

Contimycin

(Doxycycline Hydrochloride)

کوئی مائیسین

COMPOSITION

Each **Contimycin** 100mg capsule contains 100mg of doxycycline hydrochloride (as enteric coated pellets).

MECHANISM OF ACTION

Doxycycline is primarily bacteriostatic and is believed to exert its anti-microbial effect by the inhibition of protein synthesis by binding to the 30S ribosomal subunit.

PHARMACOKINETICS

Doxycycline is virtually completely absorbed after oral administration and bound to plasma proteins. The absorption of doxycycline is not markedly influenced by simultaneous ingestion of food or milk.

It is concentrated by the liver in the bile, and excreted in the urine and feces at high concentration and in a biologically active form. Following a 200 mg dose, normal adult volunteers averaged peak serum levels of 2.6 mcg/mL of doxycycline at 2 hours. Excretion of doxycycline by the kidney is about 40%/72 hours in individuals with normal function. Administration of doxycycline at the usual recommended doses does not lead to excessive accumulation of the antibiotic in patients with renal impairment. Serum half-life of doxycycline is 18-22 hours. Haemodialysis does not alter the serum half-life of doxycycline. The therapeutic antibacterial serum activity will usually persist for 24 hours following recommended dosage.

MICROBIOLOGY

The tetracyclines, including doxycycline, have a similar antimicrobial spectrum of activity against a wide range of gram-positive and gram-negative organisms. Cross-resistance of these organisms to tetracyclines is common.

Gram-Negative Bacteria

Neisseria gonorrhoeae Calymmatobacterium granulomatis Haemophilus influenzae	Haemophilus ducreyi Yersinia pestis Francisella tularensis	Vibrio cholerae Bartonella bacilliformis Brucella species
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Because many strains of the following groups of gram-negative microorganisms have been shown to be resistant to tetracyclines, culture and susceptibility testing are recommended:

Escherichia coli Klebsiella species	Enterobacter aerogenes Shigella species	Acinetobacter species Bacteroides species
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Gram-Positive Bacteria

Because many strains of the following groups of gram-positive microorganisms have been shown to be resistant to tetracycline, culture and susceptibility testing are recommended. 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, tetracycline should not be used for streptococcal disease unless the organism has been demonstrated to be susceptible.

Streptococcus pyogenes Streptococcus pneumoniae	Enterococcus group (Streptococcus faecalis and Streptococcus faecium) Alpha-hemolytic streptococci (viridans group)
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Other Microorganisms

Rickettsiae Chlamydia psittaci Chlamydia trachomatis Mycoplasma pneumoniae Ureaplasma urealyticum	Borrelia recurrentis Treponema pallidum Treponema pertenue Clostridium species Fusobacterium fusiforme	Actinomyces species Bacillus anthracis Propionibacterium acnes Entamoeba species Balantidium coli
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Doxycycline has been found to be active against the asexual erythrocytic forms of Plasmodium falciparum but not against the gametocytes of P. falciparum. The precise mechanism of action of the drug is not known.

INDICATIONS

Doxycycline is indicated for the treatment of the following infections:

- Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox, and tick fevers caused by Rickettsiae.
- Respiratory tract infections caused by Mycoplasma pneumoniae.
- Lymphogranuloma venereum caused by Chlamydia trachomatis.
- Psittacosis (ornithosis) caused by Chlamydia psittaci.
- Trachoma caused by Chlamydia trachomatis, although the infectious agent is not always eliminated as judged by immunofluorescence.
- Inclusion conjunctivitis caused by Chlamydia trachomatis.
- Uncomplicated urethral, endocervical or rectal infections in adults caused by Chlamydia trachomatis.
- Nongonococcal urethritis caused by Ureaplasma urealyticum.
- Relapsing fever due to Borrelia recurrentis.

Doxycycline is also indicated for the treatment of infections caused by the following gram-negative microorganisms:

- Chancroid caused by Haemophilus ducreyi.
- Plague due to Yersinia pestis
- Tularemia due to Francisella tularensis.
- Cholera caused by Vibrio cholerae
- Campylobacter fetus infections caused by Campylobacter fetus
- Brucellosis due to Brucella species (in conjunction with streptomycin).
- Bartonellosis due to Bartonella bacilliformis.
- Granuloma inguinale caused by Calymmatobacterium granulomatis.

Doxycycline 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
- Shigella species.
- Acinetobacter species
- Respiratory tract infections caused by Haemophilus influenzae.
- Respiratory tract and urinary tract infections caused by Klebsiella species.

Doxycycline is indicated for treatment of infections caused by the following gram-positive microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug:

- Upper respiratory infections caused by Streptococcus pneumoniae
- Anthrax due to Bacillus anthracis, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis.

When penicillin is contraindicated, doxycycline is an alternative drug in the treatment of the following infections:

- Uncomplicated gonorrhea caused by Neisseria gonorrhoeae.
- Syphilis caused by Treponema pallidum.
- Yaws caused by Treponema pertenue.
- Listeriosis due to Listeria monocytogenes.
- Vincent's infection caused by Fusobacterium fusiforme.
- Actinomycosis caused by Actinomyces israelii.

- Infections caused by Clostridium species.
- In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides.
- In severe acne, doxycycline may be useful adjunctive therapy.

