

**PART III: CONSUMER INFORMATION****Sandoz Ofloxacin  
Ofloxacin Ophthalmic Solution USP, 0.3%**

This leaflet is part III of a three-part "Product Monograph" published when Sandoz Ofloxacin 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 Ofloxacin. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION****What the medication is used for:**

Sandoz Ofloxacin is a topical treatment for external eye infections such as conjunctivitis.

Antibacterial drugs like Sandoz Ofloxacin treat only bacterial infections. They do not treat viral infections. Although you may feel better early in the treatment, Sandoz Ofloxacin should be used exactly as directed. Misuse or overuse of Sandoz Ofloxacin could lead to the growth of bacteria that will not be killed by Sandoz Ofloxacin (resistance). This means that Sandoz Ofloxacin may not work for you in the future. Do not share your medicine.

**What it does:**

Sandoz Ofloxacin interferes with the bacterial enzyme responsible for growth and division, thereby helping stop the infection.

**When it should not be used:**

Do not use Sandoz Ofloxacin if you:

- Have a history of hypersensitivity to ofloxacin or to any of the ingredients of this medication (See **What the important nonmedicinal ingredients are**).
- Have a history of hypersensitivity to other quinolones.

**What the medicinal ingredient is:**

Sandoz Ofloxacin contains the antibiotic, ofloxacin, which is a member of the group of antibiotics known as "quinolones".

**What the important nonmedicinal ingredients are:**

Benzalkonium chloride 0.005% w/v (as preservative), sodium chloride, hydrochloric acid and/or sodium hydroxide to adjust the pH, and purified water.

**What dosage forms it comes in:**

Sandoz Ofloxacin is supplied in plastic Drop-Tainer® dropper bottles containing 5 mL.

**WARNINGS AND PRECAUTIONS**

This product should be used with caution in patients sensitive to other quinolone antibacterial agents.

**Long term use may result in a new bacterial infection which does not respond to Sandoz Ofloxacin.**

This product should be used with caution in patients with a defect or damage to the surface of the eye.

Your sight may become blurred for a short time just after using Sandoz Ofloxacin. You should not drive or use machines until your sight is clear again.

**BEFORE** you use Sandoz Ofloxacin talk to your doctor or pharmacist if:

- You are pregnant or intend to become pregnant.
- You are breastfeeding or planning to breastfeed
- You have any allergies to this drug, or to similar drugs (ask your doctor) or to Sandoz Ofloxacin's ingredients or components of its container
- You wear contact lenses. The preservative in Sandoz Ofloxacin (benzalkonium chloride) may be absorbed by and discolour softcontact lenses. Lenses should be removed prior to application of Sandoz Ofloxacin and kept out for 15 minutes after use.

**INTERACTIONS WITH THIS MEDICATION**

Drug interaction studies have not been done for Sandoz Ofloxacin.

Tell your doctor or pharmacist if you are taking any other prescription or nonprescription (over-the-counter [OTC]) medicine, vitamins, herbals products.

**PROPER USE OF THIS MEDICATION****Usual adult dose:**

One to two drops every two to four hours for the first two days, and then four times daily in the affected eye(s) for 8 days.

**How to Use:**

1. Wash your hands. Tilt your head back and look at the ceiling.



2. Gently pull the lower eyelid down until there is a small pocket.



3. Turn the bottle upside down and squeeze it to release one or two drops 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.**

To avoid contamination and injury, do not let the tip of the dropper touch your eye or anything else.

Replace and tighten the cap straight after use.

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

**Overdose:**

**If you have placed too many drops in your eye(s), wash the eye(s) with clean water. Apply your next dose at the normal time.**

In case of drug overdose, contact a health care 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. **Don't try to catch up on missed drops by applying more than one dose at a time.**

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

You should see your doctor if any of the following side effects that affect the eye(s) prove troublesome or if they are long lasting:

- temporary burning or discomfort
- irritation
- eye/eyelid swelling
- eye pain
- redness
- stinging
- itchy eye/eyelid
- tearing
- dryness
- light sensitivity
- blurred vision
- a feeling that something is in your eye

You should see your doctor if any of the following side effects that affect the body prove troublesome or if they are longlasting:

- dizziness
- nausea
- swelling of the face

**Stop Sandoz Ofloxacin use and contact your doctor if a severe allergic (hypersensitivity) reaction occurs with symptoms such as swelling of the mouth, throat, tongue or extremities (hands, feet), difficulty in breathing, skin reactions (redness, irritation, blistering, peeling), loss of consciousness or collapse.**

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

**HOW TO STORE IT**

Sandoz Ofloxacin should be stored between 4° C to 30°C.

Keep out of reach and sight of children

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*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 obtained by contacting the sponsor, Sandoz Canada Inc., at:

1-800-361-3062

or by written request at:

145 Jules-Léger  
Boucherville QC  
J4B 7K8

Or by e-mail at :

medinfo@sandoz.com

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