

## Package leaflet: Information for the user

### /.../ 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What /.../ is and what it is used for

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

/.../ 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 /.../

**Do not use /.../:**

- **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). /.../ 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, pharmacist or nurse before using /.../

- **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)**
- **if you have 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**

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

### **Other medicines and /.../**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking another carbonic anhydrase inhibitor (acetazolamide or dorzolamide, see section 1 What /.../ is and what it is used for), talk to your doctor.

### **Pregnancy, breast-feeding and fertility**

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 /.../ treatment. The use of /.../ is not recommended during pregnancy or breast-feeding. Do not use /.../ 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 you use /.../.

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

### **/.../ contains benzalkonium chloride**

This medicine contains 0.15 mg benzalkonium chloride in each 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 /.../**

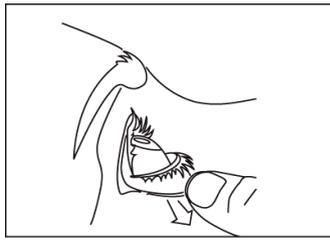
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor, pharmacist if you are not sure.

**Only** use /.../ for your eyes. Do not swallow or inject.

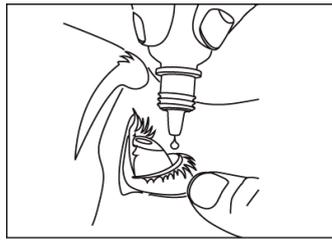
### **The recommended dose is**

**1 drop in the affected eye or eyes, twice a day** - morning and night.

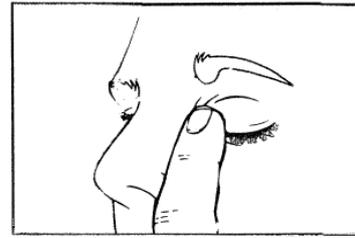
Use this much unless your doctor told you to do something different. Only use /.../ in both eyes if your doctor told you to. Use it for as long as your doctor told you to.



1



2



3

- Get the /.../ 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 forefinger.
- 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 (picture 2).
- Gently squeeze the bottle to release one drop at a time.
- After using /.../, press a finger to the corner of your eye, by the nose (picture 3). This helps to stop /.../ 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 /.../ and the other drops. Eye ointments should be administered last.

**If you use more /.../ 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 /.../**

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 /.../**

If you stop using /.../ 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

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

The following side effects have been seen with /.../.

##### **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 to 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, corneal disorder, damage or inflammation of the cornea (transparent front part of the eye).
- **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, nightmare, 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, decreased blood pressure, increased blood pressure, increased heart rate, joint pain, asthma, pain in extremity, skin redness, inflammation, or itching, abnormal liver blood tests, swelling of the extremities, frequent urination, decreased appetite, sensation of spinning, feeling unwell

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store /.../**

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 the month.

This medicine does not require any special storage conditions.

**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.

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 /.../ contains

**The active substance is** brinzolamide 10 mg/ml.

**The other ingredients are:** benzalkonium chloride, carbomer 974P, disodium edetate, mannitol (E421), purified water, sodium chloride. Tiny amounts of hydrochloric acid or sodium hydroxide are added to keep pH levels normal.

### What /.../ looks like and the contents of the pack

/.../ is a white to off-white liquid (a suspension) supplied in a pack containing a 5 ml plastic bottle with a screw cap, tamper evident snap collar and insert dropper, or in a pack containing three 5 ml plastic bottles with screw caps, tamper evident snap collar and insert droppers.  
Not all pack sizes may be marketed.

### The Marketing Authorization Holder and Manufacturer

#### Marketing Authorization Holder

<[To be completed nationally]>

#### Manufacturer

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

**This medicinal product is authorised in the Member States of the EEA under the following names:>**

Netherlands	Brectasa 10 mg/ml oogdruppels, suspensie
Sweden	Brectasa

**This leaflet was last revised in** <{MM/YYYY}> <{month YYYY}>.