PDR

58 EDITION

2004

PHYSICIANS' DESK REFERENCE®

Executive Vice President, Directory Services: David Duplay

Vice President, Sales and Marketing: Dikran N. Barsamian
Senior Director of Pharmaceutical Sales: Anthony Sorce
National Account Manager: Marion Reid, RPh
Senior Account Manager: Frank Karkowsky
Account Managers: Marjorie A. Jaxel, Denise Kelley, Eileen Sullivan, Suzanne E. Yarrow, RN
Director of Trade Sales: Bill Gaffney
Senior Director, Marketing and Product Management: Valerie E. Berger
Senior Product Manager: Jeffrey D. Dubin
Finance Director: Mark S. Ritchin
Senior Director, Publishing Sales and Marketing: Michael Bennett
Senior Marketing Manager: Jennifer M. Fronzaglia
Direct Mail Manager: Lorraine M. Loening
Manager of Marketing Analysis: Dina A. Maeder
Promotion Manager: Linda Levine
Vice President, Regulatory Affairs: Mukesh Mehta, RPh
Editorial Director: Lisette Bralow
Manager, Professional Data Services: Thomas Fleming, PharmD
Manager, Editorial Services: Bette LaGow
Manager, Concise Data Content: Tammy Chernin, RPh

Drug Information Specialists: Greg Tallis, RPh; Min Ko, PharmD
Project Editor: Harris Fleming
Senior Editor: Lori Murray
Production Editor: Gwynned L. Kelly
Senior Director, Operations: Brian Holland
Director of PDR Operations: Jeffrey D. Schaefer
Manager of Production Operations: Thomas Westburgh
PDR Production Manager: Joseph F. Rizzo
Senior Production Coordinators: Gianna Caradonna, Christina Klinger
Production Coordinator: Yasmin Hernández
Senior Index Editor: Shannon Reilly
Index Editor: Noel Deloughery
Format Editor: Michelle S. Guzman
Production Associate: Joan K. Akerlind
Production Design Supervisor: Adeline Rich
Electronic Publishing Designers: Bryan Dix, Rosalia Sberna, Livio Udina
Digital Imaging Coordinator: Michael Labruyere
Director of Client Services: Stephanie Struble
Fulfillment Manager: Louis J. Bolcik

Officers of Thomson Healthcare,: *President and Chief Executive Officer:* Richard Noble; *Chief Financial Officer:* Paul Hilger; *Executive Vice President, Clinical Solutions:* Jeff Reihl; *Executive Vice President, Directory Services:* David Duplay; *Executive Vice President, Medical Education:* Jeff MacDonald; *Executive Vice President, Human Resources:* Pamela M. Bilash; *President, Physician's Interactive:* Marty Gearhart; *Senior Vice President, Business Development:* William Gole; *Vice President, Human Resources:* Pamela M. Bilash

ISBN: 1-56363-471-6

CONTENTS

tions should not be made into the lower and mid-third of the upper arm. As with all intramuscular injections, aspiration is necessary to help avoid inadvertent injection into a blood vessel.

Injection sites should be alternated. As higher doses or more prolonged therapy with streptomycin may be indicated for more severe or fulminating infections (endocarditis, meningitis, etc.), the physician should always take adequate measures to be immediately aware of any toxic signs or symptoms occurring in the patient as a result of streptomycin therapy.

1. TUBERCULOSIS: The standard regimen for the treatment of drug susceptible tuberculosis has been two months of INH, rifampin and pyrazinamide followed by four months of INH and rifampin (patients with concomitant infection with tuberculosis and HIV may require treatment for a longer period). When streptomycin is added to this regimen because of suspected or proven drug resistance (see **INDICATIONS AND USAGE** section), the recommended dosing for streptomycin is as follows:

	Daily	*Twice Weekly*	*Thrice Weekly*
Children	20–40 mg/kg Max 1 g	25–30 mg/kg Max 1.5 g	25–30 mg/kg Max 1.5 g
Adults	15 mg/kg Max 1 g	25–30 mg/kg Max 1.5 g	25–30 mg/kg Max 1.5 g

Streptomycin is usually administered daily as a single intramuscular injection. A total dose of not more than 120 g over the course of therapy should be given unless there are no other therapeutic options. In patients older than 60 years of age the drug should be used at a reduced dosage due to the risk of increased toxicity. (See **BOXED WARNING**).

Therapy with streptomycin may be terminated when toxic symptoms have appeared, when impending toxicity is feared, when organisms become resistant, or when full treatment effect has been obtained. The total period of drug treatment of tuberculosis is a minimum of 1 year; however, indications for terminating therapy with streptomycin may occur at any time as noted above.

2. TULAREMIA: One to 2 g daily in divided doses for 7 to 14 days until the patient is afebrile for 5 to 7 days.
3. PLAGUE: Two grams of streptomycin daily in two divided doses should be administered intramuscularly. A minimum of 10 days of therapy is recommended.
4. BACTERIAL ENDOCARDITIS:
   a. *Streptococcal endocarditis:* In penicillin-sensitive alpha and non-hemolytic streptococcal endocarditis (penicillin MIC≤0.1 mcg/mL), streptomycin may be used for 2-week treatment concomitantly with penicillin. The streptomycin regimen is 1 g b.i.d. for the first week, and 500 mg b.i.d. for the second week. If the patient is over 60 years of age, the dosage should be 500 mg b.i.d. for the entire 2-week period.
   b. *Enterococcal endocarditis:* Streptomycin in doses of 1 g b.i.d. for 2 weeks and 500 mg b.i.d. for an additional 4 weeks is given in combination with penicillin. Ototoxicity may require termination of the streptomycin prior to completion of the 6-week course of treatment.
5. CONCOMITANT USE WITH OTHER AGENTS: For concomitant use with other agents to which the infecting organism is also sensitive: Streptomycin is considered a second-line agent for the treatment of gram-negative bacillary bacteremia, meningitis, and pneumonia; brucellosis; granuloma inguinale; chancroid, and urinary tract infection.

