

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

**S3**

### AZIBRIN 1 %

Each mL contains 10 mg brinzolamide

Contains sugar alcohol: Mannitol 33,00 mg/mL

Contains preservative: Benzalkonium chloride 0,02 % w/v

### Read all of this leaflet carefully before you start using AZIBRIN 1 %

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AZIBRIN 1 % 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 AZIBRIN 1 % is and what it is used for
2. What you need to know before you use AZIBRIN 1 %
3. How to use AZIBRIN 1 %
4. Possible side effects
5. How to store AZIBRIN 1 %
6. Contents of the pack and other information

### 1. What AZIBRIN 1 % is and what it is used for

AZIBRIN 1 % contains brinzolamide which belongs to a group of medicines called carbonic

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anhydrase inhibitors. It reduces pressure within the eye.

AZIBRIN 1 % is 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.

### 2. What you need to know before you use AZIBRIN 1 %

#### Do not use AZIBRIN 1 %:

- If you are hypersensitive (allergic) to brinzolamide or any of the other ingredients of this medicine (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). Brinzolamide may cause the same allergy.
- If you have too much acidity in your blood (a condition called hyperchloraemic acidosis).
- If you have severe kidney problems.
- If you are taking other oral carbonic anhydrase inhibitors
- If you are pregnant (or trying to become pregnant).
- If you are breastfeeding your baby.

#### Warnings and precautions

##### Take special care with AZIBRIN 1 %:

- If you are taking other sulphonamide medicines.
- If you have kidney or liver problems.
- If you have dry eyes or cornea problems.

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

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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

AZIBRIN 1 % is not to be used in children less than 18 years of age.

### Other medicines and AZIBRIN 1 %

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

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

### Pregnancy, breastfeeding and fertility

AZIBRIN 1 % should not be used during pregnancy and breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking AZIBRIN 1 %.

### Driving and using machines

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 AZIBRIN 1 %.

AZIBRIN 1 % may impair the ability to perform tasks requiring mental alertness and/or physical coordination. If affected, take care when driving or using machines.

AZIBRIN 1 % 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

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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 using this medicines, talk to your doctor.

#### **3. How to use AZIBRIN 1 %**

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

Always use AZIBRIN 1 % exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one drop in the affected eye or eyes twice a day. Some patients may have a better response with one drop three times a day.

Use this much unless your doctor told you to do something different.

Only use AZIBRIN 1 % in both eyes if your doctor told you to. Take it for as long as your doctor told you to.

#### **If you use more AZIBRIN 1 % than you should**

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

#### **If you forget to use AZIBRIN 1 %**

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.

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### If you stop using AZIBRIN 1 %

If you stop using AZIBRIN 1 % without speaking to your doctor, the pressure in your eye will not be controlled which could lead to loss of sight.

### 4. Possible side effects

AZIBRIN 1 % can have side effects.

Not all side effects reported for AZIBRIN 1 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using AZIBRIN 1 %, please consult your health care provider for advice.

If any of the following happens stop using AZIBRIN 1 % and tell your doctor immediately or go to the casualty department of your nearest hospital:

- Skin rash, severe skin reaction, or severe redness and itching of the eye. These could be the signs of an allergic reaction (Hypersensitivity reactions).

These are all very serious side effects. If you have them, you may have had a serious reaction to AZIBRIN 1 %. 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:

- Pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart (angina pectoris).
- Heart rate irregular.

Sign: 

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- Chest pain.
- Narrowing or blockage of blood vessels (Vasculitis).
- Sore throat and discomfort when swallowing.
- Shortness of breath, difficulty in breathing, chest tightness.
- Changes in heart rate (fast, slow or irregular) (arrhythmia, tachycardia).
- Breathlessness, wheezing, a cough sometimes brought on by exercise, and a feeling of tightness in the chest.

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

Tell your doctor if you notice any of the following:

*Frequent:*

- Blurred vision, eye irritation, eye pain, dry eye, redness of the eye.

A bad taste in the mouth

*Less frequent:*

- Runny or blocked nose, sneezing, facial pressure or pain.
- Feeling weak in the body, increased chlorine level in blood
- Decreased emotional interest.
- Movement problems, loss of memory, dizziness, pins and needles, headache.
- Depression, decreased sex drive, male sexual difficulty, depressed mood, nightmare
- Memory loss, sleepiness and drowsiness.
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears.
- 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,

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increased pigmentation of the eye, tired eyes, eyelid crusting, or increased tear production, itchy eye, eye discharge, abnormal eye sensation.

- 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, debris in eye.
- Increased chlorine level in blood
- Generalized weakness, fatigue, feeling abnormal, pain, movement problems, cold symptoms, 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, muscle pain, muscle spasms, back pain, runny nose, stuffy nose, sneezing
- Dry mouth.
- Nose bleeds (epistaxis).
- Feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell.

#### *Frequency not known*

- Low or high blood pressure
- Decreased appetite
- Red blood cell count decreased, blood chloride increased

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- shaking, decreased sense of touch or sensation, loss or decrease in taste
- nervousness, difficulty sleeping.
- Nasal congestion, dry nose, ringing in ears, hair loss, feeling jittery, irritability, body weakness, wheezing.
- Spinning sensation
- Eyelid abnormality, visual disturbance, corneal disorder, eye allergy, decreased growth or number of eyelashes, eyelid redness.
- Joint pain, pain in extremity, abnormal liver blood tests, swelling of the extremities, frequent urination.

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. 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 AZIBRIN 1 %.

### 5. How to store AZIBRIN 1 %

Store below 25 °C.

DO NOT USE MORE THAN 30 DAYS AFTER OPENING.

**KEEP OUT OF REACH OF CHILDREN.**

### 6. Contents of the pack and other information

#### What AZIBRIN 1 % contains

Each 5 mL of suspension contains Brinzolamide 10 mg

Sign: 

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The other ingredients are Carbomer Homopolymer Type B (Carbopol 974P), Sodium Chloride (Parenteral grade), Mannitol, Tyloxapol, Edetate disodium, Benzalkonium chloride solution (50 %), Water for Injection, Sodium Hydroxide, Hydrochloric acid.

#### Holder of Certificate of Registration and Manufacturer

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