Minocin Pellet-Filled Capsules (minocycline hydrochloride) - Drug Summary

Onset Dermatologics, LLC

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Minocin
(minocycline)

THERAPEUTIC CLASS

Tetracyclines

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

General Dosing

Cap:
Initial: 200mg
Maint: 100mg q12h
Alternate Dosing:
Initial: If more frequent doses are preferred, give two or four 50mg caps
Maint: One 50mg cap qid

Inj:
Initial: 200mg
Maint: 100mg q12h
Max: 400mg/24 hrs

Parenteral therapy is indicated only when oral therapy is not adequate or tolerated; institute oral therapy as soon as possible

Gonococcal Infections

Uncomplicated Infections Other Than Urethritis and Anorectal Infections in Men:
Cap:
Initial: 200mg
Maint: 100mg q12h for a minimum of 4 days, w/ post-therapy cultures w/in 2-3 days

Urethral Infections

Cap:
Uncomplicated Gonococcal Urethritis in Men When Penicillin is Contraindicated:
100mg q12h for 5 days

Uncomplicated Infections Caused by *Chlamydia trachomatis*/*Ureaplasma urealyticum*:
100mg q12h for at least 7 days

Syphilis

When Penicillin is Contraindicated:
Cap:
Initial: 200mg
Maint: 100mg q12h over a period of 10-15 days

Meningococcal Carrier State

Cap:
Usual: 100mg q12h for 5 days

Mycobacterial Infections

***Mycobacterium marinum* Infections:**
Cap:
Optimal doses have not been established; 100mg q12h for 6-8 weeks have been successfully used

Endocervical Infections

Uncomplicated Infections Caused by *Chlamydia trachomatis*/*Ureaplasma urealyticum*:
Cap:
100mg q12h for at least 7 days

Rectal Infections

Uncomplicated Infections Caused by *Chlamydia trachomatis*/*Ureaplasma urealyticum*:
Cap:
100mg q12h for at least 7 days

Other Indications

Treatment of the Following Infections Caused by Susceptible Microorganisms:
Rocky Mountain spotted fever
Typhus fever and the typhus group
Q fever
Rickettsialpox
Tick fevers
Respiratory tract infections
Lymphogranuloma venereum
Psittacosis (ornithosis)
Trachoma
Inclusion conjunctivitis
Relapsing fever
Chancroid (cap)
Plague
Tularemia
Cholera
Campylobacter fetus infections
Brucellosis (in conjunction w/ streptomycin)
Bartonellosis
Granuloma inguinale
UTIs
Skin and skin structure infections

Treatment of Infections Caused by Susceptible Strains:
Escherichia coli
Enterobacter aerogenes
Shigella species
Acinetobacter species

Treatment of the following infections caused by susceptible microorganisms When Penicillin is Contraindicated:
Infections in women caused by *Neisseria gonorrhoeae* (cap)
Meningitis (inj)
Yaws
Listeriosis
Anthrax
Vincent's infection
Actinomycosis
Clostridium species infection

Adjunctive therapy in acute intestinal amebiasis and severe acne

PEDIATRIC DOSAGE & INDICATIONS

General Dosing

>8 Years:
Cap/Inj:
Initial: 4mg/kg
Maint: 2mg/kg q12h, not to exceed usual adult dose

DOSING CONSIDERATIONS

Renal Impairment
CrCl <80mL/min:
Max Dose: 200mg/24 hrs

Elderly
Start at lower end of dosing range

ADMINISTRATION

Oral/IV routes

Cap
Take w/ or w/o food
Swallow whole w/ adequate amounts of fluids

IV
Administer as an IV infusion over 60 min
Avoid rapid administration

Reconstitution:
Reconstitute w/ 5mL of sterile water for inj and immediately further dilute in 100-1000mL w/ NaCl inj, dextrose inj, or dextrose and NaCl inj, or in 250-1000mL lactated Ringer's inj, but not w/ other sol containing Ca^{2+}

Incompatibilities:
Do not add additives or other medications or infuse simultaneously through the same IV line including Y-connectors; if the same IV line is used for sequential infusion of additional medications, the line should be flushed before and after infusion of minocycline w/ NaCl inj, dextrose inj, dextrose and NaCl inj, or lactated Ringer's inj

