NOVARTIS

Simbrinza

(brinzolamide 10 mg/brimonidine tartrate 2 mg per mL)

Eye drops, suspension

Patient Information Leaflet

Document status: Final

Release date: 06 February 2023

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S3**

SIMBRINZA® 10 mg/mL + 2 mg/mL eye drops, suspension

Brinzolamide and Brimonidine tartrate

Read all of this leaflet carefully before you start using SIMBRINZA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- SIMBRINZA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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.

What you need to know before you use SIMBRINZA

Do not use SIMBRINZA:

- if you are hypersensitive (allergic) to brinzolamide or brimonidine tartrate or any of the other ingredients of SIMBRINZA
- 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

Take special care with SIMBRINZA:

If you experience a severe skin reaction such as skin rash, red skin, blistering of the lips, eyes or mouth, skin peeling and fever (signs of Stevens-Johnson syndrome or toxic epidermal necrolysis), discontinue the use of this product and seek medical attention immediately.

Tell your doctor, optometrist (optician), pharmacist or health care provider before using SIMBRINZA if you have now or have had in the past:

- Severe skin reactions like skin rash, skin peeling, blistering of the lips, eyes or mouth
- 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 SIMBRINZA 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 SIMBRINZA 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

Always tell your doctor, optometrist (optician), pharmacist or healthcare provider if you are using, have recently used, or might use any other medicines (this includes all complementary or traditional 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 food and drink and alcohol

If you regularly consume alcohol, ask your doctor, optometrist (optician), pharmacist, or healthcare provider for advice before taking SIMBRINZA.

SIMBRINZA can be affected by alcohol.

Pregnancy and breastfeeding and fertility

If you are pregnant, or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, optometrist (optician), pharmacist or healthcare provider for advice before taking SIMBRINZA.

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 breastfeeding, SIMBRINZA may pass into your milk. The use of SIMBRINZA is not recommended during breastfeeding.

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.

Patients should ensure that they do not engage in driving or using machines until they are aware of how SIMBRINZA affects them.

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

SIMBRINZA contains benzalkonium chloride

SIMBRINZA 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 SIMBRINZA 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 SIMBRINZA, talk to your doctor or healthcare provider.

How to use SIMBRINZA

- Do not share medicines prescribed for you with any other person.
- Always use SIMBRINZA 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.

- Your doctor will tell you how long your treatment with SIMBRINZA will last.
- Do not stop treatment early because this may affect your condition.
- If you have the impression that the effect of SIMBRINZA is too strong or too weak, tell your doctor, optometrist (optician) or pharmacist.

How to use:

Wash your hands before you start.

	
1	2

- Shake bottle gently before use.
- Twist off the bottle cap. After the cap is removed, if the tamper evident snap collar is loose, remove it before using SIMBRINZA.
- Do not touch the dropper with your fingers when opening or closing the bottle as 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 accidently 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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

If you forget a dose of 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 SIMBRIMZA

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 SIMBRINZA, ask your doctor, optometrist (optician) or pharmacist.

Possible side effects

SIMBRINZA can have side effects.

Not all side effects reported for SIMBRINZA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SIMBRINZA, please consult your healthcare professional for advice.

If any of the following happens, stop using SIMBRINZA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

- rash or itching
- red skin, skin peeling blistering of the lips, eyes or mouth, fever or any combination of these (Stevens-Johnson syndrome/ toxic epidermal necrolysis)
- extreme tiredness, dizziness, fainting
- trouble breathing
- chest pain, irregular heartbeat

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SIMBRINZA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Allergic conjunctivitis (eye allergy), eye surface inflammation, eye pain, eye discomfort, blurred or abnormal vision, eye redness
- drowsiness, bad taste in mouth, dry mouth

The following side effects have been reported less frequently:

- 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
- decreased blood pressure, slow or fast heart rate, palpitations
- difficulty sleeping (insomnia), nightmares, depression, generalised weakness, headache, dizziness, nervousness, irritability; general feeling of being unwell, memory loss

- 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, 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
- decreased pupil size
- increased blood pressure

The following side effects have been reported but the frequency is unknown:

- Decreased growth of eyelashes
- 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
- Skin rash, red skin, skin peeling, blistering of the lips, eyes or mouth, fever or any combination of these (Stevens-Johnson syndrome/ toxic epidermal necrolysis)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SIMBRINZA.

How to store SIMBRINZA

- Store all medicines out of out of reach of children.
- Do not use SIMBRINZA 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.
- Do not store above 30 ºC.
- Throw away the bottle 30 days after first opening to prevent infections and use a new bottle. Write down the date of opening on the carton.
- 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.
- Store in the original package / container.
- Do not store in a bathroom.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets)

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.

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

White to-off-white uniform suspension.

A white, low-density polyethylene (LDPE) bottle with a natural LDPE dispensing plug and white polypropylene (PP) closure containing 5 ml suspension.

Holder of Certificate of Registration and Manufacturer

Novartis South Africa (Pty) Ltd.

Magwa Crescent West

Waterfall City

Jukskei View

Johannesburg, 2090

This leaflet was last revised in

Date of registration: 07 September 2021

Date of revision of text: 06 February 2023

Registration number

50/15.4/0358

Botswana: S2	Namibia: NS2	Zimbabwe: P.P
Reg. No.: BOT1903607	Reg. No.: 16/15.4/0209	Reg. No.: 2017/19.1/5324

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website