



**Tetrax<sup>®</sup>**  
Tetracycline  
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### COMPOSITION

Tetrax<sup>®</sup> 500 capsule : Each capsule contains Tetracycline Hydrochloride BP 500 mg.

### PHARMACOLOGY

Tetracycline (Tetrax<sup>®</sup>) has its main mechanism of action on protein synthesis, and an energy-dependent active transport system pumps the drug through the inner cytoplasmic membrane of bacteria. Once inside the bacterial cell, tetracycline (Tetrax<sup>®</sup>) binds specifically to the 30s ribosomes and inhibit bacterial protein synthesis.

Many Gram positive aerobic Cocci are susceptible, but many strains of staphylococci, streptococci and even some pneumococci are resistant to tetracycline (Tetrax<sup>®</sup>). Thus, tetracycline is not the drug of choice in infections due to gram positive aerobes.

Pseudomonas and many Enterobacteriaceae are resistant. Urinary concentrations are adequate for some community - acquired *E. coli* and consequently, tetracycline (Tetrax<sup>®</sup>) is still used in uncomplicated initial UTIs. Tetracycline (Tetrax<sup>®</sup>) is also active against and is the drug of choice for *Brucella* species, *Calymmatobacterium granulomatis*, *Vibrio cholerae* and *V. vulnificus*.

Tetracycline (Tetrax<sup>®</sup>) is also active against anaerobic species of bacteria and since concentrations of the drug are quite high in the gastrointestinal contents, the enteric flora are usually altered by the drug.

Tetracycline HCl is incompletely absorbed from the gastro-intestinal tract, about 60 to 80% of a dose of tetracycline usually being available. It is widely distributed through the body tissues and fluids.

Tetracycline HCl has a half-life of about 12 hours. It is excreted in the urine and in the faeces.

### INDICATION

Tetracycline (Tetrax<sup>®</sup>) is the drug of choice in the following infections :

1. *Rickettsial infection* (Rocky Mountain spotted fever, endemic and scrub typhus fever and human ehrlichiosis).
2. *Mycoplasma pneumoniae infections* in adults. Outbreaks of pneumonia caused by this organism are common in barracks and institutions. Most cases occur in children and young adults. Maculopapular rashes, haemolytic anaemia and meningo-encephalitis occur rarely.

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3. *Chlamydial Infections - Chlamydia psittaci*: This organism is the cause of psittacosis (ornithosis), a systemic illness contracted from infected birds. The pneumonia associated with it may be extensive, and severe systemic upset and death are common. Headache is a prominent early symptom.
4. *Non-gonococcal or non specific urethritis*: Inflammation of the urethra not resulting from gonococcal, chlamydial, or other specific infectious agents.
5. *Lyme disease*
6. *Brucellosis*
7. Miscellaneous infections, including granuloma inguinale, cholera, glanders, relapsing fever and *V. vulnificans*.

Other common uses of tetracycline (Tetrax<sup>®</sup>) include the following :

1. Urinary Tract Infections with susceptible organisms (including the acute urethral syndrome in women).
2. Bronchitis in patients with known underlying chronic lung diseases.
3. Pelvic inflammatory disease and other sexually transmitted diseases (STDs) regimen.
4. Travelers diarrhoea.
5. Acne vulgaris
6. Prostatitis.
7. As an alternative agent in the penicillin allergic patient with syphilis.
8. Anaerobic infections with susceptible organisms.

### **DOSAGE AND ADMINISTRATION**

The usual adult oral dosage of Tetrax<sup>®</sup> is 1-2 g daily given in 2-4 divided doses. The usual oral dosage of Tetrax<sup>®</sup> for children older than 8 years of age is 25-50 mg/kg daily given in 2-4 divided doses. Alternatively some clinicians recommended that children should receive 0.6-1.2 g/m<sup>2</sup> daily.

Tetrax<sup>®</sup> should be taken preferably one hour before or 2 hours after meals.

Some specific indications along with some information on dosage is given in the table :

<b>Infection</b>	<b>Dosage and duration</b>	<b>Remarks</b>
Acne vulgaris	250 mg four times daily or 500 mg 12 hourly for 1 week ; 125-250 mg for several weeks or months	Duration of therapy is determined by individual progress
Acute staphylococcal infections	1-2 g daily in divided doses for 10-14 days	
Acute streptococcal infections	1-2 g daily in divided doses for 10 days	Prolonged therapy is needed to avoid risk of rheumatic fever or glomerulonephritis
Amoebiasis	1 g daily in four divided doses or 500 mg 12 hourly for 7 days	Given in association with amoebicidal agents
Brucellosis	500 mg four times daily plus 1 g streptomycin twice daily for 1 week ; then 500 mg four times daily (no streptomycin) for 1 week	Prolonged therapy is necessary to avoid relapse
Subacute bacterial endocarditis	1-2 g daily in divided doses for 6 weeks	Usually given in combination with a bactericidal agent
Syphilis	Total 30-40 g given in divided doses over 10-15 days	Serology and spinal fluid examination should follow the administration of tetracycline (Tetrax <sup>®</sup> ).

**CONTRAINDICATION AND PRECAUTION**

Tetracycline Hydrochloride is contraindicated in patients hypersensitive to any of the member of tetracycline groups, since cross-sensitivity may occur. Tetracycline Hydrochloride should be avoided in patients with systemic lupus erythematosus. Tetracycline Hydrochloride is considered to be contraindicated in renal impairment, particularly if severe ; if it must be given, doses should be reduced. Care should be taken if Tetracycline Hydrochloride is given to patients with impaired liver function and high doses should be avoided. Potentiality hepatotoxic drugs (including

## Tetrax<sup>®</sup>

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erythromycin, chloramphenicol, isoniazide and sulphonamides) should not be given concomitantly.

### **SIDE EFFECT**

*Teeth and bone:* Tetracycline (Tetrax<sup>®</sup>) can cause depression of bone growth, permanent graybrown discoloration of the teeth and enamel hypoplasia when given during tooth development (i.e. during the later half of pregnancy, during infancy and in childhood).

Hypersensitivity reactions such as anaphylaxis, urticaria and rashes are uncommon. Photosensitivity reactions consisting of a red rash on areas exposed to intense sunlight can occur with tetracycline (Tetrax<sup>®</sup>).

Gastrointestinal effects - Epigastric distress and nausea are commonly seen after oral administration, and these symptoms are somewhat dose related. Vomiting can occur.

Accentuated prerenal azotemia - Tetracycline (Tetrax<sup>®</sup>) appears to aggravate pre-existing renal failure by inhibiting protein synthesis, which increases the azotemia from amino acid metabolism.

Superinfections with oral and anogenital candidiasis are relatively common in patients taking tetracycline (Tetrax<sup>®</sup>).

Esophageal ulcerations - In most cases, the patients were taking the capsules with little or no fluid before going to bed. To help minimize this, oral doses should be given with adequate amounts of fluid.

### **USE IN PREGNANCY, LACTATION AND CHILDREN**

Tetracycline should not be used during pregnancy because of the risk of hypertoxicity in the mother as well as the effects on the developing foetus. Use in pregnancy potentially during breast-feeding and in children up to the age of 8, or some authorise say 12 years, may result in impaired bone growth and permanent discoloration of the child's teeth.

### **HOW SUPPLIED**

Tetrax<sup>®</sup> 500 capsule: Box containing 10 x 10 capsules in strip pack.

