

PRESCRIBING INFORMATION
INCLUDING PATIENT MEDICATION INFORMATION

OPTIMYXIN PLUS

Gramicidin, Neomycin and Polymyxin B Sulfate

**Each mL of solution contains Gramicidin 0.025 mg
Neomycin 1.75 mg (as neomycin sulfate) and
Polymyxin B Sulfate 10 000 units**

Ophthalmic/Otic

USP

Antibiotic

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**Optimyxin Plus
Eye/Ear Solution**

(Neomycin and Polymyxin B Sulfate and Gramicidin Ophthalmic Solution USP)

Antibiotic

INDICATIONS

Optimyxin Plus is used for the prophylaxis and treatment of eye and ear infections.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of OPTIMYXIN PLUS and other antibacterial drugs, OPTIMYXIN PLUS 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.

The presence of preexisting nerve deafness is a contraindication to the use of any topical aminoglycoside in circumstances where significant systemic absorption could occur.

WARNINGS AND PRECAUTIONS

The manifestations of sensitization to neomycin are usually itching, reddening and edema of the conjunctiva and eyelid. It may be manifest simply as a failure to heal. During long-term use of neomycin-containing products, periodic examination for such signs is advisable, and the patient should be told to discontinue the product if they are observed. These symptoms subside quickly on withdrawing the medication. Neomycin-containing applications should be avoided for the patient thereafter.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing OPTIMYXIN PLUS in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Potential for Microbial Overgrowth

The use of OPTIMYXIN PLUS may promote the selection of non-susceptible organisms. Should superinfection occur during therapy, appropriate measures should be taken.”

Articles in current medical literature indicate an increase in the incidence of allergies to neomycin in patients with stasis ulcers or eczema. The possibility of an allergic reaction to neomycin should be borne in mind.

As with any antibiotic-containing medication, prolonged use may result in the overgrowth of nonsusceptible organisms, including fungi. Should superinfection occur, the preparation should be discontinued and/or appropriate therapy instituted.

Because of the potential hazard of nephrotoxicity and ototoxicity due to neomycin, care should be exercised when treating extensive burns, trophic ulceration and other extensive conditions where absorption of neomycin is possible.

The eye and ear solution should not be given subconjunctivally or intraocularly, nor should it be used for the irrigation of fistulous tracts in or about the eye or its socket.

Treatment should be continued until at least 48 hours after the eye has apparently recovered. In patients with perforated eardrums or long-standing otitis media, treatment should be restricted to 10 days.

ADVERSE EFFECTS

Topical neomycin occasionally causes skin sensitization, especially when used for prolonged periods of time. Sensitivity to topical neomycin has been reported to occur in 5-15% of patients treated with the drug. Hypersensitivity reactions including contact conjunctivitis, burning, erythema, rash, and urticaria have occurred following topical application of neomycin to patients who are sensitive to the drug or other ingredients in the formulations.

Ototoxicity and nephrotoxicity have also been reported (see **PRECAUTIONS**).

Polymyxin B has a low order of toxicity when applied topically. Allergic hypersensitivity reactions to polymyxin B are rare but have been reported.

DOSAGE AND ADMINISTRATION

The suggested dose is one or two drops in the affected eye or ear, two to four times a day or more frequently as required.

If the infection does not subside within a few days, medical consultation is indicated.

To avoid contaminating the sterile solution, be sure not to touch the infected area with the dropper, when administering the drops.

To prevent the eye drops from being drained from the eye, apply a gentle pressure to the inside corner of the eye with your fingers for one minute.

To administer the drops into the ear, tilt the head or lie on the side, remain in this position for two minutes after administering the drops. For therapy to be most effective, the ear canal should be clean and dry.

AVAILABILITY OF DOSAGE FORMS

Each mL contains Polymyxin B sulfate 10 000 units, gramicidin 0.025 mg and neomycin 1.75 mg (as neomycin sulfate 2.5 mg). Also contains ethyl alcohol and benzalkonium chloride 0.005% (preservative).

**Available in plastic dropper bottles of 10 mL, boxes of 1.
Store between 15 and 30°C.**

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

OPTIMYXIN Plus
(Neomycin and Polymyxin B Sulfate and Gramicidin Ophthalmic Solution USP)

Read this carefully before you start taking **OPTIMYXIN Plus** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **OPTIMYXIN Plus**.

What is OPTIMYXIN Plus used for?

- **OPTIMYXIN Plus** is used to prevent and treat infections of the eye and ear.
- Antibacterial drugs like **OPTIMYXIN Plus** treat only bacterial infections. They do not treat viral infections.

How does OPTIMYXIN Plus work?

OPTIMYXIN Plus is an antibiotic that kills and stops the growth of bacteria in the eye and ear.

What are the ingredients in OPTIMYXIN Plus?

Medicinal ingredients: Gramicidin, neomycin and polymyxin B sulfate

Non-medicinal ingredients: benzalkonium chloride and ethyl alcohol

OPTIMYXIN Plus comes in the following dosage form:

As a solution containing 10 000 units of Polymyxin B sulfate, 0.025 mg gramicidin and 1.75 mg neomycin (as neomycin sulfate).

Do not use OPTIMYXIN Plus if you:

- are allergic to gramicidin, neomycin or Polymyxin B sulfate
 - are allergic to any of the other ingredients in **OPTIMYXIN Plus**
- are deaf or have hearing loss

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

- have skin sores or eczema, a skin condition;
- have a hole or tear in your eardrum;
- have had ear infections in the past;

Other warnings you should know about:

- Your vision may be blurred for a few minutes after you apply **OPTIMYXIN Plus**. Do

not drive or operate machinery until you can see clearly.

- OPTIMYXIN Plus is for external use only;
- Do not use if solution changes color or becomes cloudy.
- Do not touch tip of bottle to any surface, including your eye or ear, to avoid contamination;

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take OPTIMYXIN Plus:

- Although you may feel better early in treatment, OPTIMYXIN Plus should be used exactly as directed.
- Misuse or overuse of OPTIMYXIN Plus could lead to the growth of bacteria that will not be killed by OPTIMYXIN Plus (resistance). This means that OPTIMYXIN Plus may not work for you in the future.
- Do not share your medicine

Applying OTIMYXIN Plus into your eye:

- Wash hands with soap and water
- Tilt your head back or lie down and look up at the ceiling.
- With the eyes open, gently pull the lower eyelid below the eyelashes away from the eye to form a pouch.
- Hold the bottle at least 2 cm away and squeeze one drop into the eye pouch.
- Slowly release the lower lid.
- To prevent the eye drops from being drained from the eye, apply a gentle pressure to the inside corner of the eye with your fingers for one minute..
- If multiple drops are used, wait three to five minutes between each drop.
- Do not let the bottle touch your eye.
- Contact lenses should not be worn until the infection has resolved.

Applying OTIMYXIN Plus into your ear:

- Make sure that your ear is clean and dry before you apply OPTIMYXIN Plus.
- Lie on your side or tilt your head so that that your ear is facing up;
- Gently pull your earlobe up, away from the neck, and squeeze the drop into your ear;
- If multiple drops are to be applied, you can apply them at the same time.
- Let the drops flow into your ear and gently massage the ear around the opening to help them go down;
- Remain in this position for two minutes;

Usual dose:

- The usual dose is one or two drops in the affected eye or ear.

- It is applied two to four times a day.
- Take OPTIMYXIN Plus exactly as directed by your doctor.

Overdose:

If you think you have taken too much OPTIMYXIN Plus, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using OPTIMYXIN Plus?

These are not all the possible side effects you may feel when taking OPTIMYXIN Plus. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- itching, redness, or swelling of the eyes or skin ;
- burning sensation in the eye;
- feeling of grittiness or having something in the eye
- eye discharge

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Kidney problems: abdominal or back pain, changes in your urine, confusion, fatigue, irregular heartbeat, nausea, shortness of breath, swelling, weakness.		✓	
Hearing problems: changes in hearing, dizziness, poor hearing, problems with balance, ringing in the ears, vertigo (spinning sensation).		✓	
Allergic reactions: difficulty breathing, difficulty swallowing, fever, hives, itchy skin, rash, swelling of your tongue or throat.			✓

Eye pain, continued redness or irritation of the eye.		✓	
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If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) 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.

Storage:

OPTOMYXIN Plus should be stored between 15 and 30°C.

Keep out of reach and sight of children.

If you want more information about OPTIMYXIN Plus:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website www.sandoz.ca, or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

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