

Package leaflet: Information for the patient

Brinzolamide 10 mg/ml Eye Drops, Suspension brinzolamide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Brinzolamide is and what it is used for
2. What you need to know before you use Brinzolamide
3. How to use Brinzolamide
4. Possible side effects
5. How to store Brinzolamide
6. Contents of the pack and other information

1. What Brinzolamide is and what it is used for

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

Brinzolamide 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 Brinzolamide

Do not use Brinzolamide:

- if you have severe kidney problems
- if you are allergic to brinzolamide or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to medicines called sulfonamides. 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 further questions ask your doctor for advice.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Brinzolamide:

- 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 been told you have the following eye conditions: pseudoexfoliative, pigmentary or narrow angle glaucoma.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using brinzolamide or other related medicines.

Take special care with brinzolamide:

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with brinzolamide treatment. Stop using brinzolamide and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children and adolescents

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

Other medicines and Brinzolamide

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.

Pregnancy and breast-feeding

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

You should not use Brinzolamide if you are pregnant, or might become pregnant.

Your doctor will advise if you can use brinzolamide while you are breast-feeding as it is not known whether it can be excreted in milk.

Driving and using machines

You may find that your vision is blurred or have other changes to your vision for a time just after you use Brinzolamide. Do not drive or use machines until your vision is clear.

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

Brinzolamide contains benzalkonium chloride

This medicine contains 0.15 milligrams of benzalkonium chloride in each milliliter.

Benzalkonium chloride 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.

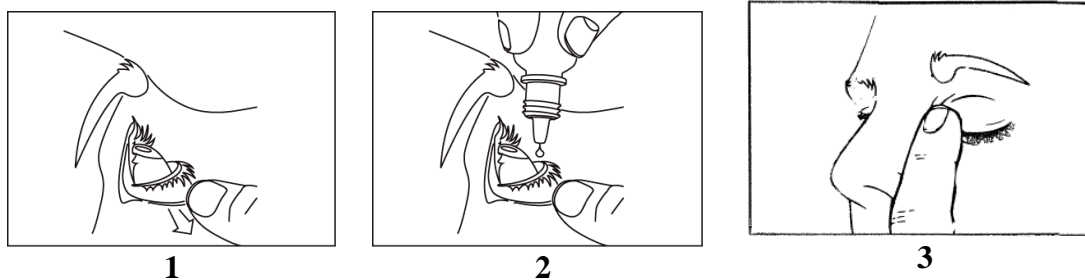
3. How to use Brinzolamide

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

The recommended dose is 1 drop in the affected eye or eyes, twice a day - morning and night.

Use this much unless your doctor told you to do something different. Only use Brinzolamide in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

Only use this medicine for dropping in your eyes – **do not swallow**.
See below for more advice



1. Get the eye drops bottle. You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you use it the first time.
2. Wash your hands.
3. Shake the bottle well and twist off the cap.
4. Bend your head backwards and gently pull your lower eyelid down until there is a small “pocket” (picture 1). It is easier if you sit or stand in front of a mirror.
5. Hold the bottle upside down between your thumb and forefinger, above one eye. Squeeze one drop into the formed pocket. **Do not touch your eye or eyelashes, surrounding areas or anything else with the dropper tip** (picture 2).
6. If a drop misses your eye, try again.
7. Let go of the eyelid and gently press a finger to the corner of your eye, by the nose. This helps to stop Brinzolamide getting into the rest of the body (picture 3).
8. If you take drops in both eyes, repeat the steps 4 to 7 for your other eye.
9. Tighten the cap on the bottle immediately after use.
10. Use up one bottle before opening the next bottle.

If you are using other eye drops or ointment, leave at least 5 minutes between putting in Brinzolamide and the other drops. If you use an eye ointment, this should always be applied last.

If you use more Brinzolamide than you should

If you use more Brinzolamide than you should, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

If you forget to use Brinzolamide

If you forget to use Brinzolamide, 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 stop using Brinzolamide

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. You can usually carry on using the drops, unless the effects are serious.

Stop using Brinzolamide immediately if you get any of the following effects and go straight away to hospital or seek medical advice from your doctor:

Common: may affect up to 1 in 10 people:

- eye pain, redness of the eye, blurred vision, increased tear production with possible sensitivity to light, or a feeling that something is in the eye.

Uncommon: may affect up to 1 in 100 people:

- difficulty breathing, increase in rate of breathing with sweating, wheezing or crackling sounds. You may also have blue lips, pale or grey skin. This may indicate you are not getting enough oxygen into the body.

