

Oxytetracycline HCl  
Polymyxin B Sulfate

Terramycin®  
5 mg + 10,000 Units/g  
Ophthalmic Ointment

**1. PHARMACOLOGIC CATEGORY**

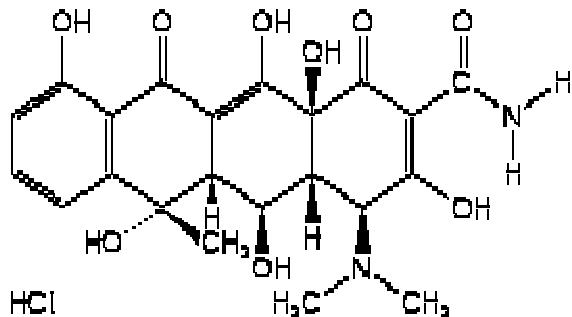
Antibacterial

**2. DESCRIPTION**

Oxytetracycline is a product of the metabolism of *Streptomyces rimosus* and is one of the family of tetracycline antibiotics. A 1% solution in water is acidic (pH about 2.5). Its potency is reduced in solutions more acidic than pH 2 and it is rapidly destroyed by alkali hydroxides.

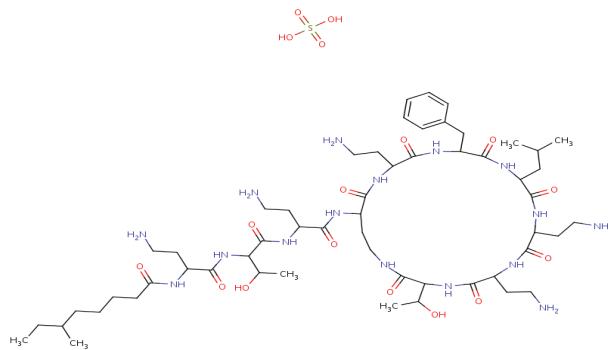
Oxytetracycline is chemically designated as 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenacarboxamide and has a molecular formula of C<sub>22</sub>H<sub>24</sub>N<sub>2</sub>O<sub>9</sub>.

The molecular weight of oxytetracycline hydrochloride is 496.90. It is an odorless, bitter, yellow crystalline powder soluble in water. It forms a cloudy or turbid solution in water due to liberation of oxytetracycline base. Molecular structure



Polymyxin B Sulfate is a white or buff-colored, hygroscopic powder, odorless or with a slight odor. It is very soluble in water with a 2% solution producing a pH of 5 to 7.

Molecular structure



### 3. FORMULATION

Terramycin Ophthalmic Ointment contains 5 mg oxytetracycline and 10,000 units of Polymyxin B Sulfate per gram of sterile petrolatum base.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

Oxytetracycline with Polymyxin B ophthalmic preparations are indicated in the treatment of superficial ocular infections involving the conjunctiva and/or cornea due to susceptible microorganisms.<sup>1</sup>

Topical application of Oxytetracycline with Polymyxin B Ophthalmic preparation should be supplemented with systemic administration when infections are severe or do not respond to topical therapy alone.

## **4.2 Dosage and Method of Administration**

Oxytetracycline with Polymyxin B ophthalmic preparations are administered as a small quantity (approximately 1 cm) of the ointment. The preparation should be applied into the conjunctival sac of the lower lid 4 to 6 times daily until the infection is cleared and healing is complete. This may take from one day to several weeks depending on the nature and severity of the infection. In blepharitis, scales and crusts should be removed before applying medication. For prophylaxis, the same procedure is followed on the day before the operation and subsequently for several days following it.

The patient should be instructed to avoid contamination of the tip of the tube when applying the ointment.

## **4.3 Contraindications**

These products are contraindicated in persons who have shown hypersensitivity to Oxytetracycline HCl, Polymyxin B Sulfate and any of their components.

## **4.4 Special Warnings and Precautions for Use**

As with other antibiotic preparations, Oxytetracycline may result in overgrowth of nonsusceptible organisms, including fungi. Constant observation of the patient for this possibility is essential. If new infections due to nonsusceptible bacteria or fungi appear during therapy, appropriate measures should be taken.

Oxytetracycline with Polymyxin B should be supplemented with systemic administration when infections are severe or do not respond to topical therapy alone.

### *Usage in Children*

Systemic administration of tetracyclines during tooth development (last half of pregnancy, infancy, and childhood to the age of 8 years) may cause permanent discoloration of the teeth as well as retardation in the development of the skeleton. Enamel hypoplasia has also been reported. Although these effects are unlikely following topical application of tetracyclines because of the low doses used, the possibility that these effects could occur should be considered.

