BioFemme®
Unilab Women's Health Care

Doxycycline hyclate
Doxin®
100 mg Capsule
Antibacterial

Rx

FORMULATION
Each capsule contains:
Doxycycline (as hyclate)
Equivalent to Doxycycline .... 100 mg

PRODUCT DESCRIPTION
Doxycycline hyclate (Doxin) 100 mg: hard gelatin capsule with scarlet opaque cap and body

PHARMACODYNAMICS
Doxycycline is a semi-synthetic, broad-spectrum tetracycline antibiotic. It is primarily bacteriostatic and exerts its antimicrobial effect by inhibiting bacterial protein synthesis. Doxycycline is more lipid soluble than other tetracyclines (except minocycline) and passes directly through the lipid bilayer of the bacterial cell wall. As with other tetracyclines, an energy-dependent active transport system pumps the drug through the inner cytoplasmic membrane. Once inside the bacterial cell wall, doxycycline inhibits protein synthesis by binding specifically to the 30S ribosomes. The drug prevents the binding of amino-acyl-tRNA to the messenger RNA-30S ribosomal subunit. This prevents the addition of amino acids to the growing peptide chain. Doxycycline only inhibits rapidly multiplying organisms.

ANTIMICROBIAL SPECTRUM OF ACTIVITY
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.

Since many strains of Gram-positive and Gram-negative microorganisms have been shown to be resistant to tetracyclines, culture and susceptibility testing are recommended. Up to 44% of strains of *Streptococcus pyogenes* and 74% of *Streptococcus faecalis* have been found resistant to tetracyclines. Therefore, tetracyclines should not be used for streptococcal infections unless the organism has been demonstrated to be susceptible.

Doxycycline has been found to be active against the asexual erythrocytic forms of *Plasmodium falciparum* but not against the gametocytic form of this organism.

PHARMACOKINETICS
Doxycycline is rapidly and almost completely absorbed (90% to 100%) from the GI tract after oral administration. Absorption takes place primarily in the stomach and upper small intestine.

When a 200 mg dose of doxycycline is administered to normal adult subjects, the mean peak serum concentrations (Cmax) of 2.6 mcg/mL are attained at 2 hours, decreasing to 1.45 mcg/mL at 24 hours.

The ingestion of food or milk does not significantly influence the absorption of doxycycline.

Doxycycline readily penetrates into most body tissues, fluid and/or cavities and the volume of distribution has been measured as 0.7 L/kg. Plasma protein binding is variable (25% to 93%).

Excessive accumulation of doxycycline does not appear to occur when usual recommended dosages of the drug are used in patients with normal or impaired renal function. In patients with normal renal function, the serum half-life (t½) of doxycycline is about 15 to 16 hours after a single dose and about 22 hours after multiple doses. In patients with severe renal impairment, the serum t½ is reported to be 18 to 26 hours after a single dose, and 20 to 30 hours after multiple doses. The serum t½ of the drug is not altered in patients undergoing hemodialysis.

In patients with normal renal function, about 20% to 26% of a single oral dose of doxycycline undergoes urinary excretion and 20% to 40% is excreted in feces within 48 hours as active drug. The fraction of doxycycline excreted in urine within 72 hours may decrease to about 1% to 5% in patients with creatinine clearance less than 10 mL/minute. Studies show that doxycycline does not appear to be metabolized but is partially deactivated in the intestines by chelate formation.

