc. (PO BOX 420, Crows Nest 1585 telephone 1800 500 880).

Ask your doctor if you have any questions about why Azopt has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Azopt Eye Drops are not addictive.

Use in Children

Azopt Eye Drops are not recommended for use in children. The safety and effectiveness of Azopt Eye Drops in children has not been established.

Before you use Azopt

When you must not use it

Do not use Azopt if:

- You have an allergy to AZOPT Eye Drops or other medicines containing brinzolamide, other carbonic anhydrase inhibitors or any ingredients in Azopt Eye

Drops that are 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.
- You have severe kidney disease
- You have high levels of chloride in your blood (hyperchloraemia).

Do not take this medicine if the expiry date has passed, the packaging is torn or the safety seal around the closure and neck area is broken.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if:

- **You have an allergy to sulfonamide medicines**
The active ingredient of Azopt Eye Drops, brinzolamide, is a sulfur-containing medicine (a sulfonamide). If you are allergic to sulfur medicines, such as some antibiotics, medicines used to treat diabetes and also diuretics (water tablets), you may be allergic to Azopt Eye Drops. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfonamides.
- **You are pregnant, or intend to become pregnant**
Your doctor will discuss the possible risks and benefits of using Azopt during pregnancy.
- **You are breast-feeding or intend to breast-feed**

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

- **You have or have had any medical conditions such as problems with your liver or kidneys.**
- **You have impaired corneas which can occur in diabetes mellitus, low endothelial cell counts or in a condition called corneal dystrophies**

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

- **You have an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.**
- **If you have or have had any severe skin reactions like skin rash, skin peeling, blistering of the lips, eyes or mouth.**

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

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

The preservative in Azopt Eye Drops, benzalkonium chloride, may cause eye irritation and is also known to discolour soft contact lenses.

You can put your contact lenses back into your eyes 15 minutes after you have used Azopt Eye Drops.

Taking other medicines

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

Some medicines and Azopt Eye Drops may interfere with each other.

These include:

- Aspirin, in high doses

- High dose of salicylate-containing medicines which are used to relieve pain
- Other medicines known as "carbonic anhydrase inhibitors" that you take to treat glaucoma.

These medicines may be affected by Azopt Eye Drops 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 taking another carbonic anhydrase inhibitor (acetazolamide or dorzolamide) or medicines that are nonsteroidal anti-inflammatory drugs (NSAIDs) or salicylates, talk to your doctor or healthcare provider.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Azopt

Use Azopt Eye Drops only as prescribed by your doctor.

Follow all directions given to you by your doctor or healthcare provider carefully.

They may differ from the information contained in this leaflet.

Use Azopt Eye Drops only when prescribed by your doctor.

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

How much to use

The usual dose of Azopt Eye Drops is ONE DROP in the affected eye(s) TWICE A DAY. This will normally be in the morning and at night. Your doctor will tell you how many drops you need to use each day.

After using Azopt Eye Drops wait at least 5 minutes before putting any other eye drops in your eye(s). Eye ointment should be administered last.

If you are being changed from one eye drop to another, follow your

doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

If you are unsure about when, or how, to stop using Azopt Eye Drops you should talk to your doctor.

How to use Azopt

You may find it easier to use your eye drops if you are sitting or lying down.

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

Follow these steps to use AZOPT 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. Mix the contents of the bottle by inverting 5 to 10 times.
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).

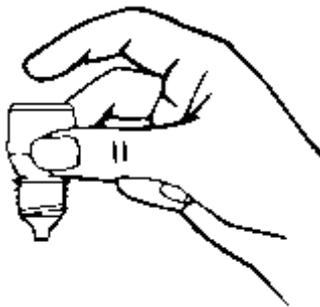


Diagram 1

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.
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).

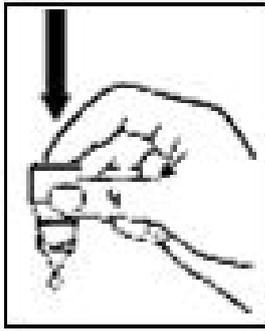


Diagram 2



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 Azopt 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.

