

DOXYCYCLINE CAPSULES

COMPOSITION:

Each capsule contains

Doxycycline hyclate B.P.

equivalent to Anhydrous Doxycycline ... 100mg

THERAPEUTIC CLASSIFICATION

Pharmacotherapeutic group: Tetracyclines antibacterial; ATC code: J01M02

PHARMACODYNAMICS:

Doxycycline is a tetracycline antibiotic with bacteriostatic mode of action. Doxycycline reversibly binds to the 30 S ribosomal subunits and possibly the 50S ribosomal subunit(s), blocking the binding of aminoacyl tRNA to the mRNA and inhibiting bacterial protein synthesis. Doxycycline prevents the normal function of the apicoplast of *Plasmodium falciparum*, a malaria causing organism.

SPECTRUM OF ACTIVITY:

The following microorganisms are susceptible to doxycycline under in vivo conditions:

Streptococcus pneumoniae, *Haemophilus influenzae*, *Klebsiella pneumoniae*,
Mycoplasma pneumoniae, *Klebsiella* species, *Escherichia*

coli, *Streptococcus faecalis*, *Chlamydia trachomatis*, *Ureaplasma*

urealyticum (T-mycoplasma), susceptible strains of staphylococci, gonococci,
Borrelia sp., *Bacillus anthracis*, *Treponema pallidum*

PHARMACOKINETICS:

Absorption is rapid (effective concentrations are attained as from the first hour), and the peak serum concentration (3 µg/ml) occurs after 2 to 4 hours. Almost all of the product is absorbed in the upper part of the digestive tract. Absorption is not modified by administration with meals, and milk has little effect.

In adults, an oral dose of 200 mg results in residual concentration of more than 1 µg/ml after 24 hours, protein binding varying between 82 and 93% (labile binding) intra- and extracellular diffusion is good. With usual dosages, effective concentrations are found in the ovaries, uterine tubes, uterus, placenta, testicles, prostate, bladder, kidneys, lung tissue, skin, muscles, lymph glands, sinus secretions, maxillary sinus, nasal polyps,

tonsils, liver, hepatic and gallbladder bile, gallbladder, stomach, appendix, intestine, omentum, saliva and gingival fluid. Doxycycline is transferred into breast milk.

Only small amounts are diffused into the cerebrospinal fluid.

No significant metabolism occurs and Doxycycline is cleared intact by renal and biliary mechanisms. The antibiotic is concentrated in the bile. About 40% of the administered dose is eliminated in 3 days in active form in the urine and about 32% in the faeces. Urinary concentrations are roughly 10 times higher than plasma concentrations at the same time. In the presence of impaired renal function, urinary elimination decreases, faecal elimination increases and the half-life remains unchanged. The half-life is not affected by haemodialysis.

INDICATIONS:

KODOXY capsules are indicated for the treatment of following Infections due to sensitive Gram-positive and Gram-negative bacteria:

- Chronic prostatitis;
- Sinusitis;
- Syphilis;
- Pelvic inflammatory disease;
- Treatment and prophylaxis of anthrax;
- Malaria treatment and prophylaxis;
- Recurrent aphthous ulceration;
- Adjunct to gingival scaling and root planning for periodontitis;
- Oral herpes simplex;
- Rosacea;
- Acne vulgaris;
- Lyme disease.



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CONTRAINDICATIONS:

- Known hypersensitivity to doxycycline or other tetracyclines, or a history of a previous major allergic response to a tetracycline due to the possibility of cross sensitivity.
- Deposition of tetracyclines in growing bone and teeth (by binding to calcium) causes staining and occasionally dental hypoplasia, and they should not be given to children under 12 years.
- Doxycycline should not be given to patients with acute porphyria.

