



Azopt® eye drop suspension

Novartis Pharma Schweiz AG

What is Azopt and when is it used?

Azopt eye drop suspension contains brinzolamide as its active substance, a “carbonic anhydrase inhibitor” that decreases pressure in the eye. Azopt eye drop suspension is medically prescribed to treat increased pressure in the eye and certain forms of glaucoma. Azopt eye drop suspension may be used alone or with other medicines that lower pressure in the eye (“beta blockers”).

What else should I be aware of?

This medicine has been prescribed for you personally by your doctor for your eye condition. You should not use these eye drops for other symptoms and should not give them to anyone else. Even if someone else has similar symptoms to you, the non-prescription use of this medicine can be dangerous for other people.

Note for contact lens wearers: if you wear contact lenses, remove them before using Azopt eye drop suspension, as benzalkonium chloride, one of the ingredients of this medicine, may discolour soft contact lenses. Wait at least 10 to 15 minutes after using Azopt eye drop suspension before reinserting your lenses.

When should Azopt eye drop suspension not be used?

Do not use Azopt eye drop suspension if you are hypersensitive (allergic) to any of its ingredients. Brinzolamide is a sulphonamide. Therefore, inform your doctor if you are allergic to substances in this group (e.g. certain antibiotics).

Azopt eye drop suspension may also not be used if you suffer from severe kidney function impairment and/or have hyperchloraemic acidosis (excess acid in the blood).

When is caution advised when using Azopt eye drop suspension?

Consult your doctor immediately if you notice any symptoms or problems involving your eye, e.g. eye redness or eyelid swelling.

If you suspect that Azopt eye drop suspension is causing an allergic reaction (e.g. skin rash or itching), stop using it immediately and contact your doctor.

Azopt should be used with caution in patients with existing kidney function impairment or those at risk of kidney function impairment due to the possible risk of metabolic acidosis.

Treatment with Azopt may cause drowsiness and memory problems, which can impair the ability to drive or use machines. If blurred vision occurs after using Azopt, patients should wait until their sight has returned to normal before driving or using machines.

Azopt may not be used by those under 18 years of age unless instructed by a doctor.

Use in elderly patients over 65 years of age: studies on Azopt eye drop suspension have shown that its efficacy and safety in younger and elderly patients is similar.

If you have, or have had, problems with your kidneys or liver, tell your doctor.

Inform your doctor or pharmacist if you are suffering from any other illnesses, have any allergies, are taking any other medicines (including non-prescription medicines) or applying any other medicines to your eye(s).

Can Azopt eye drop suspension be used by women who are pregnant or breast-feeding?

If you are pregnant, think that you may be pregnant or wish to become pregnant, inform your doctor or pharmacist. They will decide whether you should use Azopt eye drop suspension.

If you are breast-feeding your child or would like to breast-feed your child, inform your doctor or pharmacist. They will decide whether you should use Azopt eye drop suspension.

How to use Azopt eye drop suspension

Your doctor will determine the dosage and treatment period best suited to you.

The usual dosage is 1 drop twice daily (morning and evening) into the affected eye(s).

Shake the bottle well before use.

If you forget a dose of Azopt, apply a dose as soon as you can and then continue your regular treatment schedule. If a drop does not get into your eye, apply the drop again.

If you are using Azopt eye drop suspension together with other eye drops, they must be used at least 10 minutes apart.

Take care not to let the bottle's dropper tip come into contact with your eye, the area surrounding your eye, your hands or other materials.

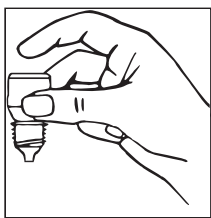
If you accidentally apply too many drops to your eye(s), you can rinse them out of your eye(s) immediately afterwards with warm water.

If you have accidentally swallowed or injected Azopt eye drop suspension, contact your doctor immediately.

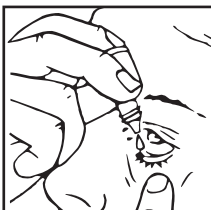
Azopt eye drop suspension is intended for use in the eye only.

