

Simbrinza®

Eye Drops

Brinzolamide 1% and brimonidine tartrate 0.2%

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Simbrinza?

Simbrinza contains the active ingredients Brinzolamide and brimonidine tartrate. Simbrinza is used to treat certain types of eye conditions such as high pressure inside your eye (ocular hypertension) and open angle glaucoma (an eye condition caused by fluid buildup that damages the optic nerve).

For more information, see Section [1. Why am I using Simbrinza?](#) in the full CMI.

2. What should I know before I use Simbrinza?

Do not use if you have ever had an allergic reaction to Simbrinza or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Simbrinza?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Simbrinza and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Simbrinza?

- Follow the instructions carefully provided by your doctor.
- Use one drop of Simbrinza in the conjunctival sac of the affected eye(s) twice daily.

More instructions can be found in Section [4. How do I use Simbrinza?](#) in the full CMI.

5. What should I know while using Simbrinza?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or

	<p>specialist you visit that you are using Simbrinza.</p> <ul style="list-style-type: none"> • Remove soft contact lenses before using Simbrinza. • Tell your doctor immediately if you develop any signs of an allergic reaction.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not give Simbrinza to anyone else, even if they seem to have the same condition as you. • Do not use Simbrinza in children and adolescents aged up to 17 years.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools or perform tasks requiring mental alertness and/or physical coordination until you know how Simbrinza affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.

Looking after your medicine	<ul style="list-style-type: none"> • Store below 25 °C • Do not freeze
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For more information, see Section [5. What should I know while using Simbrinza?](#) in the full CMI.

6. Are there any side effects?

Common side effects include eye pain, dry eye, eye swelling, eye discharge, vision problems, blurred vision, tiredness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Simbrinza®

Eye Drops

Active ingredients: *Brinzolamide 1% and brimonidine tartrate 0.2%*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Simbrinza. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Simbrinza.**

Where to find information in this leaflet:

- [1. Why am I using Simbrinza?](#)
- [2. What should I know before I use Simbrinza?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Simbrinza?](#)
- [5. What should I know while using Simbrinza?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Simbrinza?

Simbrinza contains the active ingredients Brinzolamide and brimonidine tartrate. Brinzolamide is a carbonic anhydrase inhibitor and brimonidine tartrate is an alpha 2 adrenergic receptor agonist.

Simbrinza is used to treat certain types of eye conditions such as high pressure inside your eye (ocular hypertension) and open angle glaucoma (an eye condition caused by fluid buildup that damages the optic nerve).

Simbrinza helps in reducing eye pressure within the eye by reducing the production of fluid.

2. What should I know before I use Simbrinza?

Warnings

Do not use Simbrinza:

- If you are allergic to Brinzolamide and brimonidine tartrate or other sulphonamides or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of an allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.
- If you are taking any antidepressant medicines including monoamine oxidase (MAO) inhibitor therapy or other antidepressant medications (e.g. tricyclic antidepressants and mianserin)
- If you have symptoms such as headache, lack of energy, vomiting and feeling sick

- In children and adolescents aged up to 17 years ie do not use in children under 2 years old and do not use in children and adolescents aged 2 to 17 years.
- If you suffer from severe kidney diseases.

Check with your doctor if you:

- suffer from acute angle-closure glaucoma, symptoms include severe eye pain, vision loss, headache, redness.
- take any medicines for any other condition
- have diabetes
- have heart problems
- suffer from depression
- have symptoms such as tiredness, chest pain, and shortness of breath.
- have any problems with your blood vessels such as Raynaud's disease, a condition characterized by skin colour changes, affected part feels cold or numb, skin ulcers, or Buerger disease, symptoms include pain in hands or feet, coldness, numbness.
- have low blood pressure problems, symptoms such as dizziness, lightheadedness
- suffer from any liver, kidney problems.
- have any skin rash, problems with your skin
- have any problems with your cornea.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will advise you regarding the possible risks and benefits of using Simbrinza during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will advise you regarding the possible risks and benefits of using Simbrinza during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Simbrinza and affect how it works.

Tell your doctor if you take any of the following medicines:

- Carbonic anhydrase inhibitors such as acetazolamide, methazolamide and dorzolamide.
- Digoxin, a medicine used to treat heart failure.
- Anti-inflammatory medicines, e.g. salicylates, ibuprofen or aspirin.
- Other medicines or eye drops for glaucoma.

- Drugs used to treat high blood pressure, heart problems (e.g. isoprenaline, prazosin)
- Monoamine oxidase (MAO) inhibitors, or other antidepressants including amitriptyline, nortriptyline, clomipramine and mianserin
- CNS depressants such as alcohol, barbiturates, opiates, sedatives or anaesthetics.
- Chlorpromazine, methylphenidate, reserpine
- Antiviral or antibiotics e.g. ketoconazole, itraconazole, clotrimazole, ritonavir and troleandomycin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Simbrinza.

4. How do I use Simbrinza?

How much to use

- Follow the instructions provided and use Simbrinza until your doctor tells you to stop.
- Use one drop of Simbrinza in the conjunctival sac of the affected eye(s) twice daily.
- Do not exceed the recommended dose.
- If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

When to use Simbrinza

- Simbrinza should be used at about the same time every day unless your doctor tells you otherwise.

How to use Simbrinza

- Sitting or lying down might make the process simpler.
- Remove contact lenses if you are wearing them before using the eye drops.
- Shake the bottle well prior to use.

Follow the steps below to use Simbrinza:

- Wash your hands thoroughly with soap and water.
- Before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
- Remove the cap from the bottle.
- After the cap is removed, if the tamper evident snap collar is loose, it should be removed before using Simbrinza.
- Mix the contents of the bottle by inverting 5 to 10 times.
- Hold the bottle upside down in one hand between your thumb and middle finger (refer diagram 1).

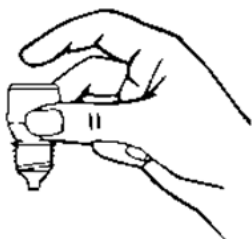


Diagram 1

- Tilt your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.
- Place the tip of the bottle close to your eye. Do not touch the tip to your eye as this may cause injury to the eye.
- Do not touch the dropper tip to eyelid or surrounding areas or any surface to avoid contamination of the dropper tip and solution.
- Release one drop into the pouch/pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger (refer diagrams 2 and 3).



Diagram 2



Diagram 3

- Gently close your eye(s) for two minutes. Do not blink or rub your eye(s).
- When your eye is closed, place your index finger against the inside corner of your eye and press

against your nose for about two minutes. This will help to prevent the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body and may result in less side effects.

- This will also help to prevent the unpleasant taste sensation that some people experience while using these eye drops.
- If necessary, repeat the above steps for the other eye.
- You may feel a slight burning sensation in the eye shortly after using Simbrinza. If it continues, or is uncomfortable, contact your doctor or pharmacist.
- If you want to use any other eye drops wait at least 5 minutes after using Simbrinza. Eye ointments should be used last.
- It is normal for a small amount of eye drops to spill onto your cheek since your eyelids can only hold less than one drop at a time. Wipe away any spillage with a tissue.
- Replace the cap on the bottle and close it tightly.
- Always keep the bottle tightly closed when not in use.
- Wash your hands again with soap and water to remove any residue.
- Wait for 15 minutes before putting your contact lenses in.
- Discard Simbrinza Eye Drops 4 weeks after opening it.

If you forget to use Simbrinza

Simbrinza should be used regularly at the same time each day. If you miss your dose at the usual time, continue the treatment with the next dose as planned.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Simbrinza

If you think that you have used too much Simbrinza, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you accidentally use several Simbrinza Eye Drops in your eyes, immediately wash your eyes with warm tap water.

5. What should I know while using Simbrinza?

Things you should do

- Simbrinza Eye Drops are for eye use only.
- Do not put Simbrinza into your eye(s) while wearing contact lenses.
- Remove soft contact lenses before using Simbrinza.
- Benzalkonium chloride, one of the ingredients in Simbrinza may cause eye irritation and is known to discolour soft contact lenses.
- Put your lenses back in 15 minutes after using the eye drops.

Call your doctor straight away if you:

- notice any signs of allergic reaction.
- become pregnant, plan to become pregnant or if you are breast feeding while using Simbrinza.
- have severe kidney problems.
- develop skin rash, hives or other skin problems while on treatment with Simbrinza.

Remind any doctor, dentist or pharmacist or specialist you visit that you are using Simbrinza.

Things you should not do

- Do not stop using this medicine suddenly.

- Do not give Simbrinza to anyone else, even if they seem to have the same condition as you.
- Do not touch the dropper tip to the eyelids, surrounding areas or any other surfaces.
- Do not use Simbrinza in children and adolescents aged up to 17 years ie do not use in children under 2 years old and do not use in children and adolescents aged 2 to 17 years.

Driving or using machines

Be careful before you drive or use any machines or tools or perform tasks requiring mental alertness and/or physical coordination until you know how Simbrinza affects you.

Simbrinza may cause temporary blurred vision or other vision problems in some people and may affect the ability to drive or use machines.

If blurred vision occurs after use, wait until your vision clears before driving or using machinery.

Brimonidine tartrate, the active ingredient of Simbrinza, may cause tiredness and/or drowsiness, which may affect the ability to drive or operate machinery. Caution should be taken.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 25°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard Simbrinza Eye Drops 4 weeks after opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Eye problems:</p> <ul style="list-style-type: none">• Redness of the eye(s)• Eye pain• Uncomfortable feeling in eye(s)• Blurred vision• Abnormal vision• Double vision• Feeling that something is in your eye(s)• Increased sensitivity to light• Eye swelling• Eyelid swelling• Dry eye• Eye discharge• Decreased vision• Excessive secretion of tears from the eye(s)• Vision problems• Eye surface swelling• Eye allergy <p>General problems:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • Tiredness • Drowsiness • Nightmare • Difficulty sleeping • Dizziness • Feeling of fullness in the nose, cheeks and behind your eyes, fever, stuffy nose. • Headache • Spinning sensation • Dry throat • Throat irritation • Nasal dryness • Sneezing • Dry mouth • Feeling sick <p>Other problems:</p> <ul style="list-style-type: none"> • Hives • Rash • Itching • Dizziness, lightheadedness, tiredness, weakness (symptoms of low blood pressure) 	

Serious side effects

Serious side effects	What to do
<p>Eye problems:</p> <ul style="list-style-type: none"> • Eye pain, redness, sensitivity to light, blurred vision. • Burning or sharp eye pain, blurred vision, feeling that something is in your eye(s) • Redness of eye(s), blurred or hazy vision, eye irritation. <p>Skin problems:</p> <ul style="list-style-type: none"> • Skin rash, red skin, skin peeling, blistering of the lips, eyes or mouth, fever. <p>Other problems:</p> <ul style="list-style-type: none"> • Taste disturbance or loss of taste • Symptoms of allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
tongue or other parts of the body, rash, hives	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Simbrinza contains

Active ingredient (main ingredient)	Brinzolamide 1% (10 mg/mL) and brimonidine tartrate 0.2% (2 mg/mL)
Other ingredients (inactive ingredients)	Propylene glycol, carbomer 974P, boric acid, mannitol, sodium chloride, tyloxapol, sodium hydroxide and/or hydrochloric acid (to adjust pH), purified water and benzalkonium chloride (0.03 mg/mL) as preservative.
Potential allergens	benzalkonium chloride May contain potential allergen such as benzoates, sulfites and hydroxybenzoates from the manufacturing process.

Do not take this medicine if you are allergic to any of these ingredients.

What Simbrinza looks like

Simbrinza is a white to off-white uniform suspension for multiple-dose topical ophthalmic use and is supplied in 8 mL round opaque low density polyethylene (LDPE) bottles with a LDPE dispensing plug and white polypropylene screw cap containing 5 mL suspension.

Australian Register Number

AUST R 219839

Who distributes Simbrinza

Simbrinza is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone No. 1800 671 203

www.novartis.com.au

Simbrinza is supplied in New Zealand by

Novartis New Zealand Limited

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