

## **Prescribing Information**

### **PrDIOSPORIN OINTMENT**

**Neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment, USP**

Antibacterial

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## Prescribing Information

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Antibacterial

## DESCRIPTION

DIOSPORIN Ophthalmic Ointment (neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment) is a sterile antimicrobial ointment for ophthalmic use. Each gram contains: neomycin sulfate equivalent to 3.5 mg neomycin base, polymyxin B sulfate equivalent to 10,000 polymyxin B units, bacitracin zinc equivalent to 400 bacitracin units, and white petrolatum, q.s.

**Neomycin sulfate** is the sulfate salt of neomycin B and C, which are produced by the growth of *Streptomyces fradiae* Waksman (Fam. Streptomycetaceae). It has a potency equivalent of not less than 600 µg of neomycin standard per mg, calculated on an anhydrous basis.

**Polymyxin B sulfate** is the sulfate salt of polymyxin B 1 and B 2, which are produced by the growth of *Bacillus polymyxa* (Prazmowski) Migula (Fam. Bacillaceae). It has a potency of not less than 6,000 polymyxin B units per mg, calculated on an anhydrous basis.

**Bacitracin zinc** is the zinc salt of bacitracin, a mixture of related cyclic polypeptides (mainly bacitracin A) produced by the growth of an organism of the licheniformis group of *Bacillus subtilis* var Tracy. It has a potency of not less than 40 bacitracin units per mg.

## ACTION AND PHARMACOLOGY

A wide range of antibacterial action is provided by the overlapping spectra of neomycin, polymyxin B sulfate, and bacitracin.

Neomycin is bactericidal for many gram-positive and gram-negative organisms. It is an aminoglycoside antibiotic which inhibits protein synthesis by binding with ribosomal RNA and causing misreading of the bacterial genetic code.

Polymyxin B is bactericidal for a variety of gram-negative organisms. It increases the permeability of the bacterial cell membrane by interacting with the phospholipid components of the membrane.

Bacitracin is bactericidal for a variety of gram-positive and gram-negative organisms. It interferes with bacterial cell wall synthesis by inhibition of the regeneration of phospholipid receptors involved in peptidoglycan synthesis.

**Microbiology:** Neomycin sulfate, polymyxin B sulfate, and bacitracin zinc together are considered active against the following microorganisms: Staphylococcus aureus, streptococci including Streptococcus pneumoniae, Escherichia coli, Haemophilus influenzae, Klebsiella/Enterobacter species, Neisseria species, and Pseudomonas aeruginosa. The product does not provide adequate coverage against Serratia marcescens.

## INDICATIONS

DIOSPORIN Ophthalmic Ointment is indicated for the topical treatment of superficial infections of the external eye and its adnexa caused by susceptible bacteria. Such infections encompass conjunctivitis, keratitis and keratoconjunctivitis, blepharitis and blepharoconjunctivitis.

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

## CONTRAINDICATIONS

DIOSPORIN Ophthalmic Ointment is contraindicated in individuals who have shown hypersensitivity to any of its components.

## WARNINGS

**NOT FOR INJECTION INTO THE EYE.** DIOSPORIN Ophthalmic Ointment should never be directly introduced into the anterior chamber of the eye. Ophthalmic ointments may retard corneal wound healing.

Topical antibiotics, particularly neomycin sulfate, may cause cutaneous sensitization. A precise incidence of hypersensitivity reactions (primarily skin rash) due to topical antibiotics is not known. The manifestations of sensitization to topical antibiotics are usually itching, reddening, and edema of the conjunctiva and eyelid. A sensitization reaction may manifest simply as a failure to heal. During long-term use of topical antibiotic products, periodic examination for such signs is advisable, and the patient should be told to discontinue the product if they are observed. Symptoms usually subside quickly on withdrawing the medication. Application of products containing these ingredients should be avoided for the patient thereafter (see **PRECAUTIONS: General**).

## **PRECAUTIONS**

**General:** As with other antibiotic preparations, prolonged use of DIOSPORIN Ophthalmic Ointment may result in overgrowth of non-susceptible organisms including fungi. If superinfection occurs, appropriate measures should be initiated.

Bacterial resistance to DIOSPORIN Ophthalmic Ointment may also develop. If purulent discharge, inflammation, or pain becomes aggravated, the patient should discontinue use of the medication and consult a physician.

There have been reports of bacterial keratitis associated with the use of topical ophthalmic products in multiple-dose containers which have been inadvertently contaminated by patients, most of whom had a concurrent corneal disease or a disruption of the ocular epithelial surface (see **PRECAUTIONS: Information for Patients**).

Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin.

**Information for Patients:** Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, eyelid, fingers, or any other surface. The use of this product by more than one person may spread infection.

Patients should also be instructed that ocular products, if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye

and subsequent loss of vision may result from using contaminated products (see PRECAUTIONS: General).

If the condition persists or gets worse, or if a rash or allergic reaction develops, the patient should be advised to stop use and consult a physician. Do not use this product if you are allergic to any of the listed ingredients.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term studies in animals to evaluate carcinogenic or mutagenic potential have not been conducted with polymyxin B sulfate or bacitracin. Treatment of cultured human lymphocytes in vitro with neomycin increased the frequency of chromosome aberrations at the highest concentration (80 µg/mL) tested; however, the effects of neomycin on carcinogenesis and mutagenesis in humans are unknown.