INDICATIONS
Indicated in the treatment of infections caused by susceptible strains of the following microorganisms in the conditions listed below:
- Sexually transmitted diseases due to *Chlamydia trachomatis, Ureaplasma urealyticum, Haemophilus ducreyi,* and *Calymmatobacterium granulomatis*
- Urinary tract infections due to *Enterobacter aerogenes, Klebsiella spp.* and *Acinetobacter spp.*
- Respiratory tract infections caused by *Mycoplasma pneumoniae, Haemophilus influenzae, Streptococcus pneumoniae,* and *Klebsiella spp.*
- Gastrointestinal infections due to *Vibrio cholerae,* and *Shigella spp.*
- Systemic infections caused by *Rickettsiae, Borrelia recurrentis, Yersinia pestis, Francisella tularensis, Bartonella bacilliformis,* and *Brucella spp.*
- Infections caused by *Escherichia coli, Enterobacter aerogenes, Shigella spp.* and *Acinetobacter spp.*

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*
- Anthrax due to *Bacillus anthracis*
- Vincent's infection caused by *Fusobacterium fusiforme*
- Actinomycosis caused by *Actinomyces israelii*
- Infections caused by *Clostridium spp.*

- In acute intestinal amebiasis, Doxycycline may be a useful adjunct to amebicides
- In severe acne, Doxycycline may be a useful adjunctive therapy
- In refractory periodontis and periodontal abscess, Doxycycline may be a useful adjunctive therapy.

Prophylaxis
Doxycycline is indicated for the prophylaxis of malaria due to *Plasmodium falciparum* in short-term travelers (<4 months) to areas with Chloroquine and/or pyrimethamine-sulfadoxine resistant strains.

DOSAGE/ADMINISTRATION
Usual adult dose: Orally, 200 mg on the first day of treatment (100 mg every 12 hours) followed by a maintenance dose of 100mg/day once daily preferably with meals to reduce gastric irritation.

- Management of more severe infections (particularly chronic infections of the urinary tract): 100 mg every 12 hours.
- Or, as prescribed by a physician.

Infection/Condition	Dose	Duration of Therapy
Sexually Transmitted Diseases • Chlamydial cervicitis	100 mg every 12 hours	7 days
• Pelvic inflammatory disease in ambulatory patients	Cefoxitin 2 g IM or oral Amoxicillin 3 g or oral Ampicillin 3.5 g or aqueous procaine penicillin G 4.8 million units IM at 2 sites or Ceftriaxone 250 mg IM. Each of these regimens except Ceftriaxone is accompanied by oral Probenecid 1 g, followed by oral Doxycycline 100 mg daily	10 to 14 days

Infection/Condition	Dose	Duration of Therapy
• Early syphilis: For non-pregnant patients allergic to penicillin	100 mg every 12 hours	14 days
• Syphilis of more than one year's duration (patients allergic to penicillin)	100 mg every 12 hours	4 weeks
• Uncomplicated gonococcal infections	100 mg every 12 hours or 300 mg stat followed in one hour by a second 300 mg dose	7 days
• Uncomplicated urethral, endocervical, or rectal infection	100 mg every 12 hours	7 days
• Nongonococcal urethritis	100 mg every 12 hours	7 days
• Acute epididymo-orchitis	100 mg every 12 hours	at least 10 days
Acne vulgaris	100 mg once daily	12 weeks
Traveller's diarrhea	Prophylaxis: 200 mg on the first day of travel (administered as a single dose or as 100 mg every 12 hours) followed by 100 mg daily throughout stay in the area. Data on the prophylactic use of the drug beyond 21 days is unavailable.	
Cholera	Treatment and prophylaxis: 300 mg	Single dose
Leptospirosis	Treatment: 100 mg every 12 hours for 7 days Prophylaxis: 200 mg on a weekly basis throughout stay in the area and 200 mg upon completion of the trip	
Tick and louse-borne relapsing fevers and louse-borne typhus	100 or 200 mg depending on severity	Single dose
Scrub typhus	Prophylaxis: 200 mg	Single dose
Malaria	Treatment of chloroquine-resistant falciparum malaria: 200 mg daily for at least 7 days. Due to the potential severity of the infection, give a rapid acting schizonticide such as quinine in conjuction with Doxycycline. Note that quinine dosage recommendations vary in different areas. Prophylaxis: 100 mg daily. Start prophylaxis 1 to 2 days before travel to malarious areas. Continue daily during travel in these areas and 4 weeks after leaving said areas.	
Dental Infections • Refractory Periodontitis in Adults • Periodontal abscess (if allergic to ß-lactam)	100 mg every 12 hours 100 mg every 12 hours	7 days 7 days

