TERRA-CORTRIL- oxytetracycline hydrochloride and hydrocortisone acetate suspension Roerig

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TERRA-CORTRIL®
Terramycin® (oxytetracycline HCl)
—Cortril® (hydrocortisone acetate)
OPHTHALMIC SUSPENSION

DESCRIPTION

Terra-Cortril suspension combines the antibiotic, oxytetracycline HCl ($C_{22}H_{24}N_2O_9$•HCl) and the adrenocorticoid, hydrocortisone acetate ($C_{23}H_{32}O_6$). **Each ml of Terra-Cortril contains Terramycin (oxytetracycline HCl) equivalent to 5 mg of oxytetracycline, and 15 mg of Cortril (hydrocortisone acetate) incorporated in mineral oil with aluminum tristearate.**

For Ophthalmic Use Only.

CLINICAL PHARMACOLOGY

Corticosteroids suppress the inflammatory response to a variety of agents and they probably delay or slow healing. Since corticoids may inhibit the body's defense mechanism against infection, a concomitant antimicrobial drug may be used when this inhibition is considered to be clinically significant in a particular case.

The anti-infective component in the combination is included to provide action against specific organisms susceptible to it.

Terramycin is considered active against the following microorganisms:

- Rickettsiae (Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox and tick fevers),
- *Mycoplasma pneumoniae* (PPLO, Eaton Agent),
- Agents of psittacosis and ornithosis,
- Agents of lymphogranuloma venereum and granuloma inguinale,
- The spirochetal agent of relapsing fever *(Borrelia recurrentis)*.

The following gram-negative microorganisms:

- *Haemophilus ducreyi* (chancroid),
- *Pasteurella pestis* and *Pasteurella tularensis*,
- *Bartonella bacilliformis*,
- *Bacteroides* species,
- *Vibrio comma* and *Vibrio fetus*,
- *Brucella* species (in conjunction with streptomycin).

Because many strains of the following groups of microorganisms have been shown to be resistant to tetracyclines, culture and susceptibility testing are recommended.

Oxytetracycline is indicated for treatment of infections caused by the following gram-negative microorganisms, when bacteriologic testing indicates appropriate susceptibility to the drug:

- *Escherichia coli*,
- *Enterobacter aerogenes* (formerly *Aerobacter aerogenes*),
- *Shigella* species,
- *Mima* species and *Herellea* species,
- *Haemophilus influenzae* (respiratory infections),

- *Klebsiella* species (respiratory and urinary infections).

Oxytetracycline is indicated for treatment of infections caused by the following gram-positive microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug:

Streptococcus species:

Up to 44 percent of strains of *Streptococcus pyogenes* and 74 percent of *Streptococcus faecalis* have been found to be resistant to tetracycline drugs. Therefore, tetracyclines should not be used for streptococcal disease unless the organism has been demonstrated to be sensitive.

For upper respiratory infections due to Group A beta-hemolytic streptococci, pencillin is the usual drug of choice, including prophylaxis of rheumatic fever.

Diplococcus pneumoniae,

Staphylococcus aureus, skin and soft tissue infections. Oxytetracycline is not the drug of choice in the treatment of any type of staphylococcal infections.

When penicillin is contraindicated, tetracyclines are alternative drugs in the treatment of infections due to:

- *Neisseria gonorrhoeae,*
- *Treponema pallidum* and *Treponema pertenue* (syphilis and yaws),
- *Listeria monocytogenes,*
- *Clostridium* species,
- *Bacillus anthracis,*
- *Fusobacterium fusiforme* (Vincent's infection),
- *Actinomyces* species.

Tetracyclines are indicated in the treatment of trachoma, although the infectious agent is not always eliminated, as judged by immunofluorescence.

Inclusion conjunctivitis may be treated with oral tetracyclines or with a combination of oral and topical agents.

When a decision to administer both a corticoid and an antimicrobial is made, the administration of such drugs in combination has the advantage of greater patient compliance and convenience, with the added assurance that the appropriate dosage of both drugs is administered, plus assured compatibility of ingredients when both types of drug are in the same formulation and, particularly, that the correct volume of drug is delivered and retained.

The relative potency of corticosteroids depends on the molecular structure, concentration, and release from the vehicle.

INDICATIONS AND USAGE

For steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists.

Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe where the inherent risk of steroid use in certain infective conjunctivitides is accepted to obtain a diminution in edema and inflammation. They are also indicated in chronic anterior uveitis and corneal injury from chemical radiation, thermal burns, or penetration of foreign bodies.

The use of a combination drug with an anti-infective component is indicated where the risk of infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

The particular anti-infective drug in this product is active against the following common bacterial eye pathogens:

- *Staphylococcus aureus*
- *Streptococci*, including *Streptococcus pneumoniae*
- *Escherichia coli*
- *Neisseria* species

The product does not provide adequate coverage against:

- *Haemophilus influenzae*
- *Klebsiella/Enterobacter* species
- *Pseudomonas aeruginosa*
- *Serratia marcescens*

CONTRAINDICATIONS

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

PRECAUTIONS

The initial prescription and renewal of the medication order beyond 20 milliliters 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. Exact incidence figures are not available since no denominator of treated patients is available.

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 (IOP) 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

Instill 1 or 2 drops of Terra-Cortril Ophthalmic Suspension into the affected eye three times daily.

Not more than 20 milliliters should be prescribed initially and the prescription should not be refilled without further evaluation as outlined in "Precautions" above.

HOW SUPPLIED

Terra-Cortril Ophthalmic Suspension (NDC 0049-0670-48) is supplied in 5 ml vials with separate sterile dropper.

Distributed by

Roerig

Division of Pfizer Inc, NY, NY 10017

LAB-0194-2.0

TERRA-CORTRIL

oxytetracycline hydrochloride and hydrocortisone acetate suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0049-0670
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
oxytetracycline hydrochloride (UNII: 4U7K4N52ZM) (oxytetracycline - UNII:X20I9EN955)		5 mg in 1 mL
hydrocortisone acetate (UNII: 3X7931PO74) (hydrocortisone - UNII:WI4X0X7BPJ)		15 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
mineral oil ()	
aluminum tristearate (UNII: U6XF9NP8HM)	

Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0049-0670-48	5 mL in 1 VIAL		

Labeler - Roerig

Revised: 4/2006 Roerig