Clostridium difficile-associated diarrhea (CDAD) has been reported: Evaluate patients if diarrhea occurs.

3 DOSAGE FORMS AND STRENGTHS

Tetracyclines are excreted in human milk; however, the extent of absorption of doxycycline in the breastfed infant has not been determined. Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on tetracyclines and require oral anticoagulant therapy should receive vitamin K before and after surgery and at intervals during therapy adequate to maintain the prothrombin time within the therapeutic range.

4 CONTRAINDICATIONS

For all pediatric patients weighing less than 45 kg with severe or life-threatening infections (e.g., anthrax, Rocky Mountain spotted fever), the recommended dose is 2.2 mg per kg of body weight administered every 12 hours is recommended.

5.2 Clostridium difficile associated diarrhea

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). (2.2, 5.2)

7.5 Barbiturates and Anti-epileptics

Because many strains of the following groups of microorganisms have been shown to be resistant to tetracyclines, these drug classes should not be used in the treatment of infections caused by them unless there is no alternative.

8.4 Smoking

Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on tetracyclines and require oral anticoagulant therapy should receive vitamin K before and after surgery and at intervals during therapy adequate to maintain the prothrombin time within the therapeutic range.

9.1 Pregnancy

In severe acne, doxycycline may be useful adjunctive therapy. In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides.

11 PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

12 CLINICAL STUDIES

13 NONCLINICAL TOXICOLOGY

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12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Doxycycline is an antibacterial drug (see microbiology). Doxycycline has bacteriostatic activity against a broad range of Gram-negative and Gram-positive bacteria. Cross-resistance between tetracyclines is common.

Doxycycline has fatal consequences if the drug is administered intravenously in a time-critical setting. Tetracyclines are excreted in the bile and not the kidneys; therefore, reductions in renal function will not alter the serum half-life of doxycycline.


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12.2 Pharmacokinetics

Absorption

Doxycycline is well absorbed from the gastrointestinal tract, with peak serum concentrations occurring 1-2 hours after oral administration. Bioavailability is high and decreases with increases in age, weight, and the presence of food.

Distribution

Doxycycline is distributed into most body tissues and fluids, and undergoes some hepatic metabolism. It is highly protein bound and is excreted in the bile. Small amounts are excreted in the urine.

Metabolism

Doxycycline is metabolized in the liver to form several active and inactive metabolites. These metabolites are then excreted in the bile and urine.

Excretion

Doxycycline is primarily excreted in the bile, with only a small amount (5-10%) excreted in the urine. This makes it ineffective in the treatment of urinary tract infections.

12.3 Indications, Usage and Dosage

12.3.1 Indications

Doxycycline is indicated for the treatment of a wide range of bacterial infections, including those caused by Gram-positive and Gram-negative bacteria. It is also used for the prevention of malaria.

12.3.2 Usage

Doxycycline is effective against a wide range of bacteria, including those that are resistant to other antibiotics. It is often used as a second-line treatment for infections that are not responsive to other antibiotics.

12.3.3 Dosage

The dosage of doxycycline should be based on the severity of the infection and the susceptibility of the causative organism. It is typically administered orally in a single daily dose.

12.4 Special Populations

Doxycycline is generally well tolerated in most individuals, but certain populations may require dosage adjustments. This includes children, elderly patients, pregnant women, and those with renal or hepatic impairment.

13. ADVERSE REACTIONS

13.1 General

The most common adverse reactions associated with doxycycline include nausea, vomiting, diarrhea, and headache. Other possible reactions include skin rash, photosensitivity, and superinfections.

13.2 Major Adverse Reactions

Doxycycline can cause anaphylaxis, severe skin reactions, and blood dyscrasias. It can also cause photosensitivity, which can be severe in dark-skinned individuals.

13.3 Special Populations

Doxycycline should be used with caution in children, elderly patients, pregnant women, and those with renal or hepatic impairment.

14. CONTRAINDICATIONS

Doxycycline is contraindicated in individuals with a history of photosensitivity, blood dyscrasias, or a penicillin allergy. It should also be avoided in individuals with known sensitivity to other tetracyclines.

15. INTERACTIONS

Doxycycline can interact with a variety of drugs, including antibiotics, antacids, and oral contraceptives. It is important to inform your healthcare provider of any medications you are taking.

16. OVERDOSAGE

Overdosage of doxycycline can result in severe gastrointestinal upset, nausea, vomiting, and diarrhea. In severe cases, it may require hospitalization and supportive care.

17. CLINICAL STUDIES

Doxycycline has been evaluated in numerous clinical trials, demonstrating its efficacy in the treatment of a wide range of bacterial infections.

17.1 Interaction for Breaking the 135 mg Doxycycline Hydrochloride Delayed-Release Tablet

The tablet is marked with separation lines (arrow mark) and may be broken at those lines to provide any of the following:

- 135 mg treatment (the entire tablet is taken)
- 100 mg treatment (two third of the tablet is taken)
- 60 mg treatment (two third of the tablet is not taken)
- 30 mg treatment (one third of the tablet is taken)
- 15 mg treatment (one third of the tablet is not taken)
- 10 mg treatment (one third of the tablet is not taken)
- 5 mg treatment (two thirds of the tablet is taken with thimble and index finger)

17.2 Interaction for Breaking the 130 mg Doxycycline Hydrochloride Delayed-Release Tablet

The tablet is marked with separation lines (arrow mark) and may be broken at those lines to provide any of the following:

- 130 mg treatment (the entire tablet is taken)
- 100 mg treatment (two thirds of the tablet is taken with thimble and index finger)
- 60 mg treatment (one third of the tablet is taken)
- 30 mg treatment (two thirds of the tablet is not taken)
- 15 mg treatment (one third of the tablet is not taken)
- 10 mg treatment (one third of the tablet is not taken)
- 5 mg treatment (two thirds of the tablet is taken with thimble and index finger)

17.3 Interaction for Breaking the 100 mg Doxycycline Hydrochloride Delayed-Release Tablet

The tablet is marked with separation lines (arrow mark) and may be broken at those lines to provide any of the following:

- 100 mg treatment (the entire tablet is taken)
- 60 mg treatment (two thirds of the tablet is taken with thimble and index finger)
- 30 mg treatment (one third of the tablet is taken)
- 15 mg treatment (one third of the tablet is not taken)
- 10 mg treatment (one third of the tablet is not taken)
- 5 mg treatment (two thirds of the tablet is taken with thimble and index finger)