**Package leaflet: information for the patient user**

**Simbrinza 10 mg/mL + / 2 mg/mL eye drops, suspension**
Brinzolamide/Brimonidine tartrate

**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, pharmacist or nurse.
- 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, pharmacist or nurse. 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

**What Simbrinza is**
Simbrinza, eye drops suspension, contains the active substances brinzolamide and brimonidine tartrate, which belong to a group of medicines called anti-glaucoma agents.

**What Simbrinza is used for**
Simbrinza, is used to lower high pressure inside the eye(s) (intraocular pressure - IOP) in adult patients with open-angle glaucoma or hypertension (high pressure) in the eye. Simbrinza is prescribed if your physician considers it appropriate for you and your condition.

**How Simbrinza works**
Simbrinza is a combination of two active substances, brinzolamide and brimonidine tartrate. Brinzolamide belongs to a group of medicines called carbonic anhydrase inhibitors. Brinzolamide lowers the pressure in your eye(s) by reducing the production of fluid within the eye. Brimonidine (brimonidine tartrate) belongs to a group of medicines called alpha-2 adrenergic agonist. Brimonidine lowers the pressure in your eye(s) by reducing the production of fluid within the eye and helps the flow of fluid out of the eye.

If you have any questions about how Simbrinza works or why this medicine has been prescribed for you, ask your doctor, pharmacist, or healthcare provider.

## 2. What you need to know before you take Simbrinza

Follow all your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

**Do not use Simbrinza**

- If you are allergic to brinzolamide or brimonidine tartrate or any of the other ingredients of this medicine. If you think you may be allergic, ask your doctor or healthcare provider for advice.
- If you are allergic to sulphonamides. Examples include medicines used to treat diabetes and infections and also diuretics (water tablets).
- If you are taking monoamine oxidase (MAO) inhibitors (examples include medicines to treat depression or Parkinson's disease). You must inform your doctor or healthcare provider 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 hyperchloremic acidosis).
- In babies and infants aged less than 2 years.

**Warnings and precautions**

If you experience allergic reactions, extreme tiredness or dizziness, discontinue the use of this product and talk to your doctor or healthcare provider.

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.

Talk to your doctor or healthcare 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.
- Disease of the surface of your eye (cornea).
- Liver or kidney 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 or Raynaud's syndrome or cerebral insufficiency).

**Children and adolescents**

Simbrinza is not recommended for children and adolescents 2 to 17 years of age due to the potential for serious side effects.

It is particularly important that the medicine is not used in children under the age of 2 years (see section 'Do not use Simbrinza').

**Other medicines and Simbrinza**

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

Tell your doctor or healthcare provider if you are using, have recently used, or might use any other medicines:

- Medicines to lower blood pressure.
- Heart medicines including digoxin (used to treat heart conditions).

If you are taking another carbonic anhydrase inhibitor (acetazolamide, methazolamide and dorzolamide) or medicines that are NSAIDs or salicylates. Medicines that can affect the metabolism like chlorpromazine, methylphenidate and reserpine.

- Monoamine oxidase (MAO) inhibitors, or antidepressants including amitriptyline, nortriptyline, clomipramine, mianserin, venlafaxine and duloxetine.
- Anaesthetics
- Sedatives, opiates, or barbiturates

Tell your doctor or healthcare provider if the dose of any of your current medicines are changed due to the potential interactions with Simbrinza.

**Simbrinza with alcohol**
If you are regularly consuming alcohol, ask your doctor, pharmacist or healthcare provider for advice before taking this medicine. Simbrinza can be affected by alcohol.

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, or you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you using this medicine.

**Driving and using machines**
Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after instillation, the patient must wait until the vision clears before driving or using machinery.

Simbrinza may cause fatigue and somnolence in some patients. Patients who engage in hazardous activities should be cautioned of the potential for a decrease in mental alertness.

**Important information about some of the ingredients of Simbrinza**
A preservative in Simbrinza (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.

If you wear contact lenses you should remove them before using Simbrinza and wait at least 15 minutes before putting your contact lenses back in.

## 3. How to take Simbrinza

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

- Shake the bottle well before use.
- Only use Simbrinza for dropping in your eye(s).
- After the cap is removed, if the tamper evident snap collar is loose, remove it before using the medicine.
- To avoid contamination, the dropper tip should not touch any surface. The dropper tip should also not touch the eye as this may cause injury to the eye. Keep the bottle tightly closed when not in use.

- After using Simbrinza, close your eyelids and press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop Simbrinza getting into the rest of the body and increases the effect in the eye.
- Do not exceed the recommended dose prescribed by your doctor or healthcare provider.

**If you are using other eye drops or eye ointment,** wait at least five minutes between using Simbrinza and the other drops. Eye Ointments should be administered last.

**If a drop misses your eye,** try again.

In case of accidental ingestion, you may experience decreased blood pressure, drowsiness, decreased heart rate and difficulty breathing. Should this happen, contact your doctor or healthcare provider 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 or healthcare provider 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.

**If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or healthcare provider.**

## 4. Possible side effects

As with all medicines, patients treated with Simbrinza may experience side effects, although not everybody gets them.

The following side effects have been seen with Simbrinza:

**Some side effects could be serious**
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).

**Common:** may affect up to 1 in every 10 people
- Effects in the eye: inflammation of the white of the eye, allergic conjunctivitis (eye allergy), inflammation of the eyelid, blurred vision, eye pain, eye irritation, dry eye, itchy eye, eye redness, eye discomfort.
- General side effects: drowsiness, bad taste, dry mouth

**Uncommon:** may affect up to 1 in every 100 people
- Effects in the eye: eye surface damage with loss of cells, eye surface inflammation, inflammation or infection of the conjunctiva, sensitivity to light, eye discharge, increased tear production, tired eyes, eyelid redness.
- General side effects: dizziness, headache, vertigo, decreased blood pressure, nasal dryness, skin inflammation, body weakness, fatigue, medication residue.

**Rare:** may affect up to 1 in every 1,000 people
- Effects in the eye: reduced vision, decreased tear production.
- General side effects: upper airway cough syndrome, nasal congestion, dry throat, nausea, upset stomach, abdominal discomfort.

**Frequency not known:**
- 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).

**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. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Simbrinza

Do not store above 30°C.

Throw away the bottle 4 weeks after first opening to prevent infections and use a new bottle.

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.

Keep out of the reach and sight of children.

## 6. Contents of the pack and other information

**What Simbrinza contains**
The active substance(s) of Simbrinza are brinzolamide and brimonidine tartrate.
The other excipients of Simbrinza are benzalkonium chloride, propylene glycol, carbomer 974P, boric acid, mannitol, sodium chloride, tyloxapol, sodium hydroxide and/or hydrochloric acid and purified water.

**What Simbrinza looks like and contents of the pack**
Simbrinza is a white-to-off-white uniform suspension.
Carton containing 1 or 3 bottles. 8 ml round, opaque, low-density polyethylene (LDPE) bottles with a LDPE dropper tip and white polypropylene screw cap containing 5 ml suspension

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
NVS Kenya Limited
27th Floor Britam Towers,
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**Manufacturer**

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Prescription only medication
Rwanda: FDA-HMP-MA-1478

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Rwanda: 20 July 2024

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