DOSAGE AND ADMINISTRATION:

- 200mg on first day, then 100mg daily; severe infections (including refractory urinary-tract infections), 200mg daily
- Early syphilis, 100mg twice daily for 14 days; late latent syphilis, 100mg twice daily for 28 days; neurosyphilis, 200mg twice daily for 28 days.
- Uncomplicated genital chlamydia, non-gonococcal urethritis, 100mg twice daily for 7 days (14 days in pelvic inflammatory disease)
- Lyme disease, 100mg twice daily for 10-14 days (28 days in Lyme arthritis)
- Anthrax (treatment or post-exposure prophylaxis), 100mg twice daily; CHILD (only if alternative antibacterial can not be given), 5mg/kg daily in 2 divided doses (max. 200mg daily)

SIDE EFFECTS:

Common: Nasopharyngitis, Sinusitis, Fungal infection, Anxiety, Sinus headache, Hypertension, Diarrhoea, Abdominal pain (upper), Dry mouth, Back pain; Rare: Thrombocytopenia, neutropenia, eosinophilia, Hypersensitivity reactions including anaphylaxis, Anaphylactoid purpura, Benign intracranial hypertension, Pericarditis, hypotension, tachycardia, Nausea, vomiting, anorexia, Hepatotoxicity, Maculopapular and erythematous rashes, skin photosensitivity, urticaria; Very rare: Anogenital candidiasis, Haemolytic anaemia, Brown-black microscopic discolouration of thyroid tissue, Bulging fontanelle in infants, angioneurotic oedema, Glossitis, dysphagia, dyspnoea, enterocolitis, Oesophagitis and oesophageal ulceration, Exfoliative



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dermatitis, angioneurotic oedema, Stevens-Johnson syndrome, Exacerbation of systemic lupus erythematosus.

DRUG-DRUG INTERACTIONS:

- Antibacterials: Plasma concentration of doxycycline reduced by rifampicin-consider increasing dose of doxycycline;
- Antiepileptics: Metabolism of doxycycline accelerated by carbamazepine (reduced effect); metabolism of doxycycline accelerated by phenobarbital and phenytoin (reduced plasma concentration);
- Cytotoxics: Doxycycline increases risk of methotrexate toxicity;
- Iron: Absorption of tetracyclines reduced by oral iron, also absorption of oral iron reduced by tetracyclines;
- Retinoids: Possible increased risk of benign intracranial hypertension when tetracyclines given with retinoids (avoid concomitant use);
- Zinc: Absorption of tetracyclines reduced by zinc, also absorption of zinc reduced by tetracyclines.

Alcohol: Decreases half-life of doxycycline.

WARNINGS&PRECAUTION:

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines, including doxycycline. Patients likely 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 use of antibiotics may occasionally result in over-growth of non-susceptible organisms, including Candida. If a resistant organism appears, the antibiotic should be discontinued and appropriate therapy instituted. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including doxycycline, and has ranged in severity from mild to life-threatening. It is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of antibacterial agents. Bulging fontanelles in infants and benign intracranial hypertension in juveniles and adults have been reported in individuals receiving full therapeutic drugs. These



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conditions disappeared rapidly when the drug was discontinued. Due to a potential for weak neuromuscular blockade, care should be taken in administering tetracyclines to patients with myasthenia gravis. Tetracyclines can cause exacerbation of systemic lupus erythematosus (SLE).

Caution is advised in administering tetracyclines with methoxyflurane.

PREGNANCY AND LACTATION:

Doxycycline should not be administered to pregnant and lactating mothers.

OVERDOSE:

Symptoms of overdose may be from those listed in side effects . Treatment of overdose / Emergency Measures: In case of overdose, Doxycycline must be discontinued. Gastric lavage and supportive treatment initiated, which includes measures to accelerate elimination and symptomatic treatment of adverse reactions. Dialysis does not alter serum half-life and thus would not be of benefit in treating cases of overdosage .

PRESENTATION:

Box of 10 X10's, 10 X1 X 10's, 14 x 2s,

Jar of 1 000's, 500's, 1 00's

STORAGE:

Store below 30°C in a dry place. Protect from light.

PRESCRIPTION ONLY MEDICINE. KEEP OUT OF SIGHT AND REACH OF CHILDREN.