

PRESCRIBING INFORMATION

OPTIMYXIN[®] OPHTHALMIC OINTMENT

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment USP

Antibiotic

Sandoz Canada Inc.
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**Optimyxin Ophthalmic Ointment
(Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment USP)**

INDICATIONS

For treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by organisms susceptible to polymyxin B and bacitracin zinc.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Optimyxin Ophthalmic Ointment and other antibacterial drugs, Optimyxin Ophthalmic Ointment should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

CONTRAINDICATIONS

Hypersensitivity to any of the components.

Patients who have glaucoma, should not use this product except under the advice and supervision of a physician.

WARNINGS AND PRECAUTIONS

Ophthalmic ointments may retard corneal healing.
If the symptoms do not start to clear in 48 hours, discontinue use and medical consultation is indicated.

The overuse of this product may increase redness of the eye.
Patients who experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists should consult a physician.

The vision may be blurred for a few minutes after using the product. Patient should not drive or operate machinery until vision returns.

Geriatrics: No specific information is available regarding the use of Optimyxin Ophthalmic Ointment in the elderly; however, the maximum dosage should be reduced in cases where a decrease in renal function may exist.

Pregnancy: The clinical benefit of treatment to the patient must be balanced against any possible, but unknown hazards to the fetus. Do not use unless advised by your doctor.

Susceptibility/Resistance

Development of Drug-Resistant Bacteria

Prescribing Optimyxin Ophthalmic Ointment in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of resistant organisms.

Potential for Microbial Overgrowth

Prolonged use of Optimyxin Ophthalmic Ointment may result in the overgrowth of nonsusceptible organisms and fungi. If such infections occur, discontinue use and institute alternative therapy.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

If toxic symptoms develop following significant systemic absorption, treatment with Optimyxin Ophthalmic Ointment should be stopped and the patient's general status, renal function and neuromuscular function should be monitored and blood levels of polymyxin B sulfate and bacitracin zinc determined.

DOSAGE AND ADMINISTRATION

Adult Dose: 2 to 5 applications daily for 7 days.

Optimyxin Ophthalmic Ointment should be used only externally.

Administration

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures to avoid eye injury and contamination.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Medicinal ingredients: Each g contains polymyxin B (as sulfate) 10 000 units and bacitracin (as zinc) 500 units.

Nonmedicinal ingredients: Light mineral oil, petrolatum.

Optimyxin Ophthalmic Ointment is available in tube of 3.5 g.

Store between 15 and 30°C.

Discard within 30 days from opening.

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

OPTIMYXIN OPHTHALMIC OINTMENT

Bacitracin Zinc and Polymyxin B Sulfate
Ophthalmic Ointment USP

Read this carefully before you or your child start using Optimyxin Ophthalmic Ointment. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your or your child's medical condition and treatment and ask if there is any new information about Optimyxin Ophthalmic Ointment.

What is Optimyxin Ophthalmic Ointment used for?

Optimyxin contains antibiotics and is used to treat external infections of the eye.

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

What ingredients are in Optimyxin Ophthalmic Ointment?

Medicinal ingredients: Each gram contains polymyxin B (as sulfate) 10 000 units and bacitracin (as zinc) 500 units.

Nonmedicinal ingredients: Light mineral oil, petrolatum.

How do I use Optimyxin Ophthalmic Ointment?

Apply one application in the affected eye or eyes, two to five times a day for 7 days. You should begin to see an improvement in your symptoms within 1 to 2 days. Even though the symptoms of the infection may be relieved within 1 to 2 days, you should use Optimyxin for 7 days to completely cure the infection.

Applying Optimyxin Ophthalmic Ointment into the eye:

- Wash hands with soap and water.
- Sit in front of a mirror so you can see what you are doing.
- Take the lid off the ointment.
- Tilt your head back.
- Gently pull down your lower eyelid and look up.
- Hold the tube above the eye and gently squeeze a 1cm line of ointment along the inside of the lower eyelid, taking care not to touch the eye or eyelashes with the tip of the tube.
- Blink your eyes to spread the ointment over the surface of the eyeball.

- Your vision may be blurred when you open your eyes - DON'T rub your eyes. The blurring will clear after a few moments if you keep blinking.
- Wipe away any excess ointment with a clean tissue.
- Repeat this procedure for the other eye if you have been advised to do so by your doctor or pharmacist.
- Replace the cap on the tube.
- Take care not to touch the tip of the tube with your fingers.
- Contact lenses should not be worn until the infection has resolved.

Do not use this product except under the advice and supervision of a physician if:

- you have glaucoma
- you are pregnant
- you have kidney disease

To help avoid side effects and ensure proper use, talk to your healthcare professional before you use Optimyxin Ophthalmic Ointment. Talk about any health conditions or problems you may have, including if:

- you have fever;
- you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a physician;
- your vision may be blurred for a few minutes after using the product. Do not drive or operate machinery until you can see clearly;
- there is no improvement within two days of starting treatment, stop use and consult a physician.

Other warnings you should know about:

- Overuse of this product may produce increased redness of the eye;
- For external use only;
- Do not use if you are allergic to any ingredient;
- Do not touch tip of tube to any surface to avoid contamination.

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 0701E
Ottawa, ON
K1A 0K9

Postage 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.

How to store?

Store between 15 and 30°C. Discard within 30 days from opening.

If you want more information about Optimyxin Ophthalmic Ointment, or pink eyes, contact your pharmacist or doctor, or call 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

Last Revised: November 29, 2017