CONTRAINDICATIONS
- Known hypersensitivity to tetracyclines or to any component of the product
- Patients who are pregnant, breastfeeding, infants and children below 8 years old (except for use as an alternative treatment for inhalational anthrax post-exposure)
- Patients with myasthenia gravis
- Patients with systemic lupus erythematosus

WARNINGS AND PRECAUTIONS

- ***Teratogenic Effects:***
  - **As with other tetracyclines, doxycycline can cause fetal harm when administered to a pregnant woman.** Results of animal studies have shown that tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus manifested by retardation of skeletal development. Evidence of embryotoxicity has also been observed in animals treated early in pregnancy. **If any tetracycline is used during pregnancy or if the patient becomes pregnant while taking these drugs, the patient should be informed of the potential hazard to the fetus and tetracycline therapy should be stopped immediately.**
  - **THE USE OF TETRACYCLINES DURING TOOTH DEVELOPMENT (LAST HALF OF PREGNANCY, INFANCY AND CHILDHOOD UP TO THE AGE OF 8 YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GRAY-BROWN).** This adverse effect is more common during long-term use of tetracyclines but has also been observed after repeated short-term courses. Enamel hypoplasia has also been reported. **Tetracyclines, including doxycycline, should therefore not be used in this age group, except for anthrax, including inhalational anthrax (post exposure), unless other drugs are not likely to be effective or are contraindicated.**
  - All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature human infants given tetracycline in oral doses of 25 mg/kg body weight every 6 hours. This reaction was shown to be reversible when the drug was discontinued.

- ***Clostridium difficile-associated diarrhea (CDAD):*** These have been observed with the use of nearly all antibacterial agents, including doxycycline, and may range in severity from mild diarrhea to fatal colitis. It is important to consider this diagnosis in patients who present with diarrhea following administration of antibacterial agents.

- ***Esophageal Injury:*** Esophagitis and esophageal ulceration have rarely been reported in patients taking oral doxycycline. Most of these patients took the medication immediately before going to bed and/or without adequate amount of fluid (see **DOSAGE AND ADMINISTRATION**). If symptoms such as dysphagia and retrosternal pain occur, doxycycline should be discontinued and an esophagic lesion must be investigated.

  Doxycycline should not be prescribed to patients with obstructive esophagic pathology, such as stenosis and achalasia.

- ***Metabolic Effects:*** The anti-anabolic action of tetracyclines may cause an increase in blood urea nitrogen (BUN). This could be a problem in patients with significant renal impairment since higher serum levels of tetracycline may lead to azotemia, hyperphosphatemia, and acidosis. However, studies to date indicate that this does not occur with the use of doxycycline in patients with renal impairment.

- ***Hypersensitivity Reactions:*** These reactions that included, but not limited to anaphylactic shock, angioneurotic edema, tachycardia, erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported with the use of doxycycline. If an allergic reaction occurs, administration of doxycycline should be discontinued and appropriate therapy be instituted.

- ***Photosensitivity:*** Photosensitivity manifested by exaggerated sunburn reaction has been observed in patients receiving tetracyclines, including doxycycline; hence, direct exposure to sunlight or UV radiation should be avoided during treatment. Therapy should be discontinued if photosensitization occurs.

- ***Tissue Hyperpigmentation:*** Tetracyclines may induce hyperpigmentation in many organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity (teeth, mucosa, alveolar bone), sclerae and heart valves. Skin and oral pigmentation has been reported to occur independently of time or amount of drug administration, whereas other pigmentation has been reported to occur upon prolonged administration. Skin pigmentation includes diffuse pigmentation as over sites of scars or injury.

- ***Autoimmune Syndromes:*** Tetracyclines have been associated with the development of autoimmune adverse drug reactions including exacerbation of systemic lupus erythematosus, rash, peripheral edema, arthralgia, myalgia, and serum sickness. In symptomatic patients, liver function tests, ANA, CBC, and other appropriate tests should be performed to evaluate the patients. Use of all tetracyclines should be discontinued immediately.

- ***Pseudotumor cerebri:*** Bulging fontanels in infants and benign intracranial hypertension in adults and adolescents have been reported in individuals receiving tetracyclines. These conditions disappeared rapidly when the drug was discontinued.

- ***Myasthenia gravis:*** Due to a potential for weak neuromuscular blockade, tetracyclines should be used with caution in patients with myasthenia gravis.

- ***Porphyria:*** Rare cases of porphyria have been observed in patients receiving tetracyclines.

- ***Venereal Disease:*** When treating venereal disease, where 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.

Other Precautions

- Doxycyline offers substantial but not complete suppression of the asexual blood stages of *Plasmodium* strains. Doxycycline does not suppress *P. falciparum's* sexual blood stage gametocytes. Individuals completing this prophylactic regimen may still transmit the infection to mosquitoes outside endemic areas.

- Incision and drainage or other surgical procedures should be performed in combination with antibiotic therapy, when indicated.

- Use with caution in patients with hepatic impairment or those receiving potentially hepatotoxic drugs since oral and parenteral tetracyclines, including doxycycline, have been rarely associated with abnormal hepatic function.

- As with any potent drug, periodic assessment of organ system functions, including renal, hepatic, hematopoietic, is recommended during prolonged therapy.

- The use of expired or deteriorated tetracyclines has been associated with the development of a reversible Fanconi-type syndrome (see **UNDESIRABLE EFFECTS**). In addition, use of expired tetracyclines has also caused a lupus erythematosus-like syndrome.

- Prescribing doxycycline in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

- As with other antibacterial drugs, long term or repeated use may result in overgrowth of non-susceptible organisms, including fungi. The use of tetracyclines may increase incidence of vaginal candidiasis. Use with caution in patients with a history of or predisposition to candidiasis overgrowth.

INTERACTIONS WITH OTHER MEDICAMENTS

Drugs	Nature of Interaction
Aminoglycosides, penicillins	Bacteriostatic drugs such as doxycycline may interfere with the bactericidal action of aminoglycosides and penicillins.
Atovaquone	Tetracyclines may decrease plasma concentrations of atovaquone.
Alcohol, barbiturates, carbamazepine, phenytoin, primidone, rifampicin (hepatic enzyme inducers)	Concomitant use of these drugs with doxycycline may decrease the serum t½ of doxycycline. This effect may last for several days after discontinuation of therapy with the interacting agent. An increase in the daily dosage of doxycycline should be considered when administered concomitantly with drugs known to be enzyme inducers.
Bismuth subsalicylate, proton pump inhibitors, antacids containing aluminum, calcium or magnesium and iron and/or zinc containing-preparations	These drugs/preparations may impair doxycycline absorption. It has been reported that concomitant administration of ferrous sulfate (iron) lowered serum concentrations of doxycycline given orally and shortened serum t½ after a single IV injection. In the event that iron and iron-containing products have to be given during doxycycline treatment, the interval between administration of each drug should be wide as possible. Quinapril contains magnesium carbonate and may interfere with the absorption of doxycycline.
Ciclosporin	Doxycycline may increase the plasma concentration of ciclosporin. Concomitant therapy should only be undertaken with appropriate monitoring.
Ergot alkaloids, methysergide, methotrexate	The toxic effects of these drugs may be increased during concomitant use with tetracyclines.
Live vaccines	There are theoretical concerns that anti-infectives with antibacterial activity against Ty21a (the live, attenuated strain of *Salmonella typhi* contained in typhoid vaccine live oral) may interfere with the immunogenicity of the vaccine. Administration of typhoid vaccine live oral containing live, attenuated *Salmonella typhi* of the Ty21a strain should be delayed for at least 24 hours after a dose of doxycycline.
Methoxyflurane	Concomitant therapy has resulted in fatal renal toxicity.
Oral anticoagulants (e.g., Warfarin)	Concomitant therapy may result in prolongation of warfarin's prothrombin time. Reduction of anticoagulant dose may be necessary.
Oral contraceptives	Doxycycline may decrease the efficacy of contraceptives and increase the incidence of breakthrough bleeding. To avoid contraceptive failure, a second form of contraception may be used during concomitant treatment with doxycycline.
Oral retinoids, vitamin A	Rare cases of benign intracranial hypertension (pseudomotor cerebri) have been reported after taking tetracyclines and oral retinoids, such as isotretinoin or etretinate, and vitamin A. Concomitant use should be avoided.
Other drugs	Colestipol, cholestyramine, kaolin-pectin, and sucralfate may decrease tetracycline absorption. Disodium hydrogen edetate, sodium bicarbonate, sodium lactate, acetazolamide, and ethoxzolamide may reduce the plasma levels of doxycycline. Strontium ranelate should not be given with tetracyclines because of possible complex formation. Tetracyclines have been reported to produce increased concentrations of digoxin, halofantrine, lithium, and theophylline (although these interactions are not strongly established).

