

TERRAMYCIN- oxytetracycline hydrochloride capsule
Pfizer Labs

TERRAMYCIN®
oxytetracycline
hydrochloride
CAPSULES

DESCRIPTION

Oxytetracycline is a product of the metabolism of *Streptomyces rimosus* and is one of the family of tetracycline antibiotics. A 1 percent solution in water is acidic (pH about 2.5). Its potency is affected in solutions more acid than pH 2 and it is rapidly destroyed by alkali hydroxides.

Oxytetracycline diffuses readily through the placenta into the fetal circulation, into the pleural fluid and, under some circumstances, into the cerebrospinal fluid. It appears to be concentrated in the hepatic system and excreted in the bile, so that it appears in the feces, as well as in the urine, in a biologically active form.

Inert ingredients in the formulation are: glucosamine hydrochloride; hard gelatin capsules (which may contain Red 3, Yellow 10 and other inert ingredients); magnesium stearate; sodium lauryl sulfate; starch.

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 antimicrobial spectra, and cross resistance among them is common. Microorganisms may be considered susceptible if the M.I.C. (minimum inhibitory concentration) is not more than 4.0 mcg/ml and intermediate if the M.I.C. is 4.0 to 12.5 mcg/ml.

Susceptibility plate testing: A tetracycline disc may be used to determine microbial susceptibility to drugs in the tetracycline class. If the Kirby-Bauer method of disc susceptibility testing is used, a 30 mcg tetracycline disc should give a zone of at least 19 mm when tested against a tetracycline-susceptible bacterial strain.

Tetracyclines are readily absorbed and are bound to plasma proteins in varying degree. They are concentrated by the liver in the bile, and excreted in the urine and feces at high concentrations and in a biologically active form.

INDICATIONS

Oxytetracycline is indicated in infections caused by the following microorganisms:

- Rickettsiae (Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox and tick fevers),
- *Mycoplasma pneumoniae* (PPL0, 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, penicillin 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.

In acute intestinal amebiasis, the tetracyclines may be a useful adjunct to amebicides.

In severe acne, the tetracyclines may be useful adjunctive therapy.

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.

CONTRAINDICATIONS

This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

WARNINGS

THE USE OF DRUGS OF THE TETRACYCLINE CLASS DURING TOOTH DEVELOPMENT (LAST HALF OF PREGNANCY, INFANCY, AND CHILDHOOD TO THE AGE OF 8 YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GRAY-BROWN). This adverse reaction is more common during long term use of the drugs but has been observed following repeated short term courses. Enamel hypoplasia has also been reported. *TETRACYCLINE DRUGS, THEREFORE, SHOULD NOT BE USED IN THIS AGE GROUP UNLESS OTHER DRUGS ARE NOT LIKELY TO BE EFFECTIVE OR ARE CONTRAINDICATED.*

If renal impairment exists, even usual oral or parenteral doses may lead to excessive systemic accumulation of the drug and possible liver toxicity. Under such conditions, lower than usual total doses are indicated and, if therapy is prolonged, serum level determinations of the drug may be advisable.

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients apt to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs, and treatment should be discontinued at the first evidence of skin erythema.

The antianabolic action of the tetracyclines may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired function, higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia, and acidosis.

Usage in pregnancy: (See above WARNINGS about use during tooth development.)

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy.

Usage in newborns, infants, and children. (See above WARNINGS about use during tooth development.)

All tetracyclines form a stable calcium complex in any bone forming tissue. A decrease in the fibula growth rate has been observed in prematures given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued.

Tetracyclines are present in the milk of lactating women who are taking a drug in this class.

PRECAUTIONS

As with other antibiotic preparations, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, the antibiotic should be discontinued and appropriate therapy instituted.

In venereal diseases when coexistent syphilis is suspected, a dark field examination should be done before treatment is started and the blood serology repeated monthly for at least 4 months.

Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage.

In long term therapy, periodic laboratory evaluation of organ systems, including hematopoietic, renal and hepatic studies should be performed.

All infections due to Group A beta-hemolytic streptococci should be treated for at least 10 days.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracycline in conjunction with penicillin.

ADVERSE REACTIONS

Gastrointestinal: anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, and inflammatory lesions (with monilial overgrowth) in the anogenital region. These reactions have been caused by both the oral and parenteral administration of tetracyclines. Rare instances of esophagitis and esophageal ulcerations have been reported in patients receiving capsule and tablet forms of drugs in the tetracycline class. Most of these patients took medications immediately before going to bed. (See DOSAGE AND ADMINISTRATION.)

Skin: maculopapular and erythematous rashes. Exfoliative dermatitis has been reported but is uncommon. Photosensitivity is discussed above. (See WARNINGS.)

Renal toxicity: Rise in BUN has been reported and is apparently dose related. (See WARNINGS.)

Hypersensitivity reactions: Urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis and exacerbation of systemic lupus erythematosus.

Bulging fontanelles in infants and benign intracranial hypertension in adults have been reported in individuals receiving full therapeutic dosages. These conditions disappeared rapidly when the drug was discontinued.

Blood: Hemolytic anemia, thrombocytopenia, neutropenia and eosinophilia have been reported.

When given over prolonged periods, tetracyclines have been reported to produce brown-black microscopic discoloration of thyroid glands. No abnormalities of thyroid function studies are known to occur.

DOSAGE AND ADMINISTRATION

Adults: Usual daily dose, 1–2 g divided in four equal doses, depending on the severity of the infection.

For children above eight years of age: Usual daily dose, 10–20 mg per pound (25–50 mg/kg) of body weight divided in four equal doses.

Therapy should be continued for at least 24–48 hours after symptoms and fever have subsided.

For treatment of brucellosis, 500 mg oxytetracycline four times daily for 3 weeks should be accompanied by streptomycin, 1 gram intramuscularly twice daily the first week, and once daily the second week.

For treatment of uncomplicated gonorrhea, when penicillin is contraindicated, tetracycline may be used for the treatment of both males and females in the following divided dosage schedule: 1.5 grams initially followed by 0.5 gram q.i.d. for a total of 9.0 grams.

For treatment of syphilis, a total of 30–40 grams in equally divided doses over a period of 10–15 days should be given. Close follow-up, including laboratory tests, is recommended.

Administration of adequate amounts of fluid along with capsule and tablet forms of drugs in the tetracycline class is recommended to wash down the drugs and reduce the risk of esophageal irritation and ulceration. (See ADVERSE REACTIONS.)

Concomitant therapy: Antacids containing aluminum, calcium, or magnesium impair absorption and should not be given to patients taking oral tetracyclines.

Food and some dairy products also interfere with absorption. Oral forms of tetracyclines should be given 1 hour before or 2 hours after meals. Pediatric oral dosage forms should not be given with milk formulas and should be given at least 1 hour prior to feeding.

In patients with renal impairment (See WARNINGS.) Total dosage should be decreased by reduction of recommended individual doses and/or by extending time intervals between doses.

In the treatment of streptococcal infections, a therapeutic dose of oxytetracycline should be administered for at least 10 days.

HOW SUPPLIED

Terramycin (oxytetracycline HCl) Capsules are available as opaque, yellow, hard gelatin capsules which contain oxytetracycline HCl equivalent to 250 mg of oxytetracycline, and glucosamine hydrochloride: bottles of 100 (NDC 0069-0730-66), 500 (NDC 0069-0730-73).

Rx only



69-0755-32-7

March 1987

TERRAMYCIN			
oxytetracycline hydrochloride capsule			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0069-0730
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Oxytetracycline Hydrochloride (UNII: 4U7K4N52ZM) (Oxytetracycline - UNII:X20I9EN955, Oxytetracycline - UNII:X20I9EN955)		250 mg
Inactive Ingredients			
	Ingredient Name		Strength
	glucosamine hydrochloride ()		
	hard gelatin capsules ()		
	Red 3 ()		
	Yellow 10 ()		
	magnesium stearate (UNII: 70097M6I30)		
	sodium lauryl sulfate (UNII: 368GB5141J)		
	starch ()		
Product Characteristics			
Color	YELLOW (Opaque Yellow)	Score	no score
Shape	CAPSULE (Capsule)	Size	22mm
Flavor		Imprint Code	Terramycin;Pfizer;073

Contains				
Coating	false	Symbol	false	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-0730-66	100 in 1 BOTTLE		
2	NDC:0069-0730-73	500 in 1 BOTTLE		

Labeler - Pfizer Labs

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