Doxycycline Hyclate Capsules (doxycycline hyclate) - Drug Summary

West-ward Pharmaceutical Corp.

Related Drug Information ▼

Vibramycin
(doxycycline calcium, doxycycline hyclate, doxycycline monohydrate)

COMMON BRAND NAMES

Vibra-Tabs, Vibramycin

THERAPEUTIC CLASS

Tetracyclines

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

General Dosing

Initial: 100mg q12h on Day 1
Maint: 100mg/day
More Severe Infections (eg, Chronic UTIs): 100mg q12h

Streptococcal Infections: Continue therapy for 10 days

Gonococcal Infections

Uncomplicated Infections (Except Anorectal Infections in Men):
100mg bid for 7 days or as an alternate single visit dose, 300mg stat followed in 1 hr by a second 300mg dose

Chlamydia trachomatis Infections

Uncomplicated Urethral/Endocervical/Rectal Infections:
100mg bid for 7 days

Nongonococcal Urethritis

Caused by *Chlamydia trachomatis* and *Ureaplasma urealyticum*:
100mg bid for 7 days

Syphilis

Patients Allergic to Penicillin (PCN):

Early Syphilis:
100mg bid for 2 weeks
Syphilis of >1-Year Duration:
100mg bid for 4 weeks

Acute Epididymo-Orchitis

Caused by *Neisseria gonorrhoeae*/*Chlamydia trachomatis*:
100mg bid for at least 10 days

Malaria

Prophylaxis of malaria due to *Plasmodium falciparum* in short-term travelers (<4 months) to areas w/ chloroquine and/or pyrimethamine-sulfadoxine resistant strains

100mg qd; begin 1-2 days before travel and continue daily during travel and for 4 weeks after leaving malarious area

Inhalational Anthrax (Postexposure)

100mg bid for 60 days

Other Indications

Treatment of the Following Infections Caused by Susceptible Microorganisms:
Rocky Mountain spotted fever
Typhus fever and the typhus group
Q fever
Rickettsialpox
Tick fevers
Respiratory tract infections
Lymphogranuloma venereum
Psittacosis (ornithosis)
Trachoma
Inclusion conjunctivitis
Relapsing fever
Chancroid
Plague
Tularemia
Cholera
Campylobacter fetus infections
Brucellosis
Bartonellosis
Granuloma inguinale
UTIs

Treatment of Infections Caused by:
Escherichia coli
Enterobacter aerogenes
Shigella species
Acinetobacter species

Treatment of the Following Infections When PCN is Contraindicated:
Uncomplicated gonorrhea
Yaws
Listeriosis
Vincent's infection
Actinomycosis
Clostridium species infections

Adjunct to amebicides in acute intestinal amebiasis

Adjunctive therapy in severe acne

PEDIATRIC DOSAGE & INDICATIONS

General Dosing

>8 Years:

≤100 lbs:
2mg/lb divided into 2 doses on Day 1 then 1mg/lb as a single dose or divided into 2 doses, on subsequent days
More Severe Infections: May use up to 2mg/lb

>100 lbs:
Initial: 100mg q12h on Day 1
Maint: 100mg/day
More Severe Infections (eg, Chronic UTIs): 100mg q12h

Streptococcal Infections: Continue therapy for 10 days

Malaria

Prophylaxis of malaria due to *Plasmodium falciparum* in short-term travelers (<4 months) to areas w/ chloroquine and/or pyrimethamine-sulfadoxine resistant strains

>8 Years:
2mg/kg qd; begin 1-2 days before travel and continue daily during travel and for 4 weeks after leaving malarious area
Max: 100mg/day

Inhalational Anthrax (Postexposure)

<100 lbs:
1mg/lb (2.2mg/kg) bid for 60 days
≥100 lbs:
100mg bid for 60 days

ADMINISTRATION

Oral route

Administer caps/tabs w/ adequate amount of fluids; if gastric irritation occurs, administer w/ food or milk.

HOW SUPPLIED

Cap (Hyclate): 100mg, (Generic) 50mg; **Oral Sus (Monohydrate):** 25mg/5mL [60mL]; **Syrup (Calcium):** 50mg/5mL [473mL]; **Tab (Hyclate):** 100mg

CONTRAINDICATIONS

Hypersensitivity to any of the tetracyclines.