Interference with Laboratory Tests:

- False negative results in urine glucose determinations using glucose oxidase reagent (e.g., Clinistix®, Tes-Tape®) have been reported.

- False elevations of urinary catecholamine levels may occur due to interference with the fluorescence test.

STATEMENT ON USAGE FOR HIGH RISK GROUPS

Pregnancy: Pregnancy Category D. Studies in animals have shown that tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy (see **WARNINGS AND PRECAUTIONS**).

Lactation: Tetracyclines are excreted in human milk. Since doxycycline may cause serious adverse effects to the infant, the drug should not be used during breastfeeding (see **WARNINGS AND PRECAUTIONS**).

Children: Until the safety of doxycycline has been established, the drug should not be used in children below 8 years old (see **WARNINGS AND PRECAUTIONS**)

Elderly: No special precautions are necessary in the elderly.

Renal Impairment: Studies to date have indicated that the administration of the usual recommended doses of doxycycline will not result in excessive accumulation of the antibiotic in patients with renal impairment.

Hepatic Impairment: Abnormal hepatic function has been reported rarely with the use of both oral and parenteral tetracyclines, including doxycycline.

Effects on Ability to Drive and Use Machines: Since doxycycline may cause visual disturbances such as blurring of vision, patients should be advised to refrain from driving and operating machinery.

UNDESIRABLE EFFECTS

Due to oral doxycycline's virtually complete absorption, side effects of the lower bowel, particularly diarrhea, have been infrequent. The following adverse reactions have been observed in patients on tetracyclines:

Hypersensitivity Reactions/Dermatologic: Anaphylaxis/anaphylactic reaction, anaphylactic shock, anaphylactoid purpura, anaphylactoid reaction, angioedema/angioneurotic edema, asthma, drug fever, dyspnea, erythema multiforme, exfoliative dermatitis, fixed-drug eruptions of the genitalia (including balanitis) and other areas; folliculitis, hypotension, nail discoloration, pericarditis, peripheral edema, photo-onycholysis, photosensitivity/photoallergic reactions (paresthesia, consisting mainly of tingling and burning of the hands, feet, and nose, may be an early indication of photosensitivity), pulmonary infiltrates, rash (erythematous, maculopapular, morbilliform, pustular), serum sickness/serum sickness-like reactions, Stevens-Johnson syndrome, exacerbation of systemic lupus erythematosus, tachycardia, toxic epidermal necrolysis, urticaria

