MINOCYCLINE HYDROCHLORIDE TABLETS, USP

INDICATIONS AND USAGE

The tetracyclines are primarily bacteriostatic and are thought to exert their action by inhibiting the bacterial protein synthesis, blocking the peptidyl transfer RNA from entering the ribosome.

MIC (mcg/mL)

For testing Neisseria gonorrhoeae,

Zone Diameter (mm)

Tetracycline       Minocycline

≥ 23 ≥ 18

Intermediate (I)

≥ 12 ≤ 14

Intermediate (I)

< 10 ≤ 14

Susceptible (S)

< 5  ≤ 10

Susceptible (S)

< 3 ≤ 5

Susceptible (S)

< 1 ≤ 3

Susceptible (S)

MIC (mcg/mL)

MICs for Neisseria gonorrhoeae were slightly decreased (12%) and delayed by 1.09 hours when administered with food.

CLINICAL PHARMACOLOGY

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Pregnancy Category D

Skipping doses or not taking all your Minocycline Hydrochloride may:

Arthralgia, arthritis, bone discoloration, myalgia, joint stiffness,
Hyperbilirubinemia, hepatic cholestasis, increases in liver
Interstitial nephritis. Elevations in BUN have been reported and
Symptoms include light-headedness, dizziness,
Minocycline Hydrochloride and penicillins
Microcrystalline Cellulose NF, Lactose Anhydrous NF,
Increased risk of ergotism when ergot alkaloids or their derivatives are given
Patients should be counseled that antibacterial drugs including minocycline
Although it is common to feel better early in the course of therapy, the med-
and will not be treatable by minocycline hydrochloride tablets or other antibac-
and mucous membranes has been reported.
Gastrointestinal
younger subjects. In general, dose selection for an elderly patient should be
Geriatric Use
Pediatric Use
Nursing Mothers
The effect of tetracyclines on labor and delivery is unknown.

Drug Interactions

Minocycline hydrochloride tablets have been shown to decrease plasma prothrombin activ-
ity. Patients who are on anticoagulant therapy may require dosing require-
ment adjustment of their anticoagulant dosage.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable

in order to avoid giving tetracycline-class drugs in conjunction with penicillin.
Absorption of tetracyclines is impaired by antacids containing calcium, calci-
mag, or magnesium. Reduce the amount of tetracycline-class drug ingested if
The concurrent use of tetracycline and methylenephthalein has been reported to
result in a yellow-to-brown discoloration of the urine.

Concurrent use of tetracyline with oral contraceptives may reduce oral contra-

Increased risk of erythema when erythromycin or their derivatives are given
with tetracyclines.

Drug/Laboratory Test Interactions

Carcinogenesis, Mutagenesis, Impairment of Fertility

Administration of tetracyclines in long-term hemoncytology studies in rats
has resulted in evidence of carcinogenic activity in studies with related antibiot-
cumulative, recent, and divided dose schedules of tetracycline, minocycline,
and chloramphenicol. Microsomal enzyme studies of minocycline have not been conducted, positive results in vitro
among oral tetracyclines, such as chloramphenicol, minocycline, doxycycline,
and tetracycline, have been demonstrated in vitro
Administration/Pharmacology

Exceeding the recommended dosage may result in an

Minocycline hydrochloride tablets may be taken with or without food (see CLIN-
Ingestion of adequate amounts of fluids along with capsule and tablet forms of
If you ingest too many tablets, this reaction can be avoided simply by drinking
For Pediatric Patients Above 8 Years of Age

The usual dosage of minocycline hydrochloride tablets is 200 mg initially followed by 2 mg/kg every 12 hours, not
to exceed the usual adult dosage.

The usual dosage of minocycline hydrochloride tablets is 200 mg initially kilogram for an adult or child weighing 50 kg or more

In the treatment of uncomplicated gonococcal men in, 100 mg every 12 hours for a minimum

For the treatment of syphilis, the usual dosage of minocycline hydrochloride tablets may be administered over a period of 10 to 15 days. Close follow-up,

In the treatment of rickets, osteomalacia, or osteoporosis, the recommended dosage is
10 mg every 2 to 3 days.

Maculobacterium minimum infections: Although optimal doses have not been established, 100 mg every 12 hours for 5 to 8 weeks has been used success-
Compliance, oral, or parenteral infections in adults caused by aerobic bacteria producing beta-

Ingestion of adequate amounts of fluids along with capsule and tablet forms of

The pharmacodynamics of Minocycline hydrochloride in patients with renal impairment (CLcr >40mL/min) have not been fully characterized. Current data are insufficient to
due to anti-anabolic effect of tetracyclines. See WARNINGS.

HOW SUPPLIED

Minocycline hydrochloride tablets are sugarless afm coated tablets containing minocycline hydrochloride equivalent to 50 mg, 75 mg and 100 mg.

The 100 mg tablet are white, uncoated, modified capsule, coated tablet containing
NDC 49884-511-91

The 50 mg tablets are white, uncoated, modified capsule, coated tablet containing
NDC 49884-510-11

The 75 mg tablet are white, uncoated, modified capsule, coated tablet containing
NDC 49884-510-13

Store at 25° to 30° C (77° to 86° F) [See USP Controlled Room Temperature]

Protect from light, moisture and excessive heat.

Your doctor or pharmacist can give you information about Minocycline

Recall about your medical condition or treatment.

REFERENCES


12. Children’s Hospital, Boston, MA. In vitro antibiotic susceptibility testing. Available at: http://www.chb.org/v10/chb94/al/191-34.html