Polymyxin B has been reported to impair the motility of equine sperm, but its effects on male or female fertility are unknown. No adverse effects on male or female fertility, litter size or survival were observed in rabbits given bacitracin zinc 100 gm/ton of diet.

**Pregnancy:** Teratogenic Effects: Pregnancy Category C. Animal reproduction studies have not been conducted with neomycin sulfate, polymyxin B sulfate, or bacitracin. It is also not known whether DIOSPORIN Ophthalmic Ointment can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DIOSPORIN Ophthalmic Ointment should be given to a pregnant woman only if clearly needed.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DIOSPORIN Ophthalmic Ointment is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

**Geriatric Use:** No overall differences in safety or effectiveness have been observed between elderly and younger patients.

***Susceptibility/Resistance Development of Drug Resistant bacteria***

***Prescribing DIOSPORIN 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 drug-resistant bacteria.***

***Potential for Microbial Overgrowth***

***The use of DIOSPORIN OINTMENT may promote the selection of non-susceptible organisms. Should superinfection occur during therapy, appropriate measures should be taken.***

**ADVERSE REACTIONS**

**Adverse Reactions:** Adverse reactions have occurred with the anti-infective components of DIOSPORIN Ophthalmic Ointment. The exact incidence is not known. Reactions occurring most often are allergic sensitization reactions including itching, swelling, and conjunctival erythema (see WARNINGS). More serious hypersensitivity reactions, including anaphylaxis, have been reported rarely. Local irritation on instillation has also been reported.

**DOSAGE AND ADMINISTRATION**

Apply the ointment every 3 or 4 hours for 7 to 10 days, depending on the severity of the infection.

**AVAILABILITY**

SUPPLIED Tube of 3.5 g with ophthalmic tip.

**STORAGE**

Store at 15° to 25°C. Keep tightly closed when not in use. Keep out of reach of children.

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

**PrDIOSPORIN OINTMENT  
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Read this carefully before you start taking **DIOSPORIN OINTMENT** 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 **DIOSPORIN OINTMENT**.

**What is DIOSPORIN OINTMENT Ointment used for?**

DIOSPORIN OINTMENT is used to treat certain infections of the eye and the area around the eye.

Antibacterial drugs like DIOSPORIN OINTMENT treat only bacterial infections. They do not treat viral infections.

**How does DIOSPORIN OINTMENT work?**

DIOSPORIN OINTMENT is an antibiotic that kills and prevents the growth of bacteria to reduce infections.

**What are the ingredients in DIOSPORIN OINTMENT?**

Medicinal ingredients: Neomycin Sulfate 3.5 mg/g, Polymyxin B Sulfate 10,000 units/g, Bacitracin Zinc 400 units/g.

Non-medicinal ingredients: White Soft Paraffin

**DIOSPORIN OINTMENT comes in the following dosage forms:**

Ointment, each gram contains: neomycin sulfate equivalent to 3.5 mg neomycin base, polymyxin B sulfate equivalent to 10,000 polymyxin B units, bacitracin zinc equivalent to 400 bacitracin units, and white petrolatum, q.s.

**Do not use DIOSPORIN OINTMENT if:**

- You are allergic to any of the ingredients in DIOSPORIN OINTMENT.

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

- Are allergic to kanamycin, paromycin, streptomycin or gentamicin.
- Are pregnant or breast-feeding.

Other warnings that you should know about:

If your infection gets worse or if you experience inflammation, pain or discharge (pus) in the eye, stop taking DIOSPORIN OINTMENT and talk to your healthcare professional.

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

**How to take DIOSPORIN OINTMENT:**

- Although you may feel better early in treatment, DIOSPORIN OINTMENT should be used exactly as directed.
- Misuse or overuse of DIOSPORIN OINTMENT could lead to the growth of bacteria that will not be killed by DIOSPORIN OINTMENT (resistance). This means that DIOSPORIN OINTMENT may not work for you in the future.
- Do not share your medicine
- Avoid touching the tip of the tube with your finger or eye to avoid contamination. Put the cap back on after use.
- To apply the ointment:
  - Pull down your lower eye lid.
  - Apply a small amount of DIOSPORIN OINTMENT inside your eyelid (conjunctival sac).
  - Blink to spread the medicine.

**Usual dose:**

Apply the ointment every 3 or 4 hours for 7 to 10 days, depending on the severity of your infection.

**Overdose:**

If you think you have taken too much **DIOSPORIN OINTMENT**, 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 DIOSPORIN OINTMENT?**

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

Side effects include:

- Local irritation

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate
	Only if severe	In all cases	
<b>Allergic Reaction:</b> difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.			X

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.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:**

Store at 15°C - 25 °C. Keep out of reach and sight of children.

**If you want more information about DIOSPORIN OINTMENT:**

- 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/services/drugs-health-products/drug-products/drug-product-database.html>) or by calling 1-855-543-9917.

This leaflet was prepared by Steri-Med Pharma Inc.

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