## **4.5 Interaction with Other Medicinal Products and Other Forms of Interaction**

No known interactions with Oxytetracycline Ophthalmic preparations.

## **4.6 Pregnancy and Lactation**

### *Pregnancy*

There are no controlled studies to date using topical tetracyclines in pregnant women. The use of systemic tetracyclines in pregnant women has resulted in retardation of skeletal development and bone growth in the fetus. None the less, topical tetracyclines should be used during pregnancy only when the possible benefits outweigh the potential risks.

### *Lactation*

It is not known whether topically applied tetracyclines are distributed into breast milk. Tetracyclines are distributed into milk following systemic administration. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

## **4.7 Effects on Ability to Drive and Use Machines**

Oxytetracycline topical preparations are not expected to have an influence on the ability to drive and to operate machinery. However, directly following the application of the ophthalmic dosage form, a short period of less acute vision may occur.

## **4.8 Undesirable Effects**

Immune System Disorders: Hypersensitivity

Nervous System Disorders: Burning sensation

Eye Disorders: Lacrimation increased

Skin & Subcutaneous Tissue Disorders: Dermatitis contact

General Disorders and Administration Site Conditions: Pain, Sensation of foreign body

#### 4.9 Overdose

No cases of overdosage with topical use of oxytetracycline have been reported.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic Properties

Oxytetracycline is a product of the metabolism of *Streptomyces rimosus* and is one of the family of tetracycline antibiotics. Oxytetracycline is primarily bacteriostatic and is thought to exert its antimicrobial effect by the inhibition of protein synthesis. Oxytetracycline is active against a wide range of gram-negative and gram-positive organisms.

The drugs in the tetracycline class have similar antimicrobial spectra, and cross resistance among them is common.

Polymyxin B Sulfate, one of a group of related antibiotics derived from *Bacillus polymyxa*, is bactericidal. This action is exclusively against gram-negative organisms. It is thought to act by altering the structure of the bacterial membrane resulting in leakage of essential intracellular components. It is particularly effective against *Pseudomonas aeruginosa* and *Haemophilus aegyptius*, frequently found in local infections of the eye.

Thus the combination of Oxytetracycline HCl and Polymyxin B sulfate is a particularly effective antimicrobial combination against primarily causative or secondarily infecting organisms.

One mg of pure Polymyxin B is equivalent to 10,000 units.

#### 5.2 Pharmacokinetic Properties

##### Oxytetracycline

In one study in rabbits with abraded corneas, oxytetracycline hydrochloride concentrations of 28 mcg/ml were detected in the aqueous humor 30 minutes after 5-minute bathing of the eye with a solution containing 5 mg/ml of oxytetracycline.

##### Polymyxin B

Polymyxin B is poorly absorbed from mucous membranes. In one study in rabbits, 0.1 mcg/ml concentrations of polymyxin B were detected in the aqueous humor and vitreous humor following six topical applications of 0.25% polymyxin B, one every 10 minutes.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 Incompatibilities**

Not applicable.

### **6.2 Shelf-life**

See end of the tube for the expiry date.

### **6.3 Storage Condition**

Store at temperatures not exceeding 25°C.

### **6.4 Availability**

Oxytetracycline Hydrochloride/ Polymyxin B Sulfate (Terramycin) Ophthalmic Ointment is available in 3.5 grams ointment tube.

## **7. FDA REGISTRATION NUMBER**

5 mg/ 10,000 Units per gram Ophthalmic Ointment: DRP-2067

## **8. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION**

5 mg/ 10,000 Units per gram Ophthalmic Ointment: 09 August 2019

KEEP OUT OF REACH OF CHILDREN.

**For suspected adverse drug reaction, report to the FDA: [www.fda.gov.ph](http://www.fda.gov.ph)  
Seek medical attention immediately at the first sign of any adverse drug reaction.**

**CAUTION:** Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

Manufactured by: PT. Pfizer Indonesia  
Jl. Raya Bogor Km. 28 Jakarta  
13710, Indonesia

Marketing Authorization Holder: Pfizer, Inc.  
19F-20F, 8 Rockwell Building, Hidalgo Drive,  
Rockwell Center, Poblacion, Makati City 1210,  
Metro Manila, Philippines

Under authority of PFIZER, INC., New York, N.Y., USA

## References

1. AHFS Drug Information. 1995: 1870-1871

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Change MAH Address/ Compliance to  
A.O. 2016-0008  
Reference Date: 23 July 2018