SUSPENSION USP
DOXYCYCLINE
Teva

DOXYCYCLINE for Oral Suspension USP
Rx only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of doxycycline and other antibacterial drugs, doxycycline monohydrate should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION
Doxycycline hyclate is a water-soluble, highly purified, synthetic derivative of oxytetracycline, a tetracyclinc. The chemical designation is 4-Dimethylamino-1,4,4a,5,5a,6,10,11-octahydro-3,5,10,12,12a-
pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide. Doxycycline monohydrate has the following structural formula:

\[
\text{Chemical formula:} \quad \text{C}_22\text{H}_{25}\text{NO}_{12}\text{O}_4\text{H}_2O
\]

ME.M. 423.4G

Doxycycline is a light-yellow crystalline powder. Doxycycline monohydrate is very slightly soluble in water, readily soluble in anhydrous alcohol, and sparingly soluble in ethylene dichloride. Doxycycline will not degrade into an anhydrous form.

Doxycycline for Oral Suspension USP contains the following inactive ingredients: confectioner’s sugar, D&C red #27 aluminum Lake, D&C yellow #10 lake, D&C yellow #6 lake, FD&C blue #1, FD&C blue #2, maltodextrin, monoglycerides, purified water, sodium benzoate (0.02%), sorbic acid (0.01%), sodium propionate, and titanium dioxide.

When reconstituted as directed each 5-mL oral suspension contains doxycycline monohydrate equivalent to 25 mg of doxycycline.

CLINICAL PHARMACOLOGY
Tetracyclines are readily absorbed and bound to plasma proteins in varying degree. They are concentrated in the liver, in the spleen, and in the kidneys. Tetracyclines are distributed into the tissues and fluids in which high antimicrobial levels are attained. A report from the laboratory giving results of the standard single-disk susceptibility test with a 15 mcg tetracycline-class disk or the 30 mcg tetracycline-class disk should be interpreted according to the criteria presented in “Organisms, Organism Zones.”

INFORMATION FOR PATIENTS
Keep this information about reconstituted doxycycline monohydrate for Oral Suspension USP at room temperature (68°F to 77°F) and protect from moisture.

DOSAGE AND ADMINISTRATION

INDICATIONS AND USAGE
Doxycycline hyclate is indicated for the treatment of the following infections:

- Acute uncomplicated urinary tract infections caused by Escherichia coli or other susceptible microorganisms.
- Acute bacterial exacerbation of chronic bronchitis caused by Haemophilus influenzae or other susceptible microorganisms.
- Acute pharyngitis and acute tonsillitis caused by Streptococcus pyogenes or other susceptible microorganisms.
- Acute maxillary sinusitis caused by Streptococcus pneumoniae or other susceptible microorganisms.
- Acute bacterial skin and skin structure infections caused by streptococci or staphylococci.
- Infection due to other susceptible bacterial species.

CONTRAINDICATIONS
Doxycycline for Oral Suspension USP is contraindicated in patients who have shown hypersensitivity to any of the tetracyclines.

WARNINGS
The use of drugs of the tetracycline class during the first trimester of pregnancy may cause tooth staining and permanent inhibition of tooth and bone growth in the developing teeth and skeleton of the fetus. These adverse effects may be prevented by using alternative antibacterial drugs with a lower potential for causing these problems. Tetracyclines, like other antibacterial drugs, may suppress the immune response to infection by a variety of microorganisms. This effect may persist for months after therapy has been completed. Patients should be warned about the potential for this serious adverse reaction and use of these drugs should be avoided during pregnancy and lactation.

PRECAUTIONS
Doxycycline for Oral Suspension USP should not be used in patients with known hypersensitivity to any tetracycline. Doxycycline for Oral Suspension USP is contraindicated in patients who have shown hypersensitivity to any of the tetracyclines.

ADVERSE REACTIONS
Doxycycline for Oral Suspension USP should not be used in patients with known hypersensitivity to any tetracycline. Doxycycline for Oral Suspension USP is contraindicated in patients who have shown hypersensitivity to any of the tetracyclines.

See PRECAUTIONS and CONTRAINDICATIONS sections for further information.

SIDE EFFECTS
Severe, unusual, and sometimes fatal) reactions have occurred with antibacterial drugs. These reactions include: jaundice, hepatic failure, and fever. Doxycycline for Oral Suspension USP should be used with caution in patients with a history of severe skin reactions to antibacterial drugs.

Other side effects reported with doxycycline are:

- Gastrointestinal effects: nausea, vomiting, diarrhea, and abdominal pain.
- Hypersensitivity reactions: rash, pruritus, urticaria, angioedema, anaphylaxis, and photosensitivity reactions.
- Central nervous system effects: dizziness, headache, drowsiness, tinnitus, and vertigo.
- Hematological effects: anemia, leukopenia, thrombocytopenia, and hemolytic anemia.
-Skin reactions: contact dermatitis, psoriasis, and exfoliative dermatitis.
- Other: malaise, fever, chills, and asthenia.

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- Skin reactions: contact dermatitis, psoriasis, and exfoliative dermatitis.
- Other: malaise, fever, chills, and asthenia.
PRECAUTIONS

Gastrointestinal disturbances, one of the side effects of this drug may result in unconsciousness or respiratory insufficiency, if used in conjunction with other drugs or after exposure to high doses. In this case, the patient must be given immediate medical care. The administration of doxycycline in such cases is contraindicated.

Bulging fontanels in infants and benign intracranial hypertension should be treated with other therapies. Only in emergencies of true intracranial hypertension has been reported to result in fatal cerebral edema. Caution use of doxycycline may result in hypertensive effects.

Children: Due to the potential for premature closure of the epiphyses, treatment with tetracyclines in growing Skeletal should be avoided. The maximum dosage of doxycycline base, oxytetracycline HCl, and tetracycline HCl were administered in the evaluation of the incidence of hyperparathyroidism in rats, mice, and dogs. In rats and mice, doxycycline has been shown to decrease the production of proestrous factors and to cause a slight depression of the hypothalamus. In dogs, doxycycline has not been shown to cause problems in the hypothalamic function.

Drug Interactions

Tetracyclines have been shown to inhibit the absorption of tetracyclines, including doxycycline, by the breast-fed infant. Nursing mothers should be advised:

All patients taking doxycycline should be advised:

Patients should be told that although it is common to feel better early in the course of therapy, treatment with antibiotics, patients can develop watery and loose stools. In addition, antibiotic therapy may decrease the effectiveness of the immediate treatment of infections caused by these strains.

Drug interactions should be avoided. Use of this drug may result in hypertensive effects.

ADVERSE REACTIONS

Skin:

Other: bulging fontanels in infants and intracranial hypertension (in adults) should be treated with other therapies. Only in emergencies of true intracranial hypertension should be treated with other therapies.

The drug is contraindicated in the treatment of infections caused by these strains.

The drug should be used with caution in patients with a history of photosensitivity.

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