* Fusobacterium fusiforme (Vincent's infection).
* Actinomyces species.

In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides. Doxycycline is indicated in the treatment of trachoma, although the infectious agent is not always eliminated, as judged by immunofluorescence.

CONTRAINDICATIONS

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

WARNINGS

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 has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. TETRACYCLINE DRUGS, THEREFORE, SHOULD 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.

The anti-anabolic 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.

Usage in Pregnancy

Doxycycline for injection has not been studied in pregnant patients.

Usage in Children

The use of doxycycline for injection in children under 8 years is not recommended because safe conditions for its use have not been established.

Tetracyclines are present in the milk of lactating women who are taking a drug in this class.

PRECAUTIONS

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.

Pregnancy: Teratogenic Effects: Pregnancy Category D

There are no adequate and well-controlled studies on the use of doxycycline in pregnant women.

Nursing Mothers

Tetracycline are excreted in human milk, however, the extent of absorption of tetracyclines, including doxycycline, by the breastfed infant is not known. **Information for Patients**

Patients should be counseled that antibacterial drugs including doxycycline should only be used to treat bacterial infections. Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

ADVERSE REACTIONS

Gastrointestinal

Anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis and inflammatory lesions (with monilial overgrowth) in the anogenital region. Hepatotoxicity has been reported rarely. These reactions have been caused by both the oral and parenteral administration of tetracyclines.

Skin

Maculopapular and erythematous rashes. Exfoliative dermatitis has been reported but is uncommon.

Renal Toxicity

Rise in BUN has been reported and is apparently dose related

Hypersensitivity Reactions

Urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis and exacerbation of systemic lupus erythematosus. Bulging fontanels in infants and benign intracranial hypertension in adults have been reported in individuals receiving full therapeutic dosages. These conditions disappeared rapidly when the drug was discontinued.

Blood

Hemolytic anemia, thrombocytopenia, neutropenia and eosinophilia have been reported.

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

DOSAGE & ADMINISTRATION

THE USUAL DOSAGE AND FREQUENCY OF ADMINISTRATION OF DOXYCYCLINE FOR INJECTION (100 TO 200 MG/DAY) DIFFERS FROM THAT OF THE OTHER TETRACYCLINES (1 TO 2 G/DAY). EXCEEDING THE RECOMMENDED DOSAGE MAY RESULT IN AN INCREASED INCIDENCE OF SIDE EFFECTS.

Adults

The usual dosage of doxycycline for injection is 200 mg on the first day of treatment administered in one or two infusions. Subsequent daily dosage is 100 to 200 mg depending upon the severity of infection, with 200 mg administered in one or two infusions.

In the treatment of primary and secondary syphilis, the recommended dosage is 300 mg daily for at least 10 days.

In the treatment of inhalational anthrax (post-exposure) the recommended dose is 100 mg of doxycycline, twice a day. Parenteral therapy is only indicated when oral therapy is not indicated and should not be continued over a prolonged period of time. Oral therapy should be instituted as soon as possible. Therapy must continue for a total of 60 days.

PREPARATION OF SOLUTION:

To prepare a solution containing 10 mg/mL, the contents of the vial should be reconstituted with 10 mL (for the 100 mg/vial container) or 20 mL (for the 200 mg/vial container) of Sterile Water for Injection or any of the 10 intravenous infusion solutions listed below. Each 100 mg of doxycycline for injection (i.e., withdraw entire solution from the 100 mg vial) is further diluted with 100 mL to 1000 mL of the intravenous solutions listed below. Each 200 mg of doxycycline for injection (i.e., withdraw entire solution from the 200 mg vial) is further diluted with 200 mL to 2000mL of the following intravenous solutions:

1. Sodium Chloride Injection, USP
2. 5% Dextrose Injection, USP
3. Ringer's Injection, USP
4. Invert Sugar, 10% in Water
5. Lactated Ringer's Injection, USP
6. Dextrose 5% in Lactated Ringer's
7. Normosol-M in D5-W (Abbott)
8. Normosol-R in D5-W (Abbott)
9. Plasma-Lyte 56 in 5% Dextrose (Baxter)
10. Plasma-Lyte 148 in 5% Dextrose (Baxter)

This will result in desired concentrations of 0.1 to 1 mg/mL. Concentrations lower than 0.1 mg/mL or higher than 1 mg/mL are not recommended.

STORAGE : Store at 20° to 25° C (68° to 77°F) [See USP Controlled Room Temperature].PROTECT FROM LIGHT.

Improper storage may be deteriorate the product.

Retain in carton until time of use.

Presentation : A yellowish crystalline powder filled in clear glass vial

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For the use only of a Registered Medical Practitioner of a Hospital or a Laboratory

℞ Doxycycline For Injection USP

AMERICAN

DOXYCIN 100

Injection

FOR INTRAVENOUS INFUSION USE ONLY

COMPOSITION

Each vial contains :

Doxycycline Hydrochloride (Sterile) I.P

Eq. to Doxycycline 100 mg

DESCRIPTION

Doxycycline for Injection, USP is a sterile, lyophilized powder .Doxycycline hyclate is a broad spectrum antibiotic derived from oxytetracycline. It is meant for INTRAVENOUS use only after reconstitution. Doxycycline hyclate is a yellowish crystalline powder which is chemically designated 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-de monohydrochloride, compound with ethyl alcohol (2:1), monohydrate. It is highly stable in normal human serum.

CLINICAL PHARMACOLOGY

Tetracyclines are readily absorbed and are bound to plasma proteins in varying degree. They are concentrated by the liver in the bile, and excreted in the urine and feces at high concentrations and in a biologically active form.Following a single 100 mg dose administered in a concentration of 0.4 mg/mL in a one-hour infusion, normal adult volunteers averaged a peak of 2.5 mcg/mL, while 200 mg of a concentration of 0.4 mg/mL administered over two hours averaged a peak of 3.6 mcg/mL.**Excretion** of doxycycline by the kidney is about 40 percent/72 hours in individuals with normal function (creatinine clearance about 75 mL/min). This percentage of excretion may fall as low as 1 to 5 percent/72 hours in individuals with severe renal insufficiency (creatinine clearance below 10 mL/min). Studies have shown no significant difference in serum half-life of doxycycline (range 18 to 22 hours) in individuals with normal and severely impaired renal function. Hemodialysis does not alter this serum half-life of doxycycline.

Microbiology

Mechanism of Action

Doxycycline inhibits bacterial protein synthesis by binding to the 30S ribosomal subunit. Doxycycline has bacteriostatic activity against a broad range of Gram-positive and Gram-negative bacteria. Cross resistance with other tetracyclines is common.

Gram-Negative Bacteria

Acinetobacter species ,Bartonella bacilliformis ,Brucella species, Calymmatobacterium granulomatis, Campylobacter fetus, Enterobacter aerogenes, Escherichia coli,Francisella tularensis,Haemophilus ducreyi,Haemophilus influenza,Klebsiella species,Neisseria gonorrhoeae,Shigella species,

Vibrio cholera,Yersinia pestis

Gram-Positive Bacteria

Bacillus anthracis, Streptococcus pneumoniae

Anaerobes

Clostridium species,Fusobacterium fusiforme,Propionibacterium acnes

Other Bacteria

Actinomyces species, Borrelia recurrentis, Chlamydophila psittaci, Chlamydia trachomatis, Mycoplasma pneumonia, Rickettsiae ,Treponema pallidum

Treponema pertenue, Ureaplasma urealyticum

Parasites

Balantidium coli, Entamoeba species, Plasmodium falciparum*

INDICATIONS & USAGE

Doxycycline for Injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Doxycycline for Injection, USP is indicated in infections caused by the following microorganisms:

* Rickettsiae (Rocky Mountain spotted fever, typhus fever, and the typhus group, Q fever, rickettsial pox and tick fevers).
* Mycoplasma pneumoniae (PPLO, Eaton Agent).
* Agents of psittacosis and ornithosis.
* Agents of lymphogranuloma venereum and granuloma inguinale.
* The spirochetal agent of relapsing fever (Borelia recurrentis).

The following gram-negative microorganisms:

* Haemophilus ducreyi (chancroid).
* Pasteurella pestis and Pasteurella tularensis.
* Bartonella bacilliformis.
* Bacteroides species
* Vibrio comma and Vibrio fetus.
* Brucella species (in conjunction with streptomycin).

Because many strains of the following groups of microorganisms have been shown to be resistant to tetracyclines, culture and susceptibility testing are recommended. Doxycycline 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 (formerly Aerobacter aerogenes).
* Shigella species.
* Mima species and Herellea species.
* Haemophilus influenzae (respiratory infections).
* Klebsiella species (respiratory and urinary infections).

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

* Anthrax due to Bacillus anthracis, including inhalational anthrax (post-exposure): to reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis.
* Streptococcus species:

Up to 44% of strains of Streptococcus pyogenes and 74% of Streptococcus pyogenes and 74% of Streptococcus faecalis have been found to be resistant to tetracycline drugs. Therefore, tetracyclines should not be used for streptococcal disease unless the organism has been demonstrated to be sensitive.

For upper respiratory infections due to group A beta-hemolytic streptococci, penicillin is the usual drug of choice, including prophylaxis of rheumatic fever.

* Diplococcus pneumoniae.
* Staphylococcus aureus, respiratory, skin and soft tissue infections. Tetracyclines are not the drugs of choice in the treatment of any type of staphylococcal infections.

When penicillin is contraindicated, doxycycline is and alternative drug in the treatment of infections due to:

* Neisseria gonorrhoeae and N. meningitidis.
* Treponema pallidum and Treponema pertenue (syphilis and yaws).
* Listeria monocytogenes.
* Clostridium species.