

SIMBRINZA® Eye Drops, Suspension

Brinzolamide 10mg/ml + Brimonidine Tartrate 2mg/ml

What is in this leaflet

1. What Simbrinza is used for
2. How Simbrinza works
3. Before you use Simbrinza
4. How to use Simbrinza
5. While you are using Simbrinza
6. Side effects
7. Storage and Disposal of Simbrinza
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What SIMBRINZA is used for

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.

How SIMBRINZA works

Works by decreasing intraocular pressure in adult patients with open-angle glaucoma or ocular hypertension.

Before you use SIMBRINZA

- When you must not use it

Do not use SIMBRINZA

- If you are allergic to brimonidine tartrate, brinzolamide or any of the other ingredients of this medicine.
- 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.

Talk to your doctor 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 have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using SIMBRINZA or other related medicines.

Take special care with SIMBRINZA:

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with brinzolamide treatment. Stop using SIMBRINZA and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 'Side effects'.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, you 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 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.

Wearing contact lenses - SIMBRINZA contains benzalkonium chloride

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.

- Before you start to use it

If you wear soft contact lenses, do not use the drops with your lenses in.

- Taking other medicines

Tell your doctor 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.

SIMBRINZA® Eye Drops, Suspension

Brinzolamide 10mg/ml + Brimonidine Tartrate 2mg/ml

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.

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

How to use SIMBRINZA

Wash your hands before you start.



1



2

- 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.

- How much to use

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

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking SIMBRINZA for as long as your doctor recommends.

- If you forget to use it

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 use too much (overdose)

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.

SIMBRINZA® Eye Drops, Suspension

Brinzolamide 10mg/ml + Brimonidine Tartrate 2mg/ml

While you are using it

- Things you must do

Shake bottle well before use.

Patients wearing soft contact lenses should be instructed to wait at least 5 minutes after instilling SIMBRINZA before inserting contact lenses.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give SIMBRINZA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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.

Side effects

Like all medicines, SIMBRINZA 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.

Stop using SIMBRINZA 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: 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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers→

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of SIMBRINZA

- Storage

Keep out of the reach and sight of children. Do not store above 30°C.

- Disposal

Dispose one month after opening. Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

SIMBRINZA is a white to off-white color suspension eye drop.

- Ingredients

- Active ingredient(s)
Brinzolamide 1% (10mg/mL) and Brimonidine tartrate: 0.2% (2mg/mL)

- Inactive ingredients
Benzalkonium chloride, propylene glycol, carbomer 974P, boric acid, mannitol, sodium chloride, tyloxapol, hydrochloric acid and/or sodium hydroxide (to adjust pH) and purified water.

- MAL number:

MAL16085016ARZ

Manufacturer

Novartis Manufacturing N.V.
Rijksweg 14,
2870 Puurs-Sint-Amands
Belgium

SIMBRINZA[®] Eye Drops, Suspension

Brinzolamide 10mg/ml + Brimonidine Tartrate 2mg/ml

Product Registration Holder

Novartis Corporation (M) Sdn. Bhd.
Level 18, Imazium,
No. 8, Jalan SS21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor,
Malaysia.

Information Issued

26/05/2022

Date of revision

10/4/2025

Serial Number

NPRA (R1/4) 12032025/048