After using Azopt Eye Drops, 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 Azopt Eye Drops at about the same time every day unless your doctor tells you otherwise.

Using your eye drops at the same time 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

Azopt Eye Drops help control your condition but will not cure it. Therefore Azopt Eye Drops must be used every day.

Continue using Azopt Eye Drops for as long as your doctor prescribes.

If you forget to take 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 the medicines as you would normally.

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

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 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 Azopt Eye Drops, immediately telephone your doctor or Poisons Information Centre on 131126 or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Azopt

Things you must do

To make sure that Azopt is working properly, have your eye pressure checked regularly.

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

If you develop an eye infection, receive an eye injury or have eye surgery tell your doctor.

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 medication and seek medical attention immediately.

Your doctor may tell you to use a new container of Azopt Eye Drops because of possible contamination of the old one, or may advise you to stop your treatment with Azopt Eye Drops.

If you become pregnant while using Azopt Eye Drops tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor

and pharmacist that you are using Azopt Eye Drops.

Tell all your doctors and pharmacists that you are using Azopt.

Things you must not do

Do not use Azopt Eye Drops to treat other complaints unless your doctor or pharmacist tells you to.

Do not give Azopt Eye Drops to anyone else, even if they appear to have the same condition as you.

Do not stop using Azopt Eye Drops without first talking to your doctor.

If you stop using your eye drops, your eye pressure may rise again and damage to your eye may occur.

Do not let children handle Azopt Eye Drops. If a child accidentally swallows any of the drops read the instructions under "If you use too much (overdose)"

Things to be careful of

Be careful of driving or operating machinery until you know how Azopt Eye Drops affect you and your vision.

As with any eye medicines, temporary blurred vision or other visual disturbances may affect the ability to drive and 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 Azopt Eye Drops.

Azopt Eye Drops help 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.

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

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

- Blurred or abnormal vision
- Discomfort, irritation or feeling of something in the eye(s)
- Redness of the eye(s)
- Dry eye(s)
- Eye pain
- Discharge from the eye(s)
- Itchy eye(s)
- Watering of the eye(s).

Additional side effects that can occur rarely include:

- Swelling of the clear front part of the eye(s)
- Red, itchy, irritated, crusty, swollen eyelid(s)
- Swelling of the skin around the eye(s)
- Crusty eyelashes
- Sticky sensation in the eye(s)
- Tired eye(s)
- Sensitivity to bright lights
- Double vision
- Seeing flashes or sparks of light
- Eye numbness.

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

- Headache
- Chest pain, shortness of breath
- Unusual tiredness or weakness
- Dry mouth and/or nose
- Blocked or running nose
- Bleeding nose
- Sore throat, irritation and/or coughing
- Mucous in the chest

- Nausea, indigestion, diarrhoea and/or upset stomach
- Tingling, numbness and/or dizziness
- Depression
- Abnormal dreams
- Muscle stiffness
- Agitation
- Change in sensation of taste
- Loss of memory
- Nervousness
- Rash, itchy skin
- Hair loss
- Persistent noises in the ear(s)
- Impotence
- Kidney pain.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- Generalised itchiness
- Chest pain
- Shortness of breath
- Severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.
- 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)

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

Tell your doctor if you notice any other effects.

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

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

After using Azopt

Storage

Keep your eye drops in a cool place where the temperature stays below 25°C. Do not freeze the eye drops.

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

Heat and dampness can destroy some medicines.

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

Keep it where children cannot reach it.

Put the top back on the bottle right away after use to avoid contaminating the eye drops. Do not leave the top off the bottle for any length of time.

Disposal

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

Open a new bottle every 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.

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

Product description

What it looks like

Azopt Eye Drops is a sterile suspension that comes in a 5mL dropper bottle with screw cap.

The safety seal must be removed before use.

Ingredients

The active ingredient in Azopt is brinzolamide 10 mg/mL (1.0%).

It also contains the inactive ingredients:

- mannitol
- carbomer 974P
- sodium chloride
- tyloxapol
- disodium edetate
- sodium hydroxide and/or hydrochloric acid (to adjust pH)
- purified water
- benzalkonium chloride 0.1 mg/mL (as a preservative),

Supplier

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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