For adults: 1 to 2 grams in divided doses every six to twelve hours for moderate to severe infections. Doses should generally not exceed 2 grams per day.

For children: 20 to 40 mg/kg/day (8 to 20 mg/lb/day) in divided doses every 6 to 12 hours. (Particular care should be taken to avoid excessive dosage in children.)

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

Streptomycin Sulfate Injection, USP is supplied in packages of 10 ampules (NDC 0049-0620-33). Each ampule contains streptomycin sulfate equivalent to 1 g of streptomycin in 2.5 mL.

Store under refrigeration at 36° to 46°F (2° to 8°C).

REFERENCES

1. National Committee for Clinical Laboratory Standards. Performance Standards for Antimicrobial Disk Susceptibility Tests—Fourth Edition. Approved Standard NCCLS Document M2-A4. Vol. 10, No. 7. NCCLS, Villanova, PA 1990.

70-4895-44-0
Pfizer
Roerig
Division of Pfizer Inc, NY, NY 10017

Issued February 1998

DESCRIPTION

TAO (troleandomycin) is a synthetically derived acetylated ester of oleandomycin, an antibiotic elaborated by a species of *Streptomyces antibioticus.* It is a white crystalline compound, insoluble in water, but readily soluble and stable in the presence of gastric juice. The compound has a molecular weight of 814 and corresponds to the empirical formula $C_{41}H_{67}NO_{15}$.

Inert ingredients in the formulation are: hard gelatin capsules (which may contain inert ingredients); lactose; magnesium stearate; sodium lauryl sulfate; starch.

ACTIONS

TAO is an antibiotic shown to be active *in vitro* against the following gram-positive organisms:

Streptococcus pyogenes
Diplococcus pneumoniae

Susceptibility plate testing: If the Kirby-Bauer method of disc sensitivity is used, a 15 mcg. oleandomycin disc should give a zone of over 18 mm when tested against a troleandomycin sensitive bacterial strain.

INDICATIONS

Diplococcus pneumoniae
Pneumococcal pneumonia due to susceptible strains.
Streptococcus pyogenes
Group A beta-hemolytic streptococcal infections of the upper respiratory tract.

Injectable benzathine penicillin G is considered by the American Heart Association to be the drug of choice in the treatment and prevention of streptococcal pharyngitis and in long term prophylaxis of rheumatic fever.

Troleandomycin is generally effective in the eradication of streptococci from the nasopharynx. However, substantial data establishing the efficacy of TAO in the subsequent prevention of rheumatic fever are not available at present.

CONTRAINDICATIONS

Troleandomycin is contraindicated in patients with known hypersensitivity to this antibiotic.

WARNINGS

Usage in Pregnancy: Safety for use in pregnancy has not been established.

The administration of troleandomycin has been associated with an allergic type of cholestatic hepatitis. Some patients receiving troleandomycin for more than two weeks or in repeated courses have shown jaundice accompanied by right upper quadrant pain, fever, nausea, vomiting, eosinophilia, and leukocytosis. These changes have been reversible on discontinuance of the drug. Liver function tests should be monitored in patients on such dosage, and the drug discontinued if abnormalities develop. Reports in the literature have suggested that the concurrent use of ergotamine-containing drugs and troleandomycin may induce ischemic reactions. Therefore, the concurrent use of ergotamine-containing drugs and troleandomycin should be avoided.

Troleandomycin should be administered with caution to patients concurrently receiving estrogen containing oral contraceptives.

Studies in chronic asthmatic patients have suggested that the concurrent use of theophylline and troleandomycin may result in elevated serum concentrations of theophylline. Therefore, it is recommended that patients receiving such concurrent therapy be observed for signs of theophylline toxicity, and that therapy be appropriately modified if such signs develop.

PRECAUTIONS

Troleandomycin is principally excreted by the liver.

Caution should be exercised in administering the antibiotic to patients with impaired hepatic function.

ADVERSE REACTIONS

The most frequent side effects of troleandomycin preparations are gastrointestinal, such as abdominal cramping and discomfort, and are dose related. Nausea, vomiting, and diarrhea occur infrequently with usual oral doses.

During prolonged or repeated therapy, there is a possibility of overgrowth of nonsusceptible bacteria or fungi. If such infections occur, the drug should be discontinued and appropriate therapy instituted.

Mild allergic reactions such as urticaria and other skin rashes have occurred. Serious allergic reactions, including anaphylaxis, have been reported.

DOSAGE AND ADMINISTRATION

Clinical judgment based on the type of infection and its severity should determine dosage within the below listed ranges.

Adults: 250 to 500 mg 4 times a day
Children: 125 to 250 mg (3-5 mg/lb or 6.6 to 11 mg/kg) every 6 hours

When used in streptococcal infection, therapy should be continued for ten days.

HOW SUPPLIED

TAO is supplied as:
Capsules 250 mg: Each capsule contains troleandomycin equivalent to 250 mg of oleandomycin; bottles of 100 (NDC 0049-1590-66).

Revised July 1995 69-1800-00-8

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.

Continued on next page

Consult 2004 PDR® supplements and future editions for revisions