Package leaflet: Information for the user

Brinzolamide Sandoz 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 Sandoz is and what it is used for

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

Brinzolamide Sandoz 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 Sandoz

Do not use Brinzolamide Sandoz
- **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 Sandoz 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 Sandoz
- **if you have kidney or liver problems**

- **if you have dry eyes or cornea problems**
- **if you are taking other sulphonamide medicines.**

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

Other medicines and Brinzolamide Sandoz
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, see section 1 'What Brinzolamide Sandoz 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 Sandoz treatment. The use of Brinzolamide Sandoz is not recommended during pregnancy or breast-feeding. Do not use Brinzolamide Sandoz 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 Sandoz.

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

Brinzolamide Sandoz contains benzalkonium chloride
This medicine contains 0.10 mg benzalkonium 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.

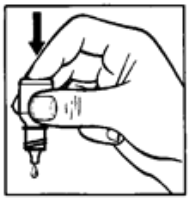
3. How to use Brinzolamide Sandoz

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 Sandoz 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 Sandoz in both eyes if your doctor told you to. Take it for as long as your doctor told you to.

How to use

1



2

3

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

Eye ointments should be administered last.

If you use more Brinzolamide Sandoz 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 Brinzolamide Sandoz
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 Sandoz
If you stop using Brinzolamide Sandoz 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 everybody gets them.

The following side effects have been seen with Brinzolamide Sandoz.

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, 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, palpitations, decreased heart rate, difficulty breathing, shortness of breath, cough, decreased red blood cell count in blood, increased chlorine level in blood, dizziness, drowsiness, difficulty with memory, depression, nervousness, generalized weakness, fatigue, feeling abnormal, pain, shaking, 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, headache, dry mouth.

Rare side effects (may affect up to 1 in 1,000 people)
Effects in the eye: corneal swelling, double or reduced vision, abnormal 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.

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.

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.

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: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Brinzolamide Sandoz

Keep out of the sight and reach of children.

Do not use Brinzolamide Sandoz 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 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 Sandoz contains
The active substance is brinzolamide 0.33 mg per drop, corresponding with 10 mg/ml.

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

What Brinzolamide Sandoz looks like and contents of the pack
Brinzolamide Sandoz is a white to off-white suspension supplied in a pack containing a 5 ml or a 10 ml plastic bottle (5 and 10 ml LDPE bottles with LDPE dropper with a PP tamper–proof screw cap (DROPTAINER).

The following pack sizes are available: outer cartons containing 1 x 5 ml, 3 x 5 ml and 1 x 10 ml bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
S.A. Alcon-Couvreur nv., Rijksweg 14, B-2870, Puurs, Belgium.
SIEGFRIED El Masnou, S.A., Camil Fabra 58, 08320 El Masnou, Barcelona, Spain.
Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, Sachsen-Anhalt, 39179 Barleben, Germany.
Novartis Pharma GmbH., Roonstraße 25 und Obere, Turnstraße 8-10, 90429 Nürnberg, Germany.
Novartis Farmaceutica S.A., Gran Via de les Corts, Catalanes, 764, 08013 Barcelona, Spain.

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

The Netherlands	Brinzolamide Sandoz 10 mg/ml, oogdruppels, suspensie
Austria	Brinzolamid Sandoz 10 mg/ml - Augentropfensuspension
Belgium	Brinzolamid Sandoz 10 mg/ml oogdruppels, suspensie
Germany	Brinzolamid HEXAL® 10 mg/ml Augentropfensuspension
Denmark	Brinzolamide Sandoz
Estonia	Brinzolamide Sandoz
Finland	Brinzolamide Sandoz 10 mg/ml silmätipat, suspensio
France	BRINZOLAMIDE SANDOZ 10 mg/ml, collyre en suspension
Ireland	Brinzolamide Sandoz 10 mg/ml eye drops, suspension
Italy	BRINZOLAMIDE SANDOZ
Lithuania	Brinzolamide Sandoz 10 mg/ml akių lašai (suspensija)
Latvia	Brinzolamide Sandoz 10 mg/ml acu pilieni, suspensija
Luxembourg	Brinzolamid Sandoz 10 mg/ml collyre en suspension
Sweden	Brinzolamide Sandoz, 10 mg/ml ögondroppar, suspension
United Kingdom	Brinzolamide Sandoz 10 mg/ml eye drops, suspension

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