HOW SUPPLIED

Cap: 50mg, 75mg, 100mg; Inj: 100mg

WARNINGS/PRECAUTIONS

May cause fetal harm. May cause permanent discoloration of the teeth (yellow-gray-brown) if used during tooth development (last 1/2 of pregnancy, infancy, and childhood to 8 yrs of age); do not use during tooth development. Enamel hypoplasia reported. May decrease fibula growth rate in premature infants. Drug rash w/ eosinophilia and systemic symptoms (DRESS), including fatal cases, reported; d/c immediately if this syndrome is recognized. May cause an increase in BUN; w/ significant impaired renal function, high levels of therapy may lead to azotemia, hyperphosphatemia, and acidosis. Photosensitivity manifested by an exaggerated sunburn reaction reported. CNS side effects reported; may impair mental/physical abilities. *Clostridium difficile*-associated diarrhea (CDAD) reported; may need to d/c if CDAD is suspected or confirmed. Associated w/ intracranial HTN (pseudotumor cerebri); increased risk in women of childbearing age who are overweight or have a history of intracranial HTN. If visual disturbance occurs, prompt ophthalmologic evaluation is warranted. Intracranial pressure can remain elevated for weeks after drug cessation; monitor patients until they stabilize. May result in bacterial resistance if used in the absence of proven or suspected bacterial infection, or a prophylactic indication; take appropriate measures if superinfection develops. Hepatotoxicity reported. False elevations of urinary catecholamine levels may occur due to interference w/ the fluorescence test. (Cap) Not indicated for the treatment of meningococcal infection; reserve prophylactic use for situations in which the risk of meningococcal meningitis is high. (Inj) Contains magnesium sulfate heptahydrate; caution in patients w/ heart block or myocardial damage.

ADVERSE REACTIONS

Neutropenia, agranulocytosis, lupus-like syndrome, serum sickness-like syndrome, fever, N/V, diarrhea, increased liver enzymes, thyroid cancer, anaphylaxis, exfoliative dermatitis, Stevens-Johnson syndrome, skin and mucous membrane pigmentation, headache.

DRUG INTERACTIONS

Caution w/ other hepatotoxic drugs. Depresses plasma prothrombin activity; may require downward adjustment of anticoagulant dosage. May interfere w/ bactericidal action of PCN; avoid concurrent use. Fatal renal toxicity reported w/ methoxyflurane. May decrease effectiveness of oral contraceptives. Avoid isotretinoin shortly before, during, and after therapy; each drug alone is associated w/ pseudotumor cerebri. Increased risk of ergotism w/ ergot alkaloids or their derivatives. (Cap) Impaired absorption w/ antacids containing aluminum, Ca^{2+}, or Mg^{2+}, and iron-containing preparations. (Inj) Potentially serious drug interactions may occur when IV magnesium sulfate heptahydrate is given concomitantly w/ CNS depressants, neuromuscular blocking agents, and cardiac glycosides.

PREGNANCY AND LACTATION

Category D, not for use in nursing.

MECHANISM OF ACTION

Tetracycline; primarily bacteriostatic and thought to exert antimicrobial effect by inhibition of protein synthesis.

PHARMACOKINETICS

Absorption: (Cap) C_{max}=3.5mcg/mL; T_{max}=2.1 hrs. **Distribution:** Crosses placenta; found in breast milk. **Elimination:** (Cap) Urine, feces; $T_{1/2}$=15.5 hrs. (IV) $T_{1/2}$=15-23 hrs.

ASSESSMENT

Assess for hypersensitivity to drug, risk for intracranial HTN, hepatic/renal impairment, pregnancy/nursing status, and possible drug interactions. Perform culture and susceptibility tests. (Cap) In venereal disease when coexistent syphilis is suspected, perform a dark-field examination and blood serology. (Inj) Assess for heart block or myocardial damage. Perform serologic test for syphilis (if treating gonorrhea). Obtain baseline serum Mg^{2+} levels in patients w/ renal impairment.

MONITORING

Monitor for DRESS, photosensitivity, CNS effects, CDAD, intracranial HTN, superinfection, and other adverse reactions. Perform periodic lab evaluations of organ systems, including hematopoietic, renal, and hepatic studies. (Cap) In venereal disease when coexistent syphilis is suspected, repeat blood serology monthly for at least 4 months. (Inj) In patients w/ gonorrhea, perform a follow-up serologic test for syphilis after 3 months. Monitor serum Mg^{2+} levels in patients w/ renal impairment. Closely monitor patients w/ heart block or myocardial damage.

PATIENT COUNSELING

Apprise of the potential hazard to fetus if used during pregnancy; instruct to notify physician if pregnant. Counsel that therapy should only be used to treat bacterial, not viral, infections. Instruct to take exactly ud even if the patient feels better early in the course of therapy. Inform that skipping doses or not completing the full course of therapy may decrease effectiveness of treatment and increase bacterial resistance. Inform that diarrhea may be experienced; instruct to immediately contact physician if watery and bloody stools (w/ or w/o stomach cramps and fever) occur, even as late as ≥2 months after the last dose. Advise that photosensitivity manifested by an exaggerated sunburn reaction may occur; instruct to d/c treatment at the 1st evidence of skin erythema. Caution patients who experience CNS symptoms about driving vehicles or using hazardous machinery while on therapy. Inform that drug may render oral contraceptives less effective.

STORAGE

20-25°C (68-77°F). (Cap) Protect from light, moisture, and excessive heat. (Inj) Once diluted into an IV bag, store either at room temperature for up to 4 hrs or refrigerated at 2-8°C (36-46°F) for up to 24 hrs; discard any unused portions after that period.

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