DOXYCYCLINE FOR INJECTION, USP
For Intramuscular Only

DESCRIPTION

Doxycycline for injection is a tetracyclines antibacterial drug derived from doxycline hydrochloride powder, and is available as doxycycline hydrochloride hemiethionate. Chemically, doxycycline is 4-(Dimethylamino)-7-dimethylamino-2,3,4,5,6,7,12,13-octahydro-6-methyl-1,11-dioxo-2-naphthacenecarboxamide nolate hemihydrate. In a one-hour infusion, normal adult volunteers averaged 0.4 mg/mL in a biologically active form.

CLINICAL PHARMACOLOGY

Doxycycline is a bacteriostatic agent that acts as a prodrug by the inhibition of protein synthesis. Doxycycline is a broad-spectrum antibiotic that has been shown to be active against a wide range of gram-positive and gram-negative organisms.

The drugs in the tetracycline class have closely similar antimicrobial spectra and, with rare exceptions, there is little cross-resistance between them. Microorganisms that are susceptible to tetracyclines respond to the drug by reducing or ceasing synthesis of protein. This effect may result from a direct action on bacterial ribosomes and/or interference with the prokaryotic translation apparatus at the site of amino acid entry. The drugs are effective against susceptible bacteria of gram-negative and gram-positive organisms, anaerobes, and some mycoplasma, pneumoniae, legionella, and mycobacteria. The drugs are also effective against some protozoa, such as the giardiasis and trichomoniasis. Many of the drugs in this class are effective against the organisms that cause acne, chlamydial infections, and typhus fever. They are so effective against the bacteria that cause such infections that the use of these drugs for such infections may result in an increased incidence of infections caused by other bacteria, particularly those caused by diphtheria, gonorrhea, and streptococcal infections. The drugs are also effective against the bacteria that cause some urinary-tract infections, some respiratory infections, and some skin and soft-tissue infections. They are also effective against the bacteria that cause some gastrointestinal infections, including those caused by Salmonella and Shigella species.

The tetracyclines are available in the following microbial targets:

- Streptococcus, including group A strep,
- Staphylococcus aureus,
- Haemophilus influenzae,
- Neisseria gonorrhoea,
- Neisseria meningitidis,
- Salmonella,
- Shigella,
- Campylobacter,
- Escherichia coli,
- Proteus mirabilis,
- Pseudomonas aeruginosa,
- Mycobacterium tuberculosis,
- Mycobacterium leprae,
- Mycobacterium marinum.

The tetracyclines are effective against the following microbial targets:

- Mycobacterium avium intracellulare,
- Mycobacterium kansasii,
- Mycobacterium fortuitum,
- Mycobacterium abscessus,
- Mycobacterium chelonae,
- Mycobacterium fortuitum (M. fortuitum like organisms),
- Mycobacterium avium complex (MAC),
- Mycobacterium leprae,
- Mycobacterium marinum,
- Mycobacterium xenopi,
- Mycobacterium tuberculosis,
- Mycobacterium bovis,
- Mycobacterium abscessus,
- Mycobacterium fortuitum,
- Mycobacterium chelonae,
- Mycobacterium leprae,
- Mycobacterium marinum,
- Mycobacterium xenopi,
- Mycobacterium tuberculosis,
- Mycobacterium bovis,
- Mycobacterium abscessus,
- Mycobacterium fortuitum,
- Mycobacterium chelonae,
- Mycobacterium leprae,
- Mycobacterium marinum,
- Mycobacterium xenopi.

The tetracyclines are effective against the following microbial targets:

- Mycobacterium kansasi,
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- Mycobacterium chelonae,
- Mycobacterium leprae,
- Mycobacterium marinum,
- Mycobacterium xenopi,
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There are no adequate and well-controlled studies on the use of doxycycline risk (the quantity and quality of data were assessed as limited) to proposed for treatment of anthrax exposure. An expert review of published information by Tuli and colleagues shows a weak but marginally statistically significant association with total malformations and use of doxycycline anytime during pregnancy.

A small prospective study of 81 pregnancies describes 43 pregnant women with penicillin, it is advisable to avoid giving tetracycline in conjunction with total malformations and use of doxycycline anytime during pregnancy. (See Tuli et al.) This association was not dose-related. (See Polifka et al.)

Anomalies and 32,804 mothers of infants with no congenital anomalies (controls) shows a weak but marginally statistically signiﬁcant association with malformations and use of doxycycline anytime during pregnancy. (See Tuli et al.)

All infections due to group A beta-hemolytic streptococci should be treated. Appropriate antibiotics, including hematopoietic, renal and hepatic studies should be performed.

Nursing Mothers Tetracyclines are excreted in human milk, however, the quantity and quality of data are assessed as limited (with no data available for doxycycline). This will result in the desired concentrations of 0.1 to 1 mg/mL. Concentrations lower than 0.1 mg/mL or higher than 1 mg/mL are not likely to be achieved. Oral therapy must continue for a total of 40 days.

ADVERSE REACTIONS

Skin: Maculopapular and erythematous rashes. Exfoliative dermatitis. Pustules, especially on the face. Photosensitive reactions, with or without pruritus. Photosensitivity may occur in patients receiving tetracycline who are exposed to ultraviolet light. The eruption usually clears upon removal of the drug.

Pharmacokinetics: Doxycycline for Injection, USP is supplied as a sterile lyophilized powder in a single-use vial. When given over prolonged periods, tetracyclines have been reported to cause permanent discoloration of the teeth. Doxycycline is indicated only when oral therapy is not indicated. Oral therapy should be continued for a total of 60 days.

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References