

Generic Name: Oxytetracycline
Trade Name: Terramycin
CDS Effective Date: December 30, 2009
Supersedes: January 31, 1995
Approved by BPOM: June 02, 2020

PT. PFIZER INDONESIA
Local Product Document

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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 affected 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-naphthacene-carboxamide and has a molecular formula of C₂₂H₂₄N₂O₉.

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

Available dosage forms:

TERRAMYCIN[®] Ophthalmic Ointment contains 1% oxytetracycline HCl equivalent to 10 mg of oxytetracycline per gram of sterile petrolatum base.

ACTIONS

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 closely similar anti-microbial spectra, and cross resistance among them is common.

INDICATIONS

TERRAMYCIN[®] Ophthalmic 1% is indicated for the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by TERRAMYCIN[®] susceptible organisms.

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CONTRAINDICATIONS

These products are contraindicated in persons who have shown hypersensitivity to any of its components.

PRECAUTIONS

As with other antibiotic preparations, TERRAMYCIN[®] may result in an overgrowth of nonsusceptible organisms, including fungi. Constant observation of the patient is essential. If new infections due to nonsusceptible bacteria or fungi appear during therapy, appropriate therapy should be instituted as indicated by susceptibility testing.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

No known interactions with Oxytetracycline Ophthalmic or Otic preparations

ADVERSE REACTIONS

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

DOSAGE AND ADMINISTRATION

TERRAMYCIN[®] Ophthalmic 1% Ointment is administered as a small quantity (approximately 1cm) of the ointment which should be instilled or applied into the conjunctiva 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 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.

SUPPLY

TERRAMYCIN[®] Ophthalmic 1% is available in tube of 3.5 g in box of 25's.

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Reg. No. DKL7219805431A1

STORE IN DRY PLACE BELOW 25°C
HARUS DENGAN RESEP DOKTER

Manufactured by PT. Pfizer Indonesia
Jakarta, Indonesia.