Rare: may affect up to 1 in 1,000 people:

- heavy or pressing sensation on your chest with chest pain. This could be signs of problems with your heart such as angina.

Not known: cannot be estimated from the available data:

- allergic reactions that may appear as a rash, swelling of the eye, eyelid, lips, tongue, face, hands or throat which may cause difficulty breathing.
- 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).

Other side effects include**Common: may affect up to 1 in 10 people:**

- bitter or unusual taste in your mouth
- eye irritation.

Uncommon: may affect up to 1 in 100 people:

- redness, flaky skin and inflammation on eyelids
- eye sensitivity to light, difficulty seeing in the presence of very bright light
- inflammation or infection of the eye
- dry or itchy eye
- eye discharge
- inflammation of the eyelid glands
- abnormal eye sensation
- growth on surface of eye
- increased pigmentation of the eye or a grey coloured band around the eye
- fatty or mineral deposits in or around the eye
- tired eyes
- eyelid crusting
- increased tear production
- decreased heart rate, palpitations, which can be felt as a thumping in your chest
- shortness of breath or a tightness of the chest with wheezing sometimes brought on by exercise
- decreased red blood cell count in the blood. You may experience tiredness, shortness of breath, cold hands and feet, pale skin and difficulty in healing after a cut
- blood tests show an increased chloride level in the blood
- dizziness
- depression or lack of enthusiasm or interest
- tingling or pins and needles sensations in the hands or feet
- having nightmares
- nervousness
- fatigue
- decreased sex drive or problems getting or maintaining an erection
- cold symptoms
- difficulty breathing through the nose with pain in the face (these may be signs of sinus problems)
- throat irritation, pain or sore throat
- mucus build up in back of nose or throat
- abnormal or decreased sensation in mouth
- inflammation of the lining of the food pipe with pain
- abdominal pain, nausea, vomiting, upset stomach or indigestion
- frequent bowel movements, diarrhoea or intestinal gas
- digestive disorder
- kidney pain
- headache
- muscle pain or muscle spasms
- back pain
- difficulty walking or lifting
- nose bleeds, runny nose, or sneezing
- red rash or an red area of skin with small bumps
- skin tightness

- finding something in the eye
- dry mouth.

Rare: may affect up to 1 in 1,000 people:

- difficulty sleeping
- drowsiness
- increased pressure in eye
- damage to the optic nerve
- abnormal, double or reduced vision
- seeing flashing lights with discomfort or pain
- decreased eye sensation
- puffy eyes or swelling around the eyes
- irregular heart rate
- dry or stuffy nose
- chest congestion or cough
- itchy rash (known as nettle rash) or hives
- itching
- loss of hair
- generalised weakness
- feeling jittery or irritable
- chest pain
- difficulty with memory
- ringing in ears.

Not known: cannot be estimated from the available data:

- General side effects: 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)
- eyelid abnormality or redness around the eye
- decreased growth or number of eyelashes
- spinning sensation with a loss of balance (known as vertigo)
- increased or decreased blood pressure, increased heart rate
- abnormal liver blood tests
- frequent urination
- swelling of the hands or feet
- decreased sensation (can be also known as numbness)
- decreased taste sensation
- joint pain or pain in hands or feet
- shaking
- general feeling of being unwell
- decreased appetite.

Reporting of side effects

If you get any 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 directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow

Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Brinzolamide

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and box after “EXP”. The expiry date refers to the last day of that month.

Keep the bottle in the outer carton.

You must throw away a bottle four weeks after you first opened it, to prevent infections. Write down the date you opened each bottle in the space below and on the bottle label and box. For a pack containing a single bottle, write only one date.

Date opened (1):

Date opened (2):

Date opened (3):

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Brinzolamide contains

The active substance is brinzolamide. One ml of the eye drop suspension contains 10 mg of brinzolamide.

The other ingredients are: benzalkonium chloride, carbomer 974P, edetate disodium, mannitol (E421), purified water, sodium chloride, hydrochloric acid or sodium hydroxide for pH adjustment.

What Brinzolamide looks like and contents of the pack

Brinzolamide Eye Drops, Suspension is a white to off white liquid.

Brinzolamide is available in a 10 ml plastic (low density polyethylene) bottle, containing 5 ml of Brinzolamide Eye Drops, Suspension, with a plastic insert dropper and a plastic cap.

Brinzolamide is available in the following pack sizes:

1 x 5 ml bottle packed in a single carton

3 x 5 ml bottles packed in a single carton

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

Lusomedicamenta Sociedade Técnica Farmacêutica, S.A., Rua Norberto de Oliveira, no 1/5, Póvoa de Santo Adrião, 2620-111, Portugal

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