

Package leaflet: Information for the user

SIMBRINZA® 10 mg/ml + 2 mg/ml eye drops, suspension brinzolamide/brimonidine tartrate

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, optometrist (optician) 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, optometrist (optician) or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SIMBRINZA is and what it is used for
2. What you need to know before you use SIMBRINZA
3. How to use SIMBRINZA
4. Possible side effects
5. How to store SIMBRINZA
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1. What SIMBRINZA is and what it is used for

SIMBRINZA contains two active substances, brinzolamide and brimonidine tartrate. Brinzolamide belongs to a group of medicines called carbonic anhydrase inhibitors and brimonidine tartrate belongs to a group of medicines called alpha-2 adrenergic receptor agonists. Both substances work together to reduce pressure within the eye.

SIMBRINZA is used to lower pressure in the eyes in adult patients (aged 18 years and over) who have eye conditions known as glaucoma or ocular hypertension and whose high pressure in the eyes cannot be controlled effectively by one medicine alone.

2. What you need to know before you use SIMBRINZA

Do not use SIMBRINZA

- if you are allergic to brinzolamide or brimonidine tartrate or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to sulphonamides (examples include medicines used to treat diabetes and infections and also diuretics (water tablets))
- if you are taking a monoamine oxidase (MAO) inhibitors (examples include medicines to treat depression or Parkinson's disease) or certain antidepressants. You must inform your doctor if you are taking any antidepressant medicines
- if you have severe kidney problems
- if you have too much acidity in your blood (a condition called hyperchloraemic acidosis)
- in babies and infants aged less than 2 years.

Warnings and precautions

Talk to your doctor, optometrist (optician) or pharmacist before using SIMBRINZA if you have now or have had in the past:

- liver problems
- a type of high pressure in the eyes called narrow-angle glaucoma
- dry eyes or cornea problems
- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or

- choking), heart failure, high or low blood pressure
- depression
- disturbed or poor blood circulation (such as Raynaud's disease, Raynaud's syndrome or cerebral insufficiency).

If you wear soft contact lenses, do not use the drops with your lenses in. See section "Wearing contact lenses - SIMBRINZA contains benzalkonium chloride" below).

Children and adolescents

SIMBRINZA is not intended for use by children and adolescents aged below 18 years because it has not been studied in this age group. It is particularly important that the medicine is not used in children under the age of 2 years (see section 'Do not use SIMBRINZA' above) because it is unlikely to be safe.

Other medicines and SIMBRINZA

Tell your doctor, optometrist (optician) or pharmacist if you are using, have recently used, or might use any other medicines.

SIMBRINZA can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

Tell your doctor if you are taking or intend to take any of the following medicines:

- medicines to lower blood pressure
- heart medicines including digoxin (used to treat heart conditions)
- other medicines for glaucoma that also treat altitude sickness known as acetazolamide, methazolamide and dorzolamide
- medicines that can affect the metabolism, such as chlorpromazine, methylphenidate and reserpine
- antiviral, antiretroviral (used to treat Human Immunodeficiency Virus (HIV)) or antibiotic medicines
- antiyeast or antifungal medicines
- monoamine oxidase (MAO) inhibitors, or antidepressants including amitriptyline, nortriptyline, clomipramine, mianserin, venlafaxine and duloxetine
- anaesthetics
- sedatives, opiates, or barbiturates

You should also tell your doctor if the dose of any of your current medicines is changed.

SIMBRINZA with alcohol

If you regularly consume alcohol, ask your doctor, optometrist (optician) or pharmacist for advice before taking this medicine. SIMBRINZA can be affected by alcohol.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, optometrist (optician) or pharmacist for advice before taking this medicine. Women who may become pregnant are advised to use effective contraception during SIMBRINZA treatment. The use of SIMBRINZA is not recommended during pregnancy. Do not use SIMBRINZA unless clearly indicated by your doctor.

If you are breast-feeding, SIMBRINZA may pass into your milk. The use of SIMBRINZA is not recommended during breast-feeding.

Driving and using machines

You may find that your vision is blurred or abnormal for a time just after using SIMBRINZA. SIMBRINZA may also cause dizziness, drowsiness or tiredness in some patients.

Do not drive or use machines until the symptoms are cleared.

Wearing contact lenses - SIMBRINZA contains benzalkonium chloride

This medicine contains 0.15 mg benzalkonium chloride in each 5 ml, which is equivalent to 0.03 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 a disorder 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 SIMBRINZA

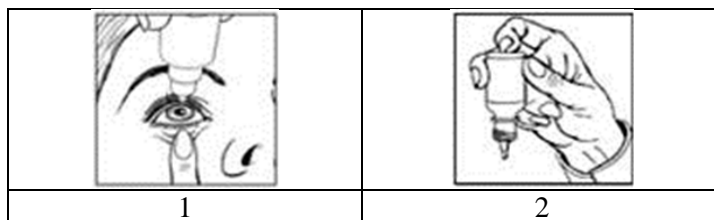
Always use this medicine exactly as your doctor, optometrist (optician) or pharmacist has told you. Check with your doctor, optometrist (optician) or pharmacist if you are not sure.

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

The recommended dose is one drop in the affected eye or eyes two times a day. Use at the same time each day.

How to use

Wash your hands before you start.



Shake well before use.

Twist off the bottle cap. After the cap is removed, if the tamper evident snap collar is loose, remove it before using the medicine.

Do not touch the dropper with your fingers when opening or closing the bottle. It could infect the drops.

Hold the bottle, pointing down, between your thumb and fingers.

Tilt your head back.

Pull down your lower 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. Do this in front of a 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 SIMBRINZA.

Do not squeeze the bottle: it is designed so that a gentle press on the bottom is all that it needs (picture 2).