DOSAGE AND DIRECTIONS FOR USE:

Administration of adequate amounts of fluid along with capsule is recommended to wash down the drugs and reduce the risk of esophageal irritation and ulceration.

Adults: The usual dose of oral doxycycline is 200 mg on the first day of treatment (administered 100 mg every 12 hours) followed by a maintenance dose of 100 mg/day.

In the management of more severe infections (particularly chronic infections of the urinary tract), 100 mg every 12 hours is recommended.

- When used in streptococcal infections, therapy should be continued for 10 days.
- Uncomplicated gonococcal infections in adults (except anorectal infections in men): 100 mg, by mouth twice a day for 7 days. As an alternate single visit dose, administer 300 mg stat followed in one hour by a second 300 mg dose.
- Uncomplicated urethral, endocervical, or rectal infection in adults caused by Chlamydia trachomatis: 100 mg by mouth twice a day for 7 days.
- Nongonococcal urethritis (NGU) caused by C. trachomatis or U. urealyticum: 100 mg by mouth twice a day for 7 days.
- Syphilis - early: Patients who are allergic to penicillin should be treated with doxycycline 100 mg by mouth twice a day for 2 weeks.
- Syphilis of more than one year's duration: Patients who are allergic to penicillin should be treated with doxycycline 100 mg by mouth twice a day for 4 weeks.
- Acute epididymo-orchitis caused by N. gonorrhoeae: 100 mg, by mouth, twice a day for at least 10 days.
- Acute epididymo-orchitis caused by C. trachomatis: 100 mg, by mouth, twice a day for at least 10 days.

SIDE EFFECTS

Gastro-intestinal: anorexia, nausea, vomiting, diarrhoea, glossitis, dysphagia and enterocolitis. **Hypersensitivity reactions:** urticaria, angioneurotic oedema, anaphylaxis, anaphylactoid purpura, serum sickness, pericarditis, and exacerbation of systemic lupus erythematosus.

Maculopapular and erythematous rashes. Exfoliative dermatitis has been reported. Photosensitivity of the skin and nails; onycholysis and nail discoloration may occur.

Increased intracranial pressure has been reported in adults.

Blood: haemolytic anaemia, thrombocytopenia, neutropenia, and eosinophilia may occur.

Increased severity of uraemia and hepatotoxicity in patients with renal disease given high doses. A Jarisch-Herxheimer like reaction has been reported in patients with relapsing fever treated with doxycycline.

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

Vitamin deficiencies may occur.

Secondary fungal overgrowth (Candida albicans) may occur: oral candidiasis, vulvovaginitis and pruritis ani.

Secondary bacterial overgrowth infections may occur: resistant coliform organisms such as Proteus spp. may cause diarrhoea; Pseudomembranous colitis due to Clostridium difficile; super-infection due to resistant staphylococci may cause fulminating enteritis.

INTERACTIONS:

- Concomitant therapy: antacids containing aluminium, calcium or magnesium impair absorption and should not be given to patients taking doxycycline.
- Because doxycycline has been shown to depress plasma prothrombin activity, patients who are on anti-coagulant therapy may require downward adjustment of their anti-coagulant dosage.
- Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving doxycycline in conjunction with penicillin.
- Alcohol, barbiturates, carbamazepine, and phenytoin decrease the half-life of doxycycline.
- When administered together with phenobarbitone and diphenylhydantoin the half life of doxycycline is decreased from 20 hours to 7 hours.
- Doxycycline may diminish the effectiveness of oral contraceptives.

PRECAUTIONS:

- Doxycycline is not indicated for treating commonly occurring infections in children under 12 years of age.
- Constant observation of the patient is essential. If a resistant organism appears, the antibiotic should be discontinued and appropriate therapy instituted.
- When treating gonorrhoea when co-existent syphilis is suspected, proper diagnostic procedures, including dark-field examinations, should be utilized. In all such cases, monthly serological tests should be made for at least four months.
- In long term therapy, periodic laboratory evaluation of organ systems, including haematopoietic, renal, and hepatic studies should be performed.

PREGNANCY:

- Should not be used in pregnant women.
- Doxycycline crosses the placenta and is deposited in foetal bones and teeth
- Pregnant women are particularly susceptible to severe doxycycline-induced liver damage.

NURSING MOTHERS

Doxycycline is present in the milk of lactating women and therefore should be avoided in nursing mothers. The use of doxycycline during tooth development (last half of pregnancy, infancy and childhood to the age of 12 years) may cause permanent discoloration of the teeth (yellow-grey-brown). Enamel hypoplasia has also been reported.

WARNINGS:

Use with care in patients with liver function impairment. Frail or elderly patients are susceptible to the hepatotoxic effects of doxycycline.

Do not use concomitantly with hepatotoxic medicines.

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

Symptoms of Myasthenia gravis may be aggravated.

CONTRAINDICATIONS

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

PRESENTATION

Contimycin 100mg capsule: 10 x 10's / pack.

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Manufactured by:
AsianContinental (Pvt.) Ltd.
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Karachi-Pakistan.

Under license from:
**YUNG SHIN PHARMACEUTICALS
INDUSTRIES CO. LTD.**
Tachia-Taiwan.

خوراک:

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