

DOXYCYCLINE HYCLATE- doxycycline hyclate capsule

Health Department, Oklahoma State

Doxycycline Hyclate

Doxycycline Hyclate 100 mg Warnings Section

The use of drugs of the tetracycline class during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term use of the drugs, but it has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Use doxycycline in pediatric patients 8 years of age or less only when the potential benefits are expected to outweigh the risks in severe or life-threatening conditions (e.g., anthrax, Rocky Mountain spotted fever), particularly when there are no alternative therapies.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including doxycycline, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following the use of antibacterial drugs. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing use of antibacterial drugs not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

Severe skin reactions, such as exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients receiving doxycycline. (See ADVERSE REACTIONS.) If severe skin reactions occur, doxycycline should be discontinued immediately and appropriate therapy should be instituted.

Intracranial hypertension (IH, pseudotumor cerebri) has been associated with the use of tetracyclines including doxycycline. Clinical manifestations of IH include headache, blurred vision, diplopia, and vision loss; papilledema can be found on fundoscopy. Women of childbearing age who are overweight or have a history of IH are at greater risk for developing tetracycline associated IH. Concomitant use of isotretinoin and doxycycline should be avoided because isotretinoin is also known to cause pseudotumor cerebri.

Although IH typically resolves after discontinuation of treatment, the possibility for permanent visual loss exists. If visual disturbance occurs during treatment, prompt ophthalmologic evaluation is warranted. Since intracranial pressure can remain elevated for weeks after drug cessation patients should be monitored until they stabilize.

All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in prematures given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued.

Results of animal studies indicate 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. If any tetracycline is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

The antianabolic action of the tetracyclines may cause an increase in BUN. Studies to date indicate that this does not occur with the use of doxycycline in patients with impaired renal function.

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Patients apt 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.

Doxycycline Packaging

STI
DOXYCYCLINE-100 MG CAPSULES
28 COUNT



11 20102228 14555555

FILLED BY _____ CK'D BY _____
 RECEIVER BY _____
 START DATE _____
 REORDERED BY _____
 ORDER DATE _____

Packaged by:
 OKLAHOMA STATE HEALTH DEPARTMENT OF HEALTH
 123 Robert S Kerr, Oklahoma City Ok 73102

Doxycycline-100mg
 Lot-770854A
 Expires-11/8/2023
 MFR-Chartwell RX
 NDC-62135-0985-05



Store at controlled room temperature 59-88 degrees Fahrenheit
 Protect from Light and moisture. CAUTION: FEDERAL LAW PROHIBITS
 DISPENSING WITHOUT A PRESCRIPTION



CAUTION: This package NOT CHILD RESISTANT. Store this and all medications out of reach of children.

MTS Medication Technologies®

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ITEM # 300-07

DOXYCYCLINE HYCLATE

doxycycline hyclate capsule

Product Information

Product Type

HUMAN PRESCRIPTION
 DRUG

**Item Code
 (Source)**

NDC:83112-985(NDC:62135-985)

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYCYCLINE HYCLATE (UNII: 19XTS3T51U) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	100 mg

Product Characteristics

Color	blue (Light Blue)	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	2985
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83112-985-28	28 in 1 PACKAGE; Type 0: Not a Combination Product	02/01/2023	
2	NDC:83112-985-42	42 in 1 PACKAGE; Type 0: Not a Combination Product	02/08/2023	
3	NDC:83112-985-56	56 in 1 PACKAGE; Type 0: Not a Combination Product	02/08/2023	
4	NDC:83112-985-05	1 in 1 PACKET; Type 0: Not a Combination Product	02/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062500	02/01/2023	

Labeler - Health Department, Oklahoma State (143673015)

Registrant - Health Department, Oklahoma State (143673015)

Establishment

Name	Address	ID/FEI	Business Operations
Health Department, Oklahoma State		143673015	repack(83112-985)

Revised: 2/2023

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