

DOXYCIN® Riyadh Pharma

COMPOSITION:

Capsule: Each capsule contains Doxycycline Hyclate (BP) equivalent to anhydrous Doxycycline 100 mg.

Other ingredients: Colloidal Anhydrous Silica, Maize Starch 1500, Purified Talc and Magnesium Stearate.

CLINICAL PHARMACOLOGY:

Doxycycline is a broad-spectrum (bacteriostatic) antibiotic derived from Oxytetracycline; acts by inhibiting bacterial protein synthesis.

Doxycycline is almost completely absorbed from the gastrointestinal tract. Doxycycline is bound to the extent of about 90% to plasma protein.

INDICATIONS:

DOXYCIN is indicated in the treatment of infections caused by a variety of micro-organisms such as:

Rickettsia, mycoplasma pneumoniae, chlamydia, brucella, spirochaete, gram-positive and negative bacteria.

These infections include:

- Tonsillitis, pharyngitis, sinusitis, otitis media and bronchitis.
- Respiratory infections include: Mycoplasma pneumoniae (eaton agent) and bronchopneumonia.
- Pyelonephritis, cystitis, non-gonococcal urethritis, furunculosis, cellulitis, abscess, impetigo, traumatic and post operative wounds.
- Amebiasis.
- Psittacosis, lymphogranuloma venereum and granuloma inguinale. Some ophthalmic infections such as:
 - trachoma and inclusive conjunctivitis.
- Relapsing fever caused by spirochetes.
- Typhus fever and other rickettsial infections.
- In destructive periodontal disease, exacerbations of chronic bronchitis and leptospirosis.
- Chronic prostatitis, syphilis and pelvic inflammatory disease.
- Treatment and prophylaxis of anthrax, malaria, rosacea and acne vulgaris.

CONTRAINDICATIONS:

Hypersensitivity to tetracyclines. Doxycycline should not be used during pregnancy and lactation.

PRECAUTIONS:

Using tetracyclines during teeth development may cause permanent discolouration of teeth.

Tetracyclines should be used with caution in patients with hepatic impairment or those receiving potentially hepatotoxic drugs.

Photosensitivity reactions by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines.

It is not recommended for children under the age of 12 years.

ADVERSE REACTIONS:

Gastrointestinal disturbances including: Anorexia, nausea, vomiting, diarrhoea, dysphagia and oesophageal irritation.

Hypersensitivity reactions including: Rash, exfoliative dermatitis, urticaria, angioedema, anaphylaxis and pericarditis.

Other side effects including: Anosmia, porphyria and benign intracranial hypertension in adults and bulging fontanelles have been reported in infants.

Unlike many tetracyclines, doxycycline does not appear to accumulate in patients with impaired renal function and aggravation of renal impairment may be less likely.

As with all other antibiotics, overgrowth of non-susceptible organisms may cause candidiasis, glossitis and pseudomembranous colitis.

DRUG INTERACTIONS:

Antacids containing aluminium, calcium and magnesium salts, iron-containing preparations, oral zinc and bismuth preparations may impair the absorption of tetracyclines.

The metabolism of doxycycline may be accelerated

by drugs that induce hepatic enzyme such as: rifampicin, carbamazepine, phenobarbital, phenytoin and primidone.

Doxycycline has lower affinity for binding with calcium than many other tetracyclines. So, its absorption is less likely to be affected by milk or food.

As bacteriostatic antibiotics may suppress the bactericidal action of antibiotics like penicillin, their concomitant use is counterproductive.

If concomitant use of tetracyclines with anticoagulants, a downward adjustment of the anticoagulants dose should be considered because tetracyclines depress plasma prothrombin activity, thus potentiating the effect of anticoagulants.

In some cases of pregnancy or breakthrough bleeding have been attributed to the concurrent use of tetracycline antibiotics with oral contraceptives.

Alcohol may decrease the half-life of Doxycycline.

USE DURING PREGNANCY AND LACTATION:

As with the other tetracyclines, doxycycline should not be used during pregnancy and lactation.

DOSAGE:

The usual dose is 200 mg on the first day, followed by 100 mg daily.

Severe infections (including refractory urinary tract infections) 200 mg daily.

Early syphilis, 100 mg twice daily for 14 days. Latent syphilis, 200 mg twice daily for 28 days.

Uncomplicated gonococcal infections and non-gonococcal urethritis, 100 mg twice daily for 7 days.

Pelvic inflammatory disease, 100 mg twice daily for 14 days.

Anthrax (treatment or post-exposure prophylaxis), 100 mg twice daily.

In treatment of *acne vulgaris*, a dose of 50 mg daily may be adequate.

For relapsing fever and louse-borne typhus, 100 or 200 mg may be given as a single dose.

For prophylaxis of scrub typhus, 200 mg may be taken as a single dose.

Doxycycline is used in some areas for the treatment

of *chloroquine-resistant falciparum malaria* in a dose of 200 mg daily for at least 7 days following treatment with quinine.

Note: Doxycycline capsules should be given with plenty of fluid with patient in an upright position. It may be given with food or milk if gastric irritation occurs.

OVERDOSAGE:

Acute overdosage with antibiotics is rare. In the event of overdose discontinue the medication. Gastric lavage plus appropriate supportive treatment is indicated. Dialysis would not be of benefit in treating cases of overdose.

STORAGE:

Store at room temperature (15 – 25)°C, protect from light.

Do not use the drug after the expiry date printed on the package.

PRESENTATION:

Capsules:

Packs contain (10) capsules of DOXYCIN 100 mg.

Hospital packs of DOXYCIN 100 mg.