

TERRAMYCIN- oxytetracycline hydrochloride and polymyxin b sulfate ointment
Zoetis Inc.

Terramycin®

Terramycin®

(Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ophthalmic Ointment)
Antibiotic Ophthalmic Ointment

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Terramycin (Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ophthalmic Ointment) is an antibiotic, bright yellow in color, possessing potent antimicrobial activity. It is one of the most versatile of the broad-spectrum antibiotics, and is effective in the treatment of infections due to gram-positive and gram-negative bacteria, both aerobic and anaerobic, spirochetes, rickettsiae, and certain of the larger viruses.

Polymyxin B sulfate is one of a group of related antibiotics derived from *Bacillus polymyxa*. The polymyxins are rapidly bactericidal, this action being exclusively against gram-negative bacteria.

The broad-spectrum effectiveness of Terramycin against both gram-positive and gram-negative organisms is enhanced by the particular effectiveness of polymyxin B against infections associated with gram-negative organisms, especially those due to *Pseudomonasaeruginosa*, where polymyxin B is the antibiotic of choice. In addition, there is evidence to indicate that polymyxin B sulfate possesses some antifungal activity. The combined antibacterial effect of Terramycin plus polymyxin is at least additive and, in many instances, an actual synergistic action is obtained.

Terramycin is an ointment of oxytetracycline hydrochloride and polymyxin B sulfate in a special petrolatum base. Each gram of ointment contains oxytetracycline HCl equivalent to 5 mg of oxytetracycline and 10,000 units of polymyxin B as the sulfate.

INDICATIONS AND USAGE

Terramycin is indicated for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline and polymyxin-sensitive organisms, including infections due to streptococci, rickettsiae, E. coli, and A. aerogenes, such as conjunctivitis, keratitis, pink eye, corneal ulcer, blepharitis in dogs, cats, cattle, sheep, and horses; ocular infections due to secondary bacterial complications of distemper in dogs, and bacterial inflammatory conditions which may occur secondary to other infectious

diseases in the above species.

WARNING

Serious, life threatening, hypersensitivity (anaphylactic) reactions have been reported in some cats following application of antibiotic ophthalmic preparations. If your cat has swelling of the face, itching, appears weak, vomits, or has difficulty breathing within 4 hours of application you should discontinue treatment and contact your veterinarian immediately.

Note: The use of oxytetracycline and other antibiotics may result in an overgrowth of resistant organisms such as *Monilia*, staphylococci, and other species of bacteria. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.

DOSAGE AND ADMINISTRATION

Terramycin (Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ophthalmic Ointment) should be administered topically to the eye 2–4 times daily.

RECOMMENDED STORAGE

Store at controlled room temperature between 20° to 25°C (68° to 77°F), with excursions between 15° to 30°C (59° to 86°F).

HOW SUPPLIED

1/8-oz (3.5-g) tube

For Animal Use Only
Not for Human Use

Approved by FDA under NADA # 008-763

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Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007



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PRINCIPAL DISPLAY PANEL - 3.5 g Tube Label

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TERRAMYCIN

oxytetracycline hydrochloride and polymyxin b sulfate ointment

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-1096
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYTETRACYCLINE HYDROCHLORIDE (UNII: 4U7K4N52Z M) (OXYTETRACYCLINE ANHYDROUS - UNII:SLF0D9077S)	OXYTETRACYCLINE HYDROCHLORIDE	5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ.07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-1096-1	3.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA008763	01/02/1953	

Labeler - Zoetis Inc. (828851555)

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Zoetis Inc.