Package leaflet: Information for the user

Brinzolamide 10mg/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

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

Brinzolamide 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.

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 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 further questions, ask your doctor for advice.

Warnings and precautions

Talk to your doctor or pharmacist 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 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 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.

If you are taking another carbonic anhydrase inhibitor (acetazolamide or dorzolamide, see section 1 'What Brinzolamide is and what it is used for'), 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 using this medicine.

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

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

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 Brinzolamide.

Brinzolamide may impair the ability 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 approximately 3.1µg benzalkonium chloride per drop (=1 dose) which is equivalent to 0.1mg/ml.

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.

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

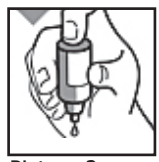
The recommended dose is

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.

How to use


Picture 1


Picture 2


Picture 3

- Get the Brinzolamide 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 the 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 Brinzolamide 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 Brinzolamide, press a finger to the corner of your eye, by the nose **(picture 3)** for at least 1 minute. This helps to stop Brinzolamide 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.

If a drop misses your eye, try again.

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

If you use more Brinzolamide 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 is time for your next regular dose.

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 take 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.

4. Possible side effects

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

The following side effects have been seen with brinzolamide.

Stop using brinzolamide 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 the mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Steven-Johnson syndrome, toxic epidermal necrolysis).

Common side effects (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 side effects (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, nightmares, 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 side effects (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,

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (website: 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.
This medicine does not require any special storage conditions.
You must throw away the bottle four weeks after you first opened it, to prevent infections. Write down the date you opened each bottle in the space below and in the space on the bottle label and box.
For a pack containing a single bottle, write only one date.

Opened (1):

Opened (2):

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. Each ml of suspension contains 10mg of brinzolamide.
- The other ingredients are: benzalkonium chloride solution 50%, carbomer 974P, disodium edetate, mannitol (E421), poloxamer 407, water for injections and sodium chloride. Tiny amounts of sodium hydroxide are added to keep acidity levels (pH levels) normal.

What Brinzolamide looks like and contents of the pack

Brinzolamide is a milky liquid (a suspension) supplied in a pack containing 1, 3 or 6 plastic (dropper container) bottles with a screw cap which includes 5ml white homogenous suspension.

The following pack sizes are available: outer cartons containing 1 x 5ml, 3 x 5ml, 6 x 5ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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