

AZOPT[®] EYE DROPS

Brinzolamide (10mg/ml)

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What AZOPT is used for

Azopt eye drops are used to treat high pressure in the eye. This pressure can lead to an illness called glaucoma.

If the pressure in the eye is too high, it can damage your sight.

How AZOPT works

Azopt contains brinzolamide which belongs to a group of medicines called carbonic anhydrase inhibitors. It reduces the pressure within the eye.

Before you use AZOPT

- When you must not use it

Do not use Azopt:

- if you have severe kidney problems.
- if you are allergic to brinzolamide or any of the other ingredients of this medicine.
- if you are allergic to medicines called sulphonamides. Examples include medicine used to treat diabetes and infections and also diuretics (water tablets). Azopt may cause the same allergy.
- if you have too much acidity in your blood (a condition called hyperchloraemic acidosis).

If you have further questions, ask your doctor for advice.

Children and adolescents

Azopt is not to be used by infants, children or adolescents under 18 years of age.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Women who may become pregnant are advised to use effective contraception during Azopt treatment. The use of Azopt is not recommended during pregnancy or breast-feeding. Do not use Azopt unless clearly indicated by your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor or pharmacist before using Azopt:

- if you have kidney or liver problems.
- if you have dry eyes or cornea problems.
- if you are taking other sulphonamide medicines
- if you have a specific form of glaucoma in which the pressure inside the eye rises due to deposits that block fluid draining out (pseudoexfoliative glaucoma or pigmentary glaucoma) or a specific form of glaucoma in which the pressure inside the eye (sometimes rapidly) rises because the eye bulges forward and blocks

fluid draining out (narrow-angle glaucoma)

- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using Azopt or other related medicines.

Azopt contains benzalkonium chloride

Azopt contains a preservative (benzalkonium chloride) which may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

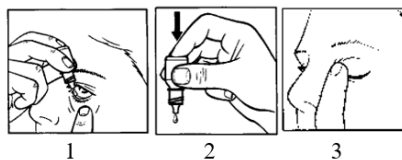
- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you are taking another carbonic anhydrase inhibitor (acetazolamide or dorzolamide), talk to your doctor.

If you are using other eye drops, leave at least 5 minutes between putting in Azopt and the other drops. Eye ointments should be administered last.

How to use AZOPT



- Get the Azopt bottle and a mirror
- Wash your hands
- Shake the bottle and twist off the cap. After the cap is removed, if the tamper evident snap collar is loose, remove before using product.
- Hold the bottle, pointing down, between your thumb and middle finger
- 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 infect the drops
- Gently press on the base of the bottle to release one drop of Azopt 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 Azopt, press a finger to the corner of your eye, by the nose (picture 3) for at least 1 minute. This helps to stop Azopt getting into the rest of the body.
- If you take drops in both eyes, repeat the steps for your other eye.
- Put the bottle cap back on firmly immediately after use
- Use up one bottle before opening the next bottle.

- How much to use

The recommended dose is one drop of Azopt in the affected eye(s) twice or thrice daily.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using Azopt for as long as your doctor recommends.

- If you forget to use it

Use a single drop as soon as you remember, and then go back to your regular routine. Do not use a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you get too much in your eyes, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

While you are using it

- Things you must do

Only use Azopt for your eyes. Do not swallow or inject.

If a drop misses your eyes, try again.

- Things you must not do

Do not drive or use machines until your vision is clear. You may find that your vision is blurred for a time just after using Azopt.

Azopt may impair the ability to perform tasks requiring mental alertness and/or physical coordination. If affected, take care when driving or using machines.

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

- Things to be careful of

If you stop using Azopt without speaking to your doctor, the pressure in your eye will not be controlled which could lead to loss of sight.

Take special care with Azopt:

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with brinzolamide treatment. Stop using Azopt and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in ‘Side effects’.

Side effects of AZOPT

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been seen with Azopt.

Stop using Azopt and seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

Common (may affect up to 1 in 10 people)

- **Effects in the eye:** blurred vision, eye irritation, eye pain, eye discharge, itchy eye, dry eye, abnormal eye sensation, redness of the eye.
- **General side effects:** bad taste

Uncommon (may affect up to 1 in 100 people)

- **Effects in the eye:** sensitivity to light, inflammation or infection of the conjunctiva, eye swelling,

eyelid itching, redness or swelling, deposits in eye, glare, burning sensation, growth on surface of eye, increased pigmentation of the eye, tired eyes, eyelid crusting, or increased tear production.

- **General side effects:** decreased or reduced heart function, a forceful heartbeat that may be rapid or irregular, decreased heart rate, difficulty breathing, shortness of breath, cough, decreased red blood cell count in blood, increased chlorine level in blood, dizziness, difficulty with memory, depression, nervousness, decreased emotional interest, nightmare, generalized weakness, fatigue, feeling abnormal, pain, movement problems, decreased sex drive, male sexual difficulty, cold symptoms, chest congestion, sinus infection, throat irritation, throat pain, abnormal or decreased sensation in mouth, inflammation of the lining of the oesophagus, abdominal pain, nausea, vomiting, upset stomach, frequent bowel movements, diarrhoea, intestinal gas, digestive disorder, kidney pain, muscle pain, muscle spasms, back pain, nose bleeds, runny nose, stuffy nose, sneezing, rash, abnormal skin sensation, itching, smooth skin rash or redness covered by elevated bumps, skin tightness, headache, dry mouth, debris in eye.

Rare (may affect up to 1 in 1,000 people)

- **Effects in the eye:** corneal swelling, double or reduced vision, abnormal vision, flashes

of light in the field of vision, decreased eye sensation, swelling around the eye, increased pressure in eye, damage to the optic nerve.

- **General side effects:** memory impairment, drowsiness, chest pain, upper respiratory tract congestion, sinus congestion, nasal congestion, dry nose, ringing in ears, hair loss, generalized itching, feeling jittery, irritability, irregular heart rate, body weakness, difficulty sleeping, wheezing, itchy skin rash.

Not known (frequency cannot be estimated from the available data)

- **Effects in the eye:** eyelid abnormality, visual disturbance, corneal disorder, eye allergy, decreased growth or number of eyelashes, eyelid redness.
- **General side effects:** increased allergic symptoms, decreased sensation, tremor, loss or decrease in taste, decreased blood pressure, increased blood pressure, increased heart rate, joint pain, asthma, pain in extremity, skin redness, inflammation, or itching, abnormal liver blood tests, swelling of the extremities, frequent urination, decreased appetite, feeling unwell, reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, which can be preceded by fever and flu-like symptoms. These serious skin rashes can be potentially life-threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of AZOPT

- *Storage*

Store below 30°C.

Keep out of reach and sight of children.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Azopt is white to off-white suspension, supplied in a 5ml bottle with a dispensing plug and screw cap.

- *Ingredients*

- Active ingredient(s)

Brinzolamide 10mg/ml

- Inactive ingredients

Benzalkonium chloride, mannitol, carbomer 974P, tyloxapol, disodium edetate, sodium chloride, hydrochloric acid and/or sodium hydroxide (for pH adjustment), purified water.

- *MAL number:*

MAL20041107ARSZ

Manufacturer

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Product Registration Holder

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26 May 22; EU PI Jun 22

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27/01/25

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