To reduce the amount of medicine that could come into the rest of the body after application of the eye drop, close your eye and apply gentle pressure to the corner of the eye next to the nose with a finger for at least 2 minutes.

If you use drops in both eyes, repeat the steps for your other eye. It is not necessary to close and shake the bottle before you apply the drop in your other eye. Close the bottle cap firmly immediately after use.

If you are using other eye drops as well as SIMBRINZA, wait at least five minutes between using SIMBRINZA and the other drops.

If a drop misses your eye, try again.

If you use more SIMBRINZA than you should

Rinse your eye with warm water. Do not put in any more drops until it is time for your next regular dose.

Adults who accidentally swallowed medicines containing brimonidine experienced a decreased heart rate, decreased blood pressure which may be followed by increased blood pressure, heart failure, difficulty breathing and effects in the nervous system. Should this happen, contact your doctor immediately.

Serious side effects have been reported in children who accidentally swallowed medicines containing brimonidine. Signs included sleepiness, floppiness, low body temperature, paleness and breathing difficulties. Should this happen, contact your doctor immediately.

If SIMBRINZA has been accidentally swallowed then you should contact your doctor immediately.

If you forget to use SIMBRINZA

Continue with the next dose as planned. Do not use a double dose to make up for a forgotten dose. Do not use more than one drop in the affected eye(s) two times a day.

If you stop using SIMBRINZA

Do not stop using SIMBRINZA without first speaking to your doctor. If you stop using SIMBRINZA 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, optometrist (optician) or pharmacist.

4. Possible side effects

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

If you experience any of the following side effects, please stop using this medicine and seek immediate medical attention as these could be signs of a reaction to the medicine. The frequency of an allergic reaction to the medicine is not known (frequency cannot be estimated from the available data).

- Severe skin reactions, including rash or redness or itching on your body or eyes
- Trouble breathing
- Chest pain, irregular heart beat

Contact your doctor immediately if you develop extreme tiredness or dizziness.

The following side effects have been observed with SIMBRINZA and other medicines containing brinzolamide or brimonidine alone.

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

- Effects in the eye: allergic conjunctivitis (eye allergy), eye surface inflammation, eye pain, eye discomfort, blurred or abnormal vision, eye redness
- General side effects: drowsiness, dizziness, bad taste in mouth, dry mouth

Uncommon side effects (may affect up to 1 in 100 people)

- Effects in the eye: eye surface damage with loss of cells, inflammation of the eyelid, deposits on the eye surface, sensitivity to light, swelling of the eye (affecting the cornea or eyelid), dry eye,

eye discharge, watery eye, eyelid redness, abnormal or decreased sensation in eye, tired eye, reduced vision, double vision, product particles in eyes.

- General side effects: decreased blood pressure, chest pain, irregular heartbeat, slow or fast heart rate, palpitations, difficulty sleeping (insomnia), nightmares, depression, generalised weakness, headache, dizziness, nervousness, irritability, general feeling of being unwell, memory loss, shortness of breath, asthma, nose bleeds, cold symptoms, dry nose or throat, sore throat, throat irritation, cough, runny nose, stuffy nose, sneezing, sinus infection, chest congestion, ringing in ear, indigestion, intestinal gas or stomach ache, nausea, diarrhoea, vomiting, abnormal sensation in mouth, increased allergic symptoms on skin, rash, abnormal skin sensation, hair loss, generalised itching, increased blood chlorine levels, or decreased red blood cell count as seen in a blood test, pain, back pain, muscle pain or spasm, kidney pain such as lower back pain, decreased libido, male sexual difficulty.

Very rare (may affect up to 1 in 10,000 people)

- Effects in the eye: decreased pupil size
- General side effects: fainting, increased blood pressure

Not known (frequency cannot be estimated from the available data)

- Effects in the eye: decreased growth of eyelashes
- General side effects: tremor, decreased sensation, loss of taste, abnormal liver function values as seen in a blood test, swelling of the face, joint pain, frequent urination, chest pain, swelling of the extremities.

Reporting of side effects

If you get any side effects, talk to your doctor, optometrist (optician) or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace, IRL - Dublin 2
Tel : +353 1 6764971
Fax : +353 1 6762517
Website : www.hpra.ie
e-mail : medsafety@hpra.ie

Malta

ADR Reporting
Website :
www.medicinesauthority.gov.mt/adportal

United Kingdom

Yellow Card Scheme
Website : www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store SIMBRINZA

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 the carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Throw away the bottle 4 weeks after first opening to prevent infections and use a new bottle. Write down the date of opening on the carton in the space provided.

Do not throw away any medicines via wastewater or household waste. Ask your optometrist (optician) or 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 SIMBRINZA contains

- The active substances are brinzolamide and brimonidine tartrate. One ml of suspension contains 10 mg of brinzolamide and 2 mg of brimonidine tartrate equivalent to 1.3 mg brimonidine.
- The other ingredients are benzalkonium chloride (see section 2 “Wearing contact lenses - SIMBRINZA contains benzalkonium chloride”), propylene glycol, carbomer 974P, boric acid, mannitol, sodium chloride, tyloxapol, hydrochloric acid and/or sodium hydroxide and purified water.

Tiny amounts of hydrochloric acid and/or sodium hydroxide are added to keep acidity levels (pH levels) normal.

What SIMBRINZA looks like and contents of the pack

SIMBRINZA eye drops, suspension, is a liquid (white-to-off-white suspension) supplied in a pack containing one or three 5 ml plastic bottles with screw cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Novartis Europharm Limited
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Elm Park, Merrion Road
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Ireland

Manufacturer

Alcon-Couvreur N.V.
Rijksweg 14
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Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Malta

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United Kingdom

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.