PART III: CONSUMER INFORMATION

Sandoz® Brimonidine
Brimonidine tartrate 0.2%, w/v

This leaflet is part III of a three-part “Product Monograph” published when Sandoz Brimonidine was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Sandoz Brimonidine. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Sandoz Brimonidine eye drops are used to reduce high pressure in the eye in patients with chronic open-angle glaucoma or ocular hypertension.

What it does:
Sandoz Brimonidine is a preserved eye drop solution that reduces the amount of fluid flowing into the eye and increases the amount of fluid flowing out of the eye. This reduces the pressure inside the eye.

When it should not be used:
Do not use Sandoz Brimonidine:
- If you are allergic to brimonidine tartrate or any of the other ingredients (see What the nonmedicinal ingredients are:)
- If you are receiving monoamine oxidase (MAO) inhibitor therapy
- In neonates and infants below the age of 2 years

What the medicinal ingredient is:
Brimonidine tartrate.

What the nonmedicinal ingredients are:
0.005% benzalkonium chloride, as preservative, citric acid, polyvinyl alcohol, purified water, sodium chloride and sodium citrate. Hydrochloric acid and/or sodium hydride may be added to adjust pH.

What dosage forms it comes in:
Ophthalmic solution, brimonidine tartrate 0.2%, w/v.

WARNINGS AND PRECAUTIONS

Sandoz Brimonidine may cause drowsiness and fatigue or blurred vision. Do not drive, use heavy machinery or engage in hazardous activities or activities requiring mental alertness, until these conditions have passed.

BEFORE you use Sandoz Brimonidine talk to your doctor or pharmacist if:
- you are breastfeeding a baby, pregnant or intend to become pregnant;
- you have any allergies to this drug, or to similar drugs (ask your doctor) or to Sandoz Brimonidine’s ingredients or components of its container;
- you are taking or intend to take other prescription or nonprescription drugs. This is particularly important if you are taking medicine to lower blood pressure or to treat heart disease;
- you wear contact lenses. The preservative in Sandoz Brimonidine (benzalkonium chloride) may be absorbed by soft (hydrophilic) contact lenses. Lenses should be removed prior to using Sandoz Brimonidine and kept out for 15 minutes after use.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Sandoz Brimonidine include:
Central nervous system depressants (alcohol, barbiturates, opiates, sedatives, or anesthetics), heart and blood pressure medications such as alpha-agonists, medication such as beta-blockers (ophthalmic and/or systemic), antihypertensives, cardiac glycoside, tricyclic antidepressants and clonidine.

Drug interaction studies have not been done for Sandoz Brimonidine.

PROPER USE OF THIS MEDICATION

Usual Adult Dose:
Normally, you should put one drop of Sandoz Brimonidine in each eye that needs treatment, twice every day, about 12 hours apart, following the instructions for use below.

You must not use the bottle if the tamper-proof seal on the cap is broken before you first use it.

Follow the following steps to help you use Sandoz Brimonidine properly:
1. Wash your hands. Tilt your head back and look at the ceiling.
2. Gently pull down the lower eyelid to create a small pocket.
3. Turn the bottle upside down and squeeze it gently to release one drop into each eye that needs treatment.
4. Let go of the lower lid, and close your eye for 30 seconds.

If a drop misses your eye, try again.

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

Always use Sandoz Brimonidine exactly as your doctor has instructed you. If you use Sandoz Brimonidine with another eye drop, leave at least five minutes between putting in Sandoz Brimonidine and then the other drops.

To help prevent infections, do not let the tip of the bottle touch your eye or anything else. Put the cap back on and close the bottle immediately after you have used it.

Overdose:
If you accidentally use too many drops, just go back to your regular twice a day dosing the next day. If you have any concerns, talk to your doctor or pharmacist.

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you forget to apply your eye drops at your normal time, simply apply them as soon as you remember. Then go back to the original schedule as directed by your doctor. Do not try to catch up on missed drops by applying more than one dose at a time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common</td>
<td>Occurs in more than 1 out of every 100 patients</td>
</tr>
<tr>
<td>Common</td>
<td>Occurs in between 1 and 10 out of every 100 patients</td>
</tr>
<tr>
<td>Uncommon</td>
<td>Occurs in between 1 and 10 out of every 1000 patients</td>
</tr>
</tbody>
</table>

The following side effects may be seen with Sandoz Brimonidine. If these persist or cause you concern, consult your doctor.

Very common:
- Dry mouth
- Irritation of the eye (eye redness, burning, stinging, a feeling of something in the eye)
- Blurred vision
- Headache
- Tiredness, sleepiness or drowsiness
Common:
- Local irritation (inflammation and swelling of the eyelid, pain and tearing)
- Sensitivity to light
- Erosion on the surface of the eye and staining
- Eye dryness
- Abnormal vision
- Dizziness
- Cold-like symptoms
- Symptoms involving the stomach and digestion
- Abnormal taste
- General weakness

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

<table>
<thead>
<tr>
<th>Symptoms/Effects</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and call your doctor or pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Only if severe</td>
<td>In all cases</td>
</tr>
<tr>
<td>Bradycardia/heart rate decreased</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Hypotension/blood pressure decreased</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

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

HOW TO STORE IT

Sandoz Brimonidine should be stored at 4°C to 30°C.

Do not use the drops after the expiry date (marked “Exp”) on the bottle and the box.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
  
  Health Canada
  Postal Locator 0701E
  Ottawa, (Ontario) K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. 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 by contacting the sponsor, Sandoz Canada Inc., at:

1-800-361-3062

Or by written request at:

145, Jules-Léger

Boucherville (Québec)

J4B 7K8 Canada

or by e-mail at: medinfo@sandoz.com

This leaflet was prepared by Sandoz Canada Inc.