

Tetrax[®] 500

Tetracycline HCl BP

COMPOSITION

Tetrax[®] 500 capsule: Each capsule contains Tetracycline Hydrochloride BP 500 mg.

INDICATION

Tetracycline is a broad spectrum antibiotic. It is highly effective in the treatment of infections caused by *Borrelia recurrentis* (relapsing fever), *Calymmatobacterium granulomatis* (granuloma inguinale), Chlamydia species (psittacosis, lymphogranuloma venereum, trachoma, inclusion conjunctivitis, *Francisella tularensis* (tularemia), *Haemophilus ducreyi* (chancroid), *Leptospira* (meningitis, jaundice), *Mycoplasma pneumoniae* (non-gonococcal urethritis), *Pseudomonas mallei* (glanders and melioidosis), Rickettsiae (typhus fever, Q-fever, rocky mountain spotted fever), *Vibrio* species (cholera). It is also highly effective alone or in combination with streptomycin in the treatment of infections due to *Brucella* species (brucellosis), plagues and severe acne vulgaris. In acute intestinal amoebiasis, Tetracycline is useful adjunct to amoebicides. Tetracycline is indicated in pneumoniae, tetanus, gas gangrene, dysentery and as second or third line therapy in gonorrhoea and syphilis. Used as an adjunct therapy with bismuth subcitrate and metronidazole for eradicating *H. pylori* in the treatment of gastric and duodenal ulcer.

DOSAGE AND ADMINISTRATION

Usual adult dosage: 250 or 500 mg every 6 hours by mouth preferably 1 hour before or 2 hours after meal. Higher doses up to 3 or 4 gm daily have occasionally been given in resistant infections. *Children over 12 years of age:* 25-50 mg/kg divided in 2 or 4 equal doses. The maximum dose should not exceed the recommended adult dose. *Children below 12 years of age:* Not recommended. *Administration:* Tetracycline should be taken orally, an hour before or two hours after meal and therapy should be continued for up to three days after characteristic symptoms of the infection have subsided. It should be used with caution in the treatment of elderly patients where accumulation is a possibility. *Specific Dosage Recommendation:* *Brucellosis:* 500 mg 6 hourly for 3 weeks. *Chlamydial infections:* 500 mg 6 hourly for at least 2 weeks. *Non-specific urethritis:* 500 mg 6 hourly for 7 days. *Severe acne:* 1 gm/day for 2-3 weeks followed by 1 capsule daily for 3-4 months. *Gonorrhoea:* Initial oral dose of 1.5 gm followed by 500 mg 6 hourly for 4 days, the total dose should be 9 gm. *Syphilis:* 500 mg 6 hourly for 15 days but therapy should be continued for 30 days if the disease has been present for longer than 1 year. *Endocervical infections:* 500 mg 6 hourly for 7 days.

ADVERSE EFFECT

Gastrointestinal disturbances e.g. glossitis, stomatitis, vaginitis or staphylococcal enterocolitis. Photosensitivity and dermatological reactions are rare. Bulging fontanelles in infants and benign intracranial hypertension in adults has been reported. Treatment should be ceased if intracranial pressure raises. Hypersensitivity reactions include purpura, pericarditis, angioneurotic oedema, anaphylaxis, anaphylactoid purpura,

and exacerbation of systemic lupus erythematosus may occur. Haemolytic anaemia, thrombocytopenia, neutropenia and eosinophilia have been reported.

CONTRAINDICATION

A history of hypersensitivity to tetracycline, in cases of overt renal insufficiency, children under 12 years of age and pregnant or lactating women.

PRECAUTIONS

Absorption of tetracycline is impaired by the concomitant administration of milk and by calcium, magnesium, iron and particularly aluminium salts commonly used as antacids. Tetracycline depresses plasma prothrombin activity. Therefore, reduced dosage of concurrent anticoagulants may be required. Lower doses are indicated in cases of renal impairment to avoid excessive systemic accumulation and if therapy is prolonged, serum level determinations are advisable. The concomitant use of oral tetracycline may reduce the efficacy of oral contraceptives and penicillins; an increased incidence of breakthrough bleeding may also be experienced. It should only be used with great caution in conjunction with other potentially hepatotoxic drugs.

DRUG INTERACTION

Tetracycline in combination with methoxy-fluorane may result in nephrotoxicity. Antacids containing calcium, aluminium or magnesium impair the absorption of tetracycline and result in decreased serum level. Tetracycline inhibits the antimicrobial activity of penicillin when used concomitantly.

USE IN PREGNANCY & LACTATION

Tetracycline crosses the placenta, found in foetal tissues and has embryotoxic effect. Therefore, tetracycline should not be used in pregnancy unless considered essential in which case maximum daily dose should be 1 g. Tetracycline has been found in human milk. Permanent tooth discoloration may occur in the developing infant and enamel hypoplasia has been reported.

STORAGE

Store in a cool and dry place. Protect from light. Keep out of reach of children.

HOW SUPPLIED

Tetrax[®] 500 Capsule: Box containing 100 capsules in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH