

## **PRESCRIBING INFORMATION**

### **OPTIMYXIN**

Gramicidin and Polymyxin B Sulfate Oto-Ophthalmic Solution  
sterile

**Eye/Ear Drops**

**Antibiotic**

Euro-Pharm International Canada Inc.  
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## **Optimyxin**

Gramicidin and Polymyxin B Sulfate Oto-Ophthalmic Solution  
Eye/Ear Drops

Antibiotic

### **INDICATIONS**

Optimyxin is used topically in the treatment of superficial infection of the eye involving the conjunctiva and cornea. Topical therapy alone is usually adequate for the treatment of blepharitis, conjunctivitis and keratitis. It can also be used before and after eye surgery or removal of foreign bodies in the eye.

Optimyxin is also used topically in the treatment of superficial and ear infections.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of OPTIMYXIN and other antibacterial drugs, OPTIMYXIN 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. Not to be administered subconjunctivally.

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

### **WARNINGS AND PRECAUTIONS**

As with any medication containing an antibiotic, 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.

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.

### **Susceptibility/Resistance**

## **Development of Drug Resistant Bacteria**

Prescribing OPTIMYXIN 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 organisms.

## **Potential for Microbial Overgrowth**

Prolonged use of OPTIMYXIN may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur, discontinue use and institute alternative therapy.

## **DOSAGE AND ADMINISTRATION**

Optimyxin is a clear, non-irritation solution. It can be safely used in children and adults. The suggested dosage is one or two drops in the infected eye or ear, two to four times a day or more frequently as required.

If the appearance of the solution changes colour or becomes cloudy, discontinue use of the solution.

Optimyxin 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 of the solution.

To prevent the eye drops from being drained from the eye, a gentle pressure to the inside corner of the eye with the fingers should be applied for a 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.

## **DOSAGE FORMS, COMPOSITION AND PACKAGING**

Medicinal ingredients: Each mL contains Polymyxin B (as sulfate) 10000 units and gramicidin 0.025 mg.

Non-medicinal ingredients: benzalkonium chloride 0.005% (preservative), boric acid, ethyl alcohol, poloxamer 188, sodium hydroxide, water for injection.

Optimyxin is available in a 10 mL plastic dropper bottle.

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**  
Gramicidin and Polymyxin B Sulfate  
Sterile Eye Drops

**Read this carefully before you or your child start using Optimyxin. 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.**

**What is Optimyxin used for?**

Optimyxin contains antibiotics and is used to treat external infections of the eye such as bacterial pink eye.

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

**How to take OPTIMYXIN?**

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

**What ingredients are in Optimyxin?**

Medicinal ingredients: Each mL contains polymyxin B (as sulfate) 10,000 units and gramicidin 0.025 mg.

Nonmedicinal ingredients: benzalkonium chloride 0.005% (preservative), boric acid, ethyl alcohol, poloxamer 188, sodium hydroxide, water for injection.

**What is Pink Eye?**

Pink eye is also known as conjunctivitis and can be caused by an allergy, a bacteria or a virus.

Common signs of pink eye are:

- Redness in the white of the eye
- Swelling of the eyelids
- Watery eyes
- Itchiness or a feeling of having sand in the eye

**How do I know I have bacterial Pink Eye?**

- Pink eye caused by bacteria is accompanied by a thick, yellow-white discharge that may cause the eyelids to stick together, especially upon waking in the morning.
- Pink eye caused by virus is often accompanied by a sore throat and/or a tender node in front of the ear, and the discharge tends to be more watery than sticky.

- If the pink eye is due to an allergy, it may be accompanied by swollen eyes and other symptoms of allergy, such as a runny nose. It also often occurs during the typical seasons (spring and fall) and usually occurs in both eyes.

### **How is a bacterial Pink Eye treated?**

Since bacterial pink eye is very contagious, it is a good idea to begin the treatment with antibiotic eye drops as soon as possible. Optimyxin treats external infection and helps relieve the redness and itchiness associated with bacterial pink eye.

Without treatment, bacterial pink eye may go away by itself in 1 to 2 weeks. To help relieve discomfort, bathe eyes with warm water several times a day and apply warm packs. Clean edges of the infected eye with warm water and cotton balls to remove crusts of dried discharge that may cause the eyelids to stick together.

### **How do I use Optimyxin to treat bacterial Pink Eye?**

Instill one or two drops in the affected eye or eyes, two to four times a day for 7 to 10 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 to 10 days to completely cure the infection.

### **Applying Optimyxin drops into the eye:**

- Wash hands with soap and water.
- Tilt the head back or lie down and look toward 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 pouch.
- Slowly release the lower lid.
- Gently close the eye for one or two minutes. Do not rub the eye and try not to blink.
- If multiple drops are used, wait three to five minutes between each drop.
- Do not let the bottle directly touch the eye.
- Contact lenses should not be worn until the infection has resolved.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you use Optimyxin. 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;
- you have glaucoma, do not use this product except under the advice and supervision of 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 use if solution changes color or becomes cloudy;
- Do not touch tip of bottle to any surface to avoid contamination.

### **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.*

### **How to store?**

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

Optimyxin is available in a plastic dropper bottle of 10 mL

**If you want more information about Optimyxin, or pink eyes, contact your pharmacist or doctor, or call 1-888-929-0835.**

This leaflet was prepared by Euro-Pharm International Canada Inc.

Last Revised: July 24, 2019

**OPTIMYXIN**  
Gramicidin and Polymyxin B Sulfate  
Sterile Ear Drops

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**What is Optimyxin used for?**

Optimyxin contains antibiotics and is used to treat external infections of the ear such as bacterial swimmer's ear.

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

**How to take OPTIMYXIN?**

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

**What ingredients are in Optimyxin?**

Medicinal ingredients: Each mL contains polymyxin B (as sulfate) 10,000 units and gramicidin 0.025 mg.

Nonmedicinal ingredients: benzalkonium chloride 0.005% (preservative), boric acid, ethyl alcohol, poloxamer 188, sodium hydroxide, water for injection.

**What is a swimmer's ear?**

Swimmer's ear, also known as otitis externa, is an infection and inflammation of the outer ear canal. It typically affects people who swim frequently or otherwise get water in their ears. It is also associated with people who regularly use cotton-tipped swabs in their ears. The ear's normal acidic environment can be disrupted by constant wetness or the scraping of a cotton-tipped swab, creating conditions which allow bacteria to invade the ear canal causing infection and inflammation.

**What are some symptoms of swimmer's ear?**

- Pain especially when the earlobe is pulled or upon chewing
- Itching
- Drainage of fluid from the ear
- Possible decreased hearing since the ear is full of infected material
- Some redness of the outside part of the ear

**How is swimmer's ear treated?**

Most cases of swimmer's ear can be treated with antibiotic ear drops such as Optimyxin.

**How do I use Optimyxin to treat swimmer's ear?**

Instill one or two drops in the affected ear or ears, two to four times a day for 5 to 7 days. You should avoid getting water in the ear until the treatment is complete. 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 5 to 7 days to completely cure the infection.

**Administering Optimyxin drops in the ear:**

- Lie on the side or tilt the head over so that the infected ear is facing upwards.
- Gently pull the earlobe upwards, away from the neck, and squeeze the drops into the ear.
- Let the drops flow against the side of the ear canal and gently massage the ear around the opening to help the drops work down.
- Keep the head tilted for a few minutes.

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

- you have fever
- you experience severe pain, hearing loss, or if the condition worsens or persists, consult a physician.
- there is no improvement within two days of starting treatment, stop use and consult a physician.

**Other warnings you should know about:**

- For external use only;
- Do not use if you are allergic to any ingredient;
- Do not use if solution changes color or becomes cloudy;
- Do not touch tip of bottle to any surface to avoid contamination.

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