

Generic Name: Hydrocortisone, Oxytetracycline
Trade Name: **Terra-Cortril®**
CDS Effective Date: N/A
Supersedes: N/A
Approved by BPOM: February 14, 2018

PT. PFIZER INDONESIA

Local Product Document

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DESCRIPTION

TERRA-CORTRIL® Ophthalmic Ointment combines the antibiotic, Oxytetracycline HCl and the adrenocorticoid, Hydrocortisone. Each gram of TERRA-CORTRIL® contains TERRAMYCIN* brand of Oxytetracycline HCl equivalent to 5 mg of Oxytetracycline and 5 mg of CORTRIL* brand of hydrocortisone free alcohol in the specially prepared ointment base. For ophthalmic use only.

ACTIONS

TERRA-CORTRIL® Ophthalmic Ointment, is ideal for use in conditions where topical, nonsystemic action is desired. The TERRAMYCIN* present will prevent or overcome superficial infections caused by organisms susceptible to TERRAMYCIN*. Concomitantly, the concentration of CORTRIL* supplied is ample for inflammatory reactions of the eye resulting from allergy, infection or trauma. TERRA-CORTRIL® Ophthalmic Ointment thus provides the combined broad-spectrum activity of TERRAMYCIN* against the primarily causative or secondary infecting organisms, and the effectiveness of CORTRIL*, an antiallergic, anti-inflammatory hormone, which controls excessive tissue reaction to infections, allergens, and trauma.

INDICATIONS

Conditions of the Eyelid:

Blepharitis-acute, chronic, nonpurulent.

Conditions of the Conjunctiva:

Conjunctivitis-acute, chronic, nonpurulent phlyctenular, or nonspecific.

Conditions of the Sclera:

Scleritis, episcleritis. It may be useful in nonspecific inflammatory conditions involving the cornea, particularly where neo-vascularization is a problem.

CONTRAINDICATIONS

Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and many other viral diseases of the cornea and conjunctiva. Mycobacterial infections of the eye. Fungal diseases of ocular structures. Hypersensitivity to a component of the medication. (Hypersensitivity to the antibiotic component occurs

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at a higher rate than for other components). The use of these combinations is always contraindicated after uncomplicated removal of a corneal foreign body.

WARNINGS

Prolonged use may result in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of the topical steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Employment of steroid medication in the treatment of herpes simplex requires great cautions.

PRECAUTIONS

The initial prescription and renewal of the medication order beyond 20 g should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

The possibility of persistent fungal infections of the cornea should be considered after prolonged steroid dosing.

ADVERSE REACTIONS

Adverse reactions have occurred with steroid/anti-infective combination drugs which can be attributed to the steroid component, the anti-infective component, or the combination. Reactions occurring most often from the presence of the anti infective ingredient are allergic sensitizations. The reactions due to the steroid component in decreasing order of frequency are: elevation of intraocular pressure with possible development of glaucoma, and infrequent optic nerve damage; posterior subcapsular cataract formation; and delayed wound healing.

Secondary infection: The development of secondary infection has occurred after use of combinations containing steroids, and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroid. The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used.

Secondary bacterial ocular infection following suppression of host responses also occurs.

DOSAGE AND ADMINISTRATION

Approximately ½ inch of the TERRA-CORTRIL® Ophthalmic Ointment is squeezed from the tube onto the lower lid of the affected eye two or three times daily. The patient should be instructed to avoid contamination of the tip of the tube with exudate from the affected area.

SUPPLY

TERRA-CORTRIL® Ophthalmic Ointment is available in tube of 3.5 g in box of 25's.

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

Manufactured by PT. Pfizer Indonesia, Jakarta, Indonesia