NOVARTIS

AZOPTIC Eye Drops

(suspension)

Patient Information Leaflet

Document status: Final

Release date: 12 May 2022

SCHEDULING STATUS: S3

AZOPTIC Eye Drops (suspension)

Brinzolamide, 10 mg per ml

Read all of this leaflet carefully before you start using AZOPTIC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- AZOPTIC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AZOPTIC is and what it is used for

What AZOPTIC is:

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

What AZOPTIC is used for:

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

- **What you need to know before you use AZOPTIC**

Do not use AZOPTIC :

- if you are hypersensitive (allergic) to brinzolamide or any of the other ingredients of AZOPTIC (listed in *section 6*);
- if you are allergic to medicines called sulphonamides. Examples include medicines used to treat diabetes and infections and also diuretics (water tablets);
- if you have too much acidity in your blood (a condition called hyperchloraemic acidosis);
- if you have severe kidney problems;
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with AZOPTIC:

- 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).

Children/ and adolescents

- AZOPTIC is not to be used by infants, children or adolescents under 18 years of age unless advised by your doctor.

Other medicines and AZOPTIC

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- dorzolamide (other eye drops used for the treatment of glaucoma)
- carbonic anhydrase inhibitors e.g acetazolamide (a medicine used to treat glaucoma, epilepsy, altitude sickness)
- ketoconazole, itraconazole, clotrimazole (medicines used to treat fungus infections)
- ritonavir (an antiretroviral medicine used to treat HIV/AIDS)
- troleandomycin (an antibiotic)
- NSAIDs (non-steroidal anti-inflammatory drug) or salicylates (me[ŧ]dicines used for pain, inflammation and fever).

Pregnancy and breastfeeding and fertility

You should not use AZOPTIC if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using AZOPTIC.

Driving and using machinery

It is not always possible to predict to what extent AZOPTIC may interfere with the daily activities of a patient. Temporary blurred vision or other visual disturbances may impair the ability to perform tasks or activities requiring mental alertness and / or physical coordination, judgment and/or sound coordination and vision.

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which AZOPTIC affects them.

AZOPTIC contains benzalkonium chloride

- AZOPTIC 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.

2. How to use AZOPTIC

Do not share medicines prescribed for you with any other person.

Always use AZOPTIC exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

SHAKE WELL BEFORE USE.

The usual dose is:

- When used as monotherapy or adjunctive therapy, the dose is one drop of AZOPTIC in the conjunctival sac of the affected eye(s) twice daily.
- Some patients may have a better response with one drop three times a day.
- When substituting AZOPTIC for another ophthalmic antiglaucoma agent, discontinue the other agent after proper dosing for one day, and start AZOPTIC on the next day.
- If more than one topical ophthalmic drug is being used, the drugs should be administered at least ten minutes apart.
- The preservative in AZOPTIC, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of AZOPTIC but may be reinserted 15 minutes after instillation.
- Your doctor will tell you how long your treatment with AZOPTIC will last.
- If you have the impression that the effect of AZOPTIC is too strong or too weak, tell your doctor or pharmacist.

If you use more AZOPTIC than you should

Due to brinzolamide in AZOPTIC, electrolyte imbalance, development of an acidotic state (too much acid build up in the blood), and possibly central nervous system effects (e.g. dizziness, nausea and a feeling the room is spinning) may occur.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of AZOPTIC

Do not take a double dose to make up for forgotten individual doses.

If you stop using AZOPTIC

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

3. Possible side effects

AZOPTIC can have side effects.

Not all side effects reported for AZOPTIC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AZOPTIC, please consult your healthcare professional for advice.

If any of the following happens, stop taking AZOPTIC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AZOPTIC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- depression; memory impairment;
- shortness of breath; asthma;
- somnolence (a state of strong desire for sleep, sleeping for unusually long periods);

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- blurred vision;
- eye irritation, eye pain;
- eye discomfort, eye redness;
- taste disturbances.
- chest pain, irregular heart rate;

The following side effects have been reported less frequently:

- corneal erosion (damage to the front layer of the eyeball);
- eye surface inflammation with surface damage;
- inflammation of the conjunctiva (inflammation inside the eye);
- eye allergy, eyelid inflammation;
- sensitivity to light;
- dry eye, tired eyes;
- eye itching;
- increased tear production;
- eye discharge, eyelid crusting (itching, burning, mild foreign-body sensation; tearing and crusting around the eyes on awakening);

- headache;
- dizziness;
- abnormal skin sensation;
- nose bleeds, runny nose;
- throat pain, throat irritation;
- upper airway cough syndrome;
- nausea, diarrhoea, upset stomach, abdominal discomfort;
- dry mouth;
- fatigue;
- corneal swelling;
- double vision, reduced vision, abnormal vision;
- decreased eye sensation;
- swelling around the eye;
- drowsiness;
- upper respiratory tract congestion;
- sinus congestion, nasal congestion, dry nose;
- ringing in ears;
- hair loss;
- generalized itching;
- feeling jittery, irritability;
- difficulty sleeping;
- body weakness.

The following side effects have been reported but the frequency is unknown:

- decreased appetite;

- decreased sensation;
- low blood pressure;
- joint pain;
- vomiting;
- abnormal liver function;
- increased urinary frequency;
- malaise (a general feeling of illness).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 . By reporting side effects, you can help provide more information on the safety of AZOPTIC.

4. How to store AZOPTIC

- Store all medicines out of reach of children.
- Store between 4 °C to 25 °C.
- Do not use for more than 30 days after opening.
- Store in the original package / container.

- Do not store in a bathroom

- Do not use after the expiry date stated on the label / carton / bottle
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

5. Contents of the pack and other information

What AZOPTIC contains:

- The active substance is:

Brinzolamide

- The other ingredients are*:*

Benzalkonium chloride

Mannitol (E421)

Carbomer 974P

Tyloxapol

Edetate disodium

Sodium chloride

Hydrochloric acid/sodium hydroxide (to adjust pH)

Purified water

What AZOPTIC looks like and contents of the pack

What AZOPTIC looks like:

Colourless to off-white suspension

Contents of the pack:

Natural (colourless) plastic bottle dispenser containing 5 ml or 10 ml, with a white polypropylene cap.

Holder of Certificate of Registration and Manufacturer

Novartis South Africa (Pty) Ltd.

Magwa Crescent West

Waterfall City

Jukskei View

Johannesburg, 2090

This leaflet was last revised in

Date of revision of text: 12 May 2022

Registration number

34/15.4/0382

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website