WARNINGS/PRECAUTIONS

May cause permanent teeth discoloration (yellow-gray-brown) if used during tooth development (last 1/2 of pregnancy to 8 yrs of age); avoid use in these age groups for indications other than anthrax. Enamel hypoplasia reported. *Clostridium difficile*-associated diarrhea (CDAD) reported; may need to d/c if CDAD is suspected or confirmed. Associated w/ intracranial HTN (pseudotumor cerebri); increased risk in women of childbearing age who are overweight or have a history of intracranial HTN. Intracranial pressure can remain elevated for weeks after drug cessation; monitor patients until they stabilize. Possibility of permanent visual loss exists due to intracranial HTN; prompt ophthalmologic evaluation is needed if visual disturbance occurs during treatment. May decrease fibula growth rate in prematures or cause fetal harm during pregnancy. May increase BUN. Photosensitivity may occur; d/c at 1st evidence of skin erythema. May result in bacterial resistance if used in the absence of a proven/suspected bacterial infection or a prophylactic indication; take appropriate measures if superinfection develops. When used for malaria prophylaxis, patients may still transmit the infection to mosquitoes outside endemic areas. False elevations of urinary catecholamines may occur due to interference w/ the fluorescence test. Syrup contains sodium metabisulfite that may cause allergic-type reactions; sulfite sensitivity is seen more frequently in asthmatic patients.

ADVERSE REACTIONS

Anorexia, N/V, diarrhea, dysphagia, maculopapular rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, photosensitivity, increased BUN, hypersensitivity reactions, drug rash w/ eosinophilia and systemic symptoms, hemolytic anemia, thrombocytopenia, neutropenia, eosinophilia.

DRUG INTERACTIONS

Avoid concomitant use w/ isotretinoin; may also cause pseudotumor cerebri. May depress plasma prothrombin activity; may require downward adjustment of anticoagulant dose. May interfere w/ bactericidal action of PCN; avoid concurrent use. Bismuth subsalicylate, iron-containing preparations, and antacids containing aluminum, Ca^{2+}, or Mg^{2+} may impair absorption. Barbiturates, carbamazepine, and phenytoin may decrease $T_{1/2}$. Fatal renal toxicity reported w/ methoxyflurane. May render oral contraceptives less effective.

PREGNANCY AND LACTATION

Pregnancy: Category D.
Lactation: Excreted in human milk; extent of absorption by the breastfed infant is not known. Not for use in nursing.

MECHANISM OF ACTION

Tetracycline derivative; has bacteriostatic activity. Inhibits bacterial protein synthesis by binding to the 30S ribosomal subunit.

PHARMACOKINETICS

Absorption: Complete. (200mg dose) C_{max}=2.6mcg/mL, T_{max}=2 hrs. **Distribution:** Plasma protein binding in varying degrees; found in breast milk. **Elimination:** Urine (40%/72 hrs w/ CrCl 75mL/min, 1-5%/72 hrs w/ CrCl <10mL/min), feces; $T_{1/2}$=18-22 hrs.

ASSESSMENT

Assess for previous hypersensitivity to any tetracyclines, risk of intracranial HTN, pregnancy/nursing status, and possible drug interactions. Document indications for therapy as well as culture and susceptibility testing results. Perform dark-field exam and blood serology when coexistent syphilis is suspected.

MONITORING

Monitor for signs/symptoms of hypersensitivity reactions, photosensitivity, skin erythema, superinfection, CDAD, intracranial HTN, visual disturbance, and other adverse reactions. In venereal disease w/ coexistent syphilis, conduct blood serology monthly for at least 4 months. Perform periodic lab evaluation of organ systems, including hematopoietic, renal, and hepatic studies in long-term therapy.

PATIENT COUNSELING

Apprise pregnant women of the potential hazard to fetus. Inform that the therapy does not guarantee protection against malaria; instruct to use measures that help avoid contact w/ mosquitoes. Instruct to avoid excessive sunlight/UV light and to d/c therapy if phototoxicity occurs; advise to consider use of sunscreen or sunblock. Instruct to drink fluids liberally. Inform that drug absorption is reduced when taking bismuth subsalicylate and when taken w/ food, especially those that contain Ca^{2+}. Inform that drug may increase the incidence of vaginal candidiasis. Instruct to take exactly ud; warn that skipping doses or not completing full course may decrease effectiveness and increase resistance. Advise that therapy should only be used to treat bacterial, not viral, infections. Inform that diarrhea may be experienced and advise to notify physician as soon as possible if watery and bloody stools (w/ or w/o stomach cramps and fever) even as late as ≥2 months after last dose occur.

STORAGE

Vibramycin/Vibra-Tabs: <30°C (86°F). **Generic:** 20-25°C (68-77°F). Protect from light and moisture.

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