DOXYCYCLINE CAPSULES USP

INDICATIONS AND USAGE

Doxycycline Capsules USP is indicated for the treatment of the following infections:

- Rocky mountain spotted fever, typhus fever and the typhus group: Q fever, ricketsialpox, and tick fevers caused by Rickettsia species.
- Respiratory 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 Capsules USP is also indicated for the treatment of infections caused by the following gram-negative microorganisms:
  - Chancroid caused by Haemophilus ducreyi.
  - Pus due to Yersinia pestis.
  - Tularaemia caused 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.

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

- Antrax due to Bacillus anthracis, including inhalational anthrax (post-exposure prophylaxis) and 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.
  - Vibriosis caused by Vibrio cholerae.

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

- Ureaplasma urealyticum.
- Mycoplasma pneumoniae.
- Ureaplasma urealyticum.

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

- Antrax due to Bacillus anthracis, including inhalational anthrax (post-exposure prophylaxis) and 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.

Susceptibility Testing Methods

When available, the clinician microbiology laboratory should provide the results of in vitro susceptibility test results for antimicrobial drugs used in resident hospital to the physician as periodic reports that describe the susceptibility profile of nosocomial and community-acquired pathogens. These reports should aid the physician in selecting the most effective antimicrobial.

In acute intestinal abseiosis, doxycycline may be a useful adjunct to amoxicillin.

In severe acne, doxycycline may be useful adjunctive therapy.
it is advisable to avoid giving tetracyclines in conjunction with penicillin.

pharmacokinetics: The oral bioavailability of tetracyclines is limited because they are highly protein-bound in plasma. The tetracyclines are distributed extensively throughout the body, including the adipose tissue, bones, and joints. The drug levels are also high in the lung, nose, and gastrointestinal tract. The concentration of tetracyclines in saliva is approximately the same as that in serum.

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

WARNINGS
THE USE OF DRUGS OF THE TETRACYCLINE CLASS DURING TOOTH DEVELOPMENT (PREGNANCY, INFANCY, AND CHILDHOOD TO THE AGE OF 8 YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GOLD STIPPLING). THE INTRAVENOUS USE OF TETRACYCLINE IS NOT RECOMMENDED INTERMITTENT OR CONTINUOUS ANTHRAX (POST-EXPOSURE): Tetracyclines are effective for the treatment of infections caused by Bacillus anthracis, the causal agent of anthrax. However, they are not effective for the prevention of anthrax. The use of tetracyclines for prophylaxis of anthrax is not recommended.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No studies of carcinogenicity in animals have been done. However, a study of the mutagenic potential of tetracycline in Salmonella typhimurium revealed no mutagenic activity. There is no evidence of teratogenicity in animal studies. Studies to date indicate that this does not occur with the use of doxycycline in pregnant women treated during the first trimester of pregnancy. There are no adequate and well-controlled studies on the use of doxycycline in pregnant women such as that proposed for treatment of anthrax exposure.

Drug/Laboratory Test Interactions: Results of animal studies indicate that tetracyclines cross the placenta, are excreted in breast milk, and alter the normal flora of the colon leading to overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the symptoms of pseudomembranous colitis. Pseudomembranous colitis may be confused with, or coexist with, superinfection due to Clostridium difficile, an organism which may not be sensitive to tetracyclines. Therefore, careful medical history is necessary since C. difficile overgrowth may occur in some individuals taking tetracyclines. Patients apt to be exposed to antibiotics should be monitored for pseudomembranous colitis. Studies to date indicate that this does not occur with the use of doxycycline in pregnant women treated during the first trimester of pregnancy. The use of doxycycline for post-exposure prophylaxis of anthrax should be considered before treatment is started and the blood serology for tetracyclines should be done before treatment is started.

Doxycycline capsules USP 50 mg may have a peach opake cap printed “par 72” in brown ink. Each capsule contains doxycycline monohydrate equivalent to 50 mg of doxycycline. They are supplied as follows:

Bottles of 50
NDC 49884-724-03
Doxycycline Capsules USP 50 mg have a brown opake cap printed “par 72” in black ink.Opake body printed “305” in black ink. Each capsule contains doxycycline monohydrate equivalent to 50 mg of doxycycline. They are supplied as follows:

Bottles of 50
NDC 49884-724-04
Store at 20° to 25°C (68° to 77°F). (See USP Controlled Room Temperature). Protect from light.

DISPENSE IN A TIGHT LIGHT RESISTANT CONTAINER AS DEFINED IN THE USP.