Gastrointestinal: Abdominal discomfort/pain, anorexia, bulky loose stools, black hairy tongue, CDAD/pseudomembranous colitis, diarrhea, dry mouth, dyspepsia, dysphagia, enterocolitis, epigastric burning and distress, esophageal ulcerations, esophagitis, flatulence, glossitis, hoarseness, inflammatory lesions (with monilial overgrowth) in the anogenital region, nausea, pancreatitis, proctitis, pruritus ani, sore throat, stomatitis, teeth discoloration and enamel hypoplasia, vomiting/projectile vomiting; staphylococcal enterocolitis with severe, fulminating diarrhea, dehydration, and circulatory collapse has also been reported rarely

Hepatobiliary: Elevation of alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin values; hepatotoxicity with transient increases in liver function tests, cholestasis, hepatitis (autoimmune, cholestatic), hepatic failure, jaundice

In some cases severe and sometimes fatal hepatotoxicity, associated with fatty changes in the liver and pancreatitis, has occurred in pregnant women (particularly those with pyelonephritis) and in patients with renal impairment or those given high doses. However, hepatotoxicity has also occurred in patients without these predisposing factors but is rarely reported with doxycycline.

Renal: Acute renal failure; increased urinary excretion of nitrogen and increased BUN (apparently dose-related) concentrations, with or without increased serum creatinine concentrations; Fanconi-like syndrome (characterized by nausea, vomiting, lethargy, polydipsia, polyuria, glycosuria, aminoaciduria, phosphaturia, proteinuria, acidosis/lactic acidosis, hypophosphatemia, hypokalemia, and hyperuricemia)

Hematologic: Anemia, aplastic anemia, hemolytic anemia, agranulocytosis, atypical lymphocytes, eosinophilia, hypoprothrombinemia, increase in prothrombin time; leukocytosis, leukopenia, neutropenia, porphyria, thrombocytopenia, thrombocytopenic purpura, toxic granulation of granulocyte

Tetracyclines have also been associated with reductions in serum vitamin B concentrations, including a case of folate deficiency and concomitant megaloblastic anemia.

Musculoskeletal: Arthralgia, myalgia; Increased muscle weakness in patients with myasthenia gravis

Nervous System: Anxiety, bulging fontanels/increased intracranial pressure in infants, benign intracranial hypertension in juveniles and adults (with symptoms such as blurring of vision, scotomata, diplopia, and permanent visual loss,); confusion, depression, flushing, hallucination, headache, hypesthesia, malaise, stupor, somnolence, taste loss, tinnitus

Other Adverse Effects: Bronchospasm, candidiasis (systemic, vaginal), vulvovaginitis; conjunctivitis, papilledema/periorbital edema, myopia, hearing loss; tissue hyperpigmentation/abnormal pigmentation of the skin, conjunctiva, oral mucosa, tongue, and internal organs such as the thyroid (see below) has occurred rarely; permanent discoloration of the cornea has been reported in infants born to mothers given tetracycline in high doses during pregnancy

When given over prolonged periods, tetracyclines have been reported to produce brown-black microscopic discoloration of thyroid tissue. No abnormalities of thyroid function are known to occur.

Jarisch-Herxheimer reaction (consisting of headache, fever, chills, malaise, muscular aches, exacerbation of cutaneous lesions, and leukocytosis) has also been commonly observed in patients with relapsing fever.

Ocular inflammation has occurred after the use of ocular preparations preserved with thiomersal in some patients on tetracyclines.

OVERDOSE AND TREATMENT

Acute overdosage with tetracyclines is extremely rare, and if it occurs, no specific treatment is required. Any gastrointestinal upset should be treated symptomatically. As tetracyclines form insoluble complexes with cations, antacids may be administered in appropriate circumstances.

Dialysis does not alter serum half-life and thus would not be of benefit in treating cases of overdosage.

STORAGE CONDITION

Store at temperatures not exceeding 30°C.
Keep the product out of sight and reach of children.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY

Aluminum Foil Strip pack x 10's (Box of 50's)

CAUTION: Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

DATE OF REVISION OF THE PACKAGE INSERT: April 2018

DATE OF FIRST AUTHORIZATION: May 2007

Manufactured by:
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