

## **Package leaflet: Information for the user**

### **Brizadopt 10 mg/ml, oogdruppels, suspensie** Brinzolamide

**Read all of this leaflet carefully before you start taking 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 your 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 Brizadopt 10 mg/ml eye drops suspension is and what it is used for
2. What you need to know before you use Brizadopt 10 mg/ml eye drops suspension
3. How to use Brizadopt 10 mg/ml eye drops suspension
4. Possible side effects
5. How to store Brizadopt 10 mg/ml eye drops suspension
6. Contents of the pack and other information

#### **1. What Brizadopt 10 mg/ml eye drops suspension is and what it is used for**

Brizadopt 10 mg/ml eye drops suspension contains brinzolamide which belongs to a group of medicines called carbonic anhydrase inhibitors. It reduces pressure within the eye.

Brizadopt 10 mg/ml eye drops suspension 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 Brizadopt 10 mg/ml eye drops suspension**

##### **Do not use Brizadopt 10 mg/ml eye drops suspension**

- 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). Brizadopt 10 mg/ml eye drops suspension 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 Brizadopt 10 mg/ml eye drops suspension:

- 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**

Brizadopt 10 mg/ml eye drops suspension is not to be used by infants, children or adolescents under 18 years of age unless advised by your doctor.

### **Other medicines and Brizadopt 10 mg/ml eye drops suspension**

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 Brizadopt 10 mg/ml eye drops suspension 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 Brizadopt 10 mg/ml eye drops suspension treatment. The use of Brizadopt 10 mg/ml eye drops suspension is not recommended during pregnancy or breast-feeding. Do not use Brizadopt 10 mg/ml eye drops suspension 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 Brizadopt 10 mg/ml eye drops suspension.

Brizadopt 10 mg/ml eye drops suspension may impair the ability to perform tasks requiring mental alertness and/or physical coordination. If affected, take care when driving or using machines.

### **Brizadopt 10 mg/ml eye drops suspension contains benzalkonium chloride**

This medicine contains 0,0405 mg benzalkonium chloride in each drop which is equivalent to 0,15 mg/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 Brizadopt 10 mg/ml eye drops suspension**

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

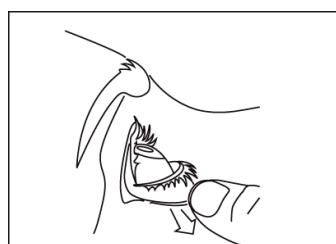
Only use Brizadopt 10 mg/ml eye drops suspension for your eyes. Do not swallow or inject.

### **The recommended dose is**

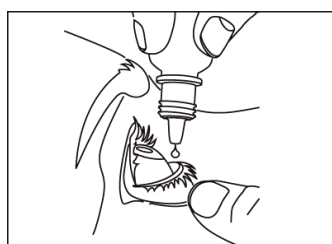
1 drop in the affected eye or eyes twice a day - morning and night.

Use this much unless your doctor told you to do something different. Only use Brizadopt 10 mg/ml eye drops suspension in both eyes if your doctor told you to. Take it for as long as your doctor told you to.

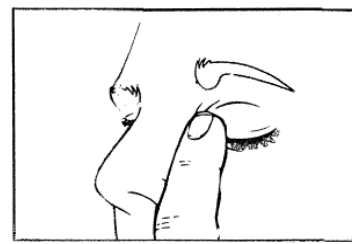
### **How to use**



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- Get the Brizadopt 10 mg/ml eye drops suspension 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 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.
- Squeeze one drop into the formed pocket (picture 2).
- After using Brizadopt 10 mg/ml eye drops suspension, press a finger to the corner of your eye, by the nose (picture 3) for at least 1 minute. This helps to stop Brizadopt 10 mg/ml eye drops suspension 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 Brizadopt 10 mg/ml eye drops suspension and the other drops. Eye ointments should be administered last.

### **If you use more Brizadopt 10 mg/ml eye drops suspension 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 Brizadopt 10 mg/ml eye drops suspension**

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 Brizadopt 10 mg/ml eye drops suspension**

If you stop using Brizadopt 10 mg/ml eye drops suspension 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 Brizadopt 10 mg/ml eye drops suspension:

Stop using Brinzolamide 10 mg/ml eye drops suspension 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 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).

#### **Common side effects** *(may affect up to 1 in 10 people)*

##### **Effects in the eye:**

blurred vision, eye irritation, eye pain, 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, eye discharge, itchy eye, dry 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, feeling unwell, 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).

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 national reporting system Nederlands Bijwerkingen Centrum Lareb. Website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Brizadopt 10 mg/ml eye drops suspension

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 Brizadopt 10 mg/ml eye drops suspension contains**

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

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

#### **What Brizadopt 10 mg/ml eye drops suspension looks like and the contents of the pack**

**Brizadopt 10 mg/ml eye drops suspension** is a white to off-white homogenous suspension. The 5 ml eye drop suspension is in a 10 ml low density polyethylene (LDPE) sterile bottle, with a LDPE sterile insert dropper and a high density polyethylene (HDPE) sterile cap with a tamper proof seal.

Pack sizes:

Carton containing one 10 ml bottle.

Carton containing three 10 ml bottles.

Carton containing six 10 ml bottles.

Not all pack sizes may be marketed.

#### **The Marketing Authorization Holder and Manufacturer**

##### **Marketing Authorization Holder**

BAUSCH + LOMB IRELAND LIMITED

3013 Lake Drive

City West Business Campus

Dublin 24, D24PPT3

Ireland

##### **Manufacturer**

Lusomedicamenta Sociedade Técnica Farmacêutica, S.A.

Rua Norberto de Oliveira, no 1/5

Póvoa de Santo Adrião, 2620-111

Portugal

#### **In het register ingeschreven onder**

RVG 112792

#### **This medicinal product is authorised in the member states of the EEA under the following names:**

Bulgaria: Brizadopt 10 mg/ml eye drops, suspension

Estonia: Brizadopt

Latvia: Brizadopt 10 mg/ml acu pilieni, suspensija

Slovak Republic: Brizadopt 10 mg/ml

The Netherlands: Brizadopt 10 mg/ml oogdruppels, suspensie

**Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.**