**DOXYCYCLINE CAPSULES USP**

**Rx only**

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

Doxycycline Capsules USP is a broad-spectrum antibacterial synthetically derived from oxytetracycline. Doxycycline 100 mg, 200 mg and 300 mg capsules contain Oxytetracycline monohydrate equivalent to 100 mg, 200 mg and 300 mg of doxycycline for oral administration. Inactive ingredients include colloidal aluminum dioxide, cellulose, croscarmelose sodium, FD&C Blue #1 and 4, FD&C Red #40, Lactose, magnesium stearate, Microcrystalline cellulose, and sodium starch glycolate.

**CLINICAL PHARMACOLOGY**

Tetracyclines are readily absorbed and are bound to proteins in varying degrees. They are distributed into the liver in the bile and excreted in the urine and feces. High concentrations in active form are found in the lymphatics and draining lymph nodes. Doxycycline will not degrade into an enterococcal form.

**Microorganisms**

Because of its mechanism of action and lack of cross-resistance with other antibiotics, doxycycline is effective against a broad range of Gram-positive and Gram-negative microorganisms. Doxycycline is active against many strains of bacteria, including certain strains that are resistant to penicillin, ampicillin, or other beta-lactams. In addition, doxycycline is active against certain anaerobic bacteria.

**Microorganisms**

**Doxycycline Capsules USP** are effective only to tested performed by broth microdilution method using a 30 mcg tetracycline-class disk and using a Mueller-Hinton agar base with 5% defibrinated sheep blood.2,3

**Microorganisms**

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>MIC (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escherichia coli</td>
<td>≤0.5</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>4-8</td>
</tr>
<tr>
<td>Streptococcus pneumoniae</td>
<td>≤8</td>
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</tbody>
</table>

**MIC Range**

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

- Rocky Mountain spotted fever, typhus fever, and the typhus group.
- Q fever, rickettsialpox, and tick-borne fever caused by Rickettsia.
- Tick-borne rickettsial infections caused by螟蛉onella trachomatis, although the infectious agent is not always eliminated as judged by immunofluorescence.
- Lymphogranuloma venereum caused by Chlamydia trachomatis.
- Peltophlebitis (mimicked) caused by Chlamydia psittaci.
- Unspecified urethritis, endocervical or rectal infections in adults caused by Chlamydia trachomatis.
- Nongonococcal urethritis caused by Ureaplasma urealyticum.
- Pelvic fever due to Eubacterium.

**MIC Range**

Doxycycline Captives USP is also indicated for the treatment of infections caused by the following gram-negative microorganisms:

- Chlamydia (caused by Chlamydia urealyticum)
- Plague due to Yersinia pestis (formerly Pasteurella pestis)
- Tularemia due to Francisella tularensis (formerly Pasteurella tularensis)
- Chlamydia psittaci by Chlamydia psittaci.
- Brucella abortus by Brucella species (in conjunction with streptomycin).
Doxycycline Capsule USP is indicated for treatment of infections caused by the following gram-negative microorganisms, when bacteriologic tests indicate appropriate susceptibility to the drug:

- Escherichia coli
- Enterobacter aerogenes (formerly Aerobacter aerogenes)
- Shigella species
- Acinetobacter species (formerly Mima species and Herellea species)

Respiratory tract infections caused by Hemophilus influenzae.

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

- Lower respiratory infections caused by Streptococcus pneumoniae (formerly Diplococcus pneumoniae).
- Skin and skin structure infections caused by Staphylococcus aureus.
- Anthrax due to Bacillus anthracis, including inhalational anthrax (post-exposure); to prevent progression or disease following exposure to Bacillus anthracis.

Doxycycline Capsule USP is NOT the drug of choice in the treatment of any type of staphylococcal infection.

When used concomitantly, doxycycline is an alternative drug in the treatment of the following infections:

- Lower respiratory infections caused by Haemophilus parainfluenzae
- Vincent's infection caused by Fusobacterium nucleatum
- Acne rosacea caused by Propionibacterium acnes.

In acute intestinal amebiasis, doxycycline may be a useful adjunct to amebicides.

In severe acne, doxycycline may be used as an alternative therapy.

CONTRAINdications

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

WARNINGS

THE USE OF DRUGS IN THE TETRACYCLINE CLASS DURING TOOTH DEVELOPMENT (1ST TO 8TH YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GRAVELY DISCOLORATION) WITH AN INCREASED INCIDENCE OF PROGRESSIVE PEROLOGY AS THE DRUG IS CONTINUED. THIS DIScoloration has been observed following repeated short-course. Ectopic calcification has also been noted. Ectopic calcification is highly unlikely to occur when the drug is given over a longer period of time (months to years). The incidence is less than 0.1% of the cases exposed. The drug should not be used in pregnant women. In postmenopausal women, the drug should be used only if clearly needed. In children, the drug should not be used in patients with renal disease. In patients with renal disease, the drug should be discontinued at the first evidence of skin erythema.

PRECAUTIONS

As with other antibiotic preparations, use of this drug may result in overgrowth of non- susceptible organisms, including fungi. If superinfection occurs, the antibiotic should be discontinued and appropriate therapy instituted.

Builing bullae in infants and benign intranuclear haemorrhage in adults have been reported in individuals receiving tetracyclines. These conditions disappeared when the drug was discontinued.

Oral or topical corticosteroids should be used in conjunction with tetracycline therapy in patients with pernicious anemia or other conditions associated with vitamin B12 deficiency.

Bear in mind that tetracycline can cause teeth to yellow or brown. In the young, this can result in permanent staining of the teeth.

Doxycycline Capsule USP 100 mg has a peach opaque cap printed “pr 72b” in black ink. Peach opaque body printed “300” in black ink. Each capsule contains doxycycline monohydrate equivalent to 150 mg of doxycycline. They are supplied as follows:

- Bottles of 10
- NDC 4884-330-03

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/NF.

ANIMAL PHARMACOLOGY AND ANIMAL TOXICOLOGY

Hypersensitivity of the monkey has been produced by members of the tetracycline class in the following species: in rats by oxytetracyline, doxycycline, tetracycline PO, and minocycline HCl in mice by minocycline, doxycycline, tetracycline PO, and minocycline in minks by minocycline, doxycycline PO, minocycline, doxycycline base, oxytetracycline HCl and tetracycline HCl were gastrointestinally fed in rats and dogs (minocycline), in chickens (chlorotetracycline) rats and mice (oxytetracycline). Adverse gastrointestinal hyperperistalsis has been observed in guinea pigs and rats treated with tetracycline.


Manufactured by:

Par Pharmaceutical Companies, Inc.
Spring Valley, NY 10977

Revision: 02/12
OS725-01-13

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