Instructions for use:

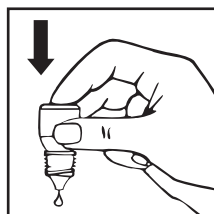
1. Shake the bottle well before use. Wash your hands and unscrew the cap. Hold the container between your thumb and middle finger (Figure 1).



2. Lean your head back and pull your lower eyelid carefully downwards with a clean finger so that there is a gap between your eyelid and eye. Bring the tip close to your eye (Figure 2). It is easier if you look in a mirror to do this.



3. Gently press the bottom of the upturned bottle with your index finger to release a drop of Azopt (Figure 3). Do not touch your eye or eyelid with the dropper tip.



4. Repeat steps 2 and 3 for the other eye if your doctor has instructed you to do so.
 5. Close the bottle tightly after use.
- Do not change the prescribed dosage yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor or pharmacist.

What side effects can Azopt eye drop suspension have?

The active substances contained in the eye drops may enter your bloodstream. This may cause side effects that affect your eye(s) and/or other parts of your body.

Some or all of the following side effects may occur during treatment with Azopt eye drop suspension:

Common (may affect up to 10 in 100 people)

Effects on the eye: blurred vision, eye irritation, eye pain, eye discomfort, eye redness, foreign body sensation.

Effects on the body: abnormal sense of taste.

Uncommon (may affect up to 10 in 1000 people)

Effects on the eye: corneal erosion, eye inflammation with damage to the surface, conjunctival inflammation, eyelid redness and inflammation, allergic reaction affecting the eye, sensitivity to light, dry eye, tired eyes, eye itching, increased tear secretion, eye discharge, eyelid crusting.

Effects on the body: headache, depression, dizziness, skin tingling, shortness of breath, nosebleed, runny nose, sore throat, tickly throat, flow of mucus into the nose and throat, throat irritation, nausea, diarrhoea, indigestion, abdominal discomfort, dry mouth, rash, tiredness.

Rare (may affect up to 10 in 10,000 people)

Effects on the eye: corneal swelling, double vision, reduced visual clarity or changes in visual clarity, photopsia, reduced sensation in the eye, swelling around the eye.

Effects on the body: impaired memory, drowsiness, chest pain, irregular heartbeat, asthma, blockage of the upper airways, nasal congestion, nasal dryness, cough, noises in the ear(s), hair loss, itching affecting the whole body, anxiety, difficulty sleeping, general weakness, irritability.

You may experience the following additional side effects if you use Azopt eye drop suspension:

Effects on the body: reduced appetite, decreased blood pressure, joint pain.

Some patients may also experience side effects not listed here.

If you experience severe reactions to Azopt eye drop suspension or reactions not mentioned here, stop using Azopt, consult a doctor immediately and follow their advice.

Further information

To prevent contamination of the dropper tip and the eye drop suspension, it is important not to touch your eyelids and the area surrounding your eyes or other surfaces with the bottle's dropper tip. The dropper tip should also not come into contact with your hands.

Close the bottle tightly immediately after use.

Shelf life:

Do not use after the expiry date marked with “Use by” on the pack.

Azopt eye drop suspension may not be used for longer than 4 weeks after the dropper bottle is first opened.

Storage:

Keep this medicine out of the reach of children and do not store above 30°C

Once your treatment has finished, return the medicine to the person who supplied it (your doctor or pharmacist) so that it can be disposed of appropriately.

Your doctor or pharmacist will be able to give you more information. They have access to the detailed prescribing information.

What does Azopt eye drop suspension contain?

Azopt is a sterile eye drop suspension and contains 1% brinzolamide as its active substance.

Azopt contains:

- Preservative: Benzalkonium Chloride, 0.01%
- Inactives: Mannitol; Carbomer 974P, Edetate Disodium, Tyloxapol, Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH), and Purified Water.

Where can I obtain Azopt eye drop suspension? Which pack sizes are available?

Azopt eye drop suspension may only be obtained in a pharmacy, with a doctor's prescription.

5 ml and 3 x 5 ml packs are available.

Not All Pack sizes are marketed.

Manufactured by

Alcon-Couvreur B-2870 Puurs (Belgium) for Novartis Pharma AG Basle, Switzerland

This package leaflet was last reviewed in February 2016.

This is a medicament

- A medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists