

PART III: CONSUMER INFORMATION

PrSIMBRINZA®

(brinzolamide / brimonidine tartrate ophthalmic suspension)
1% / 0.2% w/v

This leaflet is part III of a three-part "Product Monograph" published when SIMBRINZA® (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% w/v was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SIMBRINZA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

SIMBRINZA is used to treat high pressure in the eyes in adult patients that are more than 18 years of age with open-angle glaucoma or ocular hypertension.

What it does:

SIMBRINZA contains brinzolamide and brimonidine tartrate which reduce the production of fluid in the eye, and increases the amount of fluid flowing out of the eye, thereby reducing high pressure in the eye.

When it should not be used:

- if you are allergic to brinzolamide or brimonidine tartrate, sulfonamides or any of the other ingredients of this medicine (see What the important non-medicinal ingredients are)
- if you are taking monoamine oxidase (MAO) inhibitors or certain antidepressants. You must inform your doctor if you are taking any antidepressant drug.
- 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 and in children 2 to 17 years of age.

What the medicinal ingredients are: The active ingredients are brinzolamide and brimonidine tartrate.

One mL of suspension contains 10 mg brinzolamide and 2 mg of brimonidine tartrate.

What the important non-medicinal ingredients are:

Preservative: Benzalkonium chloride (0.003%). The other ingredients are boric acid, carbomer 974P, mannitol, propylene glycol, purified water, sodium chloride and tyloxapol. Tiny amounts of hydrochloric acid and/or sodium hydroxide are added to keep acidity levels (pH levels) normal.

What dosage forms it comes in:

SIMBRINZA is a liquid suspension supplied in 10 mL DROP-TAINER® dispenser plastic bottles with a screw cap and security-ring or sleeve.

WARNINGS AND PRECAUTIONS

Brinzolamide is a sulfonamide and severe allergic reactions have occurred with sulfonamides, including death. If signs of a serious allergic reaction occur, stop use of this product and contact your doctor (See the **SERIOUS SIDE EFFECTS TABLE** for symptoms)

BEFORE you use SIMBRINZA talk to your doctor or pharmacist if you have now or have had:

- hypersensitivity to any component of this product
- severe reactions to sulfonamide drugs
- dry eyes or cornea problems
- kidney problems
- previous treatment for glaucoma
- history of contact lens wear
- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, high or low blood pressure
- liver problems
- depression

While you are using SIMBRINZA consult your doctor immediately to get advice concerning the continued use if:

- you develop an eye infection, swelling, redness or irritation of the eyelid
- you suffer any eye injury or have eye surgery

Pregnancy or breast-feeding

If you are pregnant, or think you may be pregnant, or are planning to have a baby, talk to your doctor before you use 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 breast - feeding, SIMBRINZA may pass into your milk. The use of SIMBRINZA is not recommended during breast-feeding.

Driving and using machines

Using SIMBRINZA may cause fatigue, sleepiness, drowsiness and/or blurred vision. Do not drive or engage in hazardous activities until these symptoms pass.

If you wear contact lenses

There is a preservative in SIMBRINZA (benzalkonium chloride) that may be absorbed by and can discolour soft contact lenses and may cause eye irritation.

Therefore, do not wear contact lenses while using SIMBRINZA.

Wait 15 minutes after using SIMBRINZA before putting your lenses back in.

INTERACTIONS WITH THIS MEDICATION

There have been no specific drug interaction studies done for SIMBRINZA.

Tell your doctor about all drugs, including eye drops, that you are using or plan to use, including those without a prescription. Drugs that may interact with SIMBRINZA include other eye drops for the treatment for glaucoma, 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, antiviral or antibiotic medicines, acetylsalicylic acid, monoamine oxidases (MAO) inhibitors, or antidepressants such as amitriptyline, nortriptyline, clomipramine and mianserin. Other drugs that may interact with SIMBRINZA include chlorpromazine, methylphenidate, reserpine, ketoconazole, itraconazole, clorimazole, ritonavir, isoprenaline, prazosin, opiates, sedatives, and anesthetics.

PROPER USE OF THIS MEDICATION

Always use SIMBRINZA exactly as your doctor has told you. Check if you are not sure.

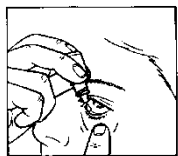
Only use SIMBRINZA for your eyes. Do not swallow or inject.

Usual adult dose:

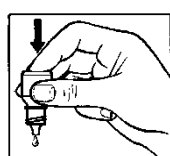
One drop in the eye or eyes, twice a day - morning and night. Use at the same times each day.

Only use SIMBRINZA in both eyes if your doctor told you to. Take it for as long as your doctor told you to.

How to Use:



1



2



3

- Get the SIMBRINZA bottle and a mirror.
- Wash your hands before use.
- Shake well before use.
- Twist off the bottle cap. Remove security-ring if loose.
- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back. Pull down your 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. Use the mirror if it helps.
- **Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** If the tip of the dispensing container contacts the eye or surrounding structures, it can become contaminated by common bacteria known to cause eye infections. It could infect the drops. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.
- Gently press on the base of the bottle to release one drop of SIMBRINZA at a time
- **Do not squeeze the bottle:** it is designed so that a gentle press on the bottom is all that it needs (picture 2).
- After using SIMBRINZA, press a finger into the corner of your eye, by the nose (picture 3) for up to 1 minute. This helps to stop SIMBRINZA getting into the rest of the body.
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Use up one bottle before opening the next bottle.
- Do not use for more than 125 days after opening the 10 mL bottle.
- If solution changes color, do not use. Do not use the product after the expiration date marked on the bottle.

If a drop misses your eye, try again.

If you are using other eye drops, wait at least 5 minutes between using SIMBRINZA and the other drops.

SIMBRINZA contains a preservative called benzalkonium chloride which may discolour soft contact lenses. If you wear contact lenses, remove them before using SIMBRINZA. Wait 15 minutes after using the drops before you put your lenses back in.

Overdose:

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.

In case of drug overdose, particularly oral ingestion, contact your doctor, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use SIMBRINZA, continue with the next dose as planned. Do not use a double dose to make up for the missed dose. Do not use more than one drop in the affected eye(s) two times a day.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

You can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop using SIMBRINZA without speaking to your doctor.

If you get any severe allergic reaction while you are using SIMBRINZA, contact your doctor immediately.

The most common side effects in the eye observed with SIMBRINZA (may affect 1-10 in 100 people) include allergic conjunctivitis (eye allergy), eye surface inflammation, eye pain, eye discomfort, blurred vision, and eye redness.

Less common side effects in the eye observed with SIMBRINZA (may affect up to 1 in 100 people) include eye surface damage with loss of cells, inflammation of the eyelid, deposits on the eye surface, sensitivity to light, eye swelling, dry eye, eye discharge, increased tear production, eyelid redness, abnormal sensation in eye, and tired eye.

The most common side effects in other areas of the body include drowsiness, bad taste in mouth, and dry mouth.

Less common side effects in other areas of the body include decreased blood pressure, difficulty sleeping (insomnia), headache, dizziness, dry nose or throat, runny nose, stuffy nose, indigestion, stomach ache, abnormal sensation in mouth, and increased allergic symptoms on skin

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Bradycardia/ heart rate decreased (symptoms may include fainting, dizziness, weakness, changes in breath)		X	
	Hypotension/ blood pressure decreased (symptoms may include fainting, dizziness, weakness, changes in breath)		X	
	Unusual eye symptoms (symptoms may include severe eye pain or sensitivity to light, or sudden decrease or loss of vision)		X	
	Hypersensitivity or allergic reaction (symptoms may include trouble breathing, tightness in throat or severe skin rash)			X

This is not a complete list of side effects. For any unexpected effects while taking SIMBRINZA ophthalmic suspension, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach and sight 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.

Store at 2°C to 25°C. This medicine does not require any special storage conditions.

Throw away the 10 mL bottle 125 days after first opening to prevent infections; and use a new bottle. Write down the date of opening on the carton label in the space provided.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator
1219C
Ottawa, ON
K1A 0K9Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found on the Health Canada website at: www.healthcanada.gc.ca
or on the Novartis Pharmaceuticals Canada Inc. website at: www.novartis.ca
or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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