Guilan University
of Medical Sciences

Drug Information Leaflet (3)

"Ciprofloxacin"

Amiralmomenin Hospital
Pharmacology Department

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NOVEMBER
2018

Introduction

Ciprofloxacin is one of the Fluoroquinolone antibiotics. Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including: tendinitis and tendon rupture, peripheral neuropathy, and CNS effects. Discontinue ciprofloxacin immediately and avoid the use of fluoroquinolones in patients who experience any of these serious adverse reactions. Because fluoroquinolones have been associated with serious adverse reactions, reserve ciprofloxacin for use in patients who have no alternative treatment options for the following indications: acute exacerbation of chronic bronchitis, acute sinusitis, and acute uncomplicated cystitis. The antimicrobial activity of ciprofloxacin is shown in table 1-1.

Indication

- Anthrax
- Bite wound infection, prophylaxis or treatment (animal and human bites) (alternative agent) (off-label use)
- Cat scratch disease, lymphadenitis (nondisseminated) (alternative agent) (off-label use)
- Chancroid (alternative agent) (off-label use)
- Cholera (Vibrio cholerae) (alternative agent) (off-label use)
- Endocarditis due to HACEK organisms (alternative agent) (off-label use)
- Granuloma inguinale (donovanosis) (alternative agent) (off-label use)
- Hematopoietic cell transplant (HCT) antibacterial prophylaxis (off-label use)
- Intra-abdominal infections (including perforated appendix, appendiceal abscess, acute diverticulitis, acute cholecystitis), community-acquired
- Meningitis, bacterial (community-acquired or health care-associated) (alternative agent) (off-label use)
- Meningococcal meningitis prophylaxis (off-label use):
- Neutropenia (chemotherapy-induced), antibacterial prophylaxis in high-risk patients anticipated to have an ANC ≤100 cells/mm3 for >7 days (off-label use)
- Neutropenic fever, low-risk cancer patients (empiric therapy) (off-label use)
- Osteomyelitis
- Peritoneal dialysis catheter, exit-site or tunnel infection (off-label use)
- Peritonitis, spontaneous bacterial (prevention), high-risk patients (eg, hospitalized patients with Child-Pugh class B or C cirrhosis and active GI bleeding) (alternative agent) (off-label use)

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- Pneumonia, community-acquired, as a component of empiric therapy for P. aeruginosa coverage (hospitalized patient) (off-label use)
- Pneumonia, hospital-acquired (nosocomial) (including ventilator-associated), as a component of empiric therapy for P. aeruginosa coverage
- Prostatitis (acute bacterial) (off-label use)
- Prostatitis (chronic bacterial)
- Prosthetic joint infection (off-label use)
- Salmonella species, GI infection
- Septic arthritis (without prosthetic material) (alternative agent)
- Shigella GI infection (off-label dose)
- Surgical (preoperative) prophylaxis (alternative agent) (off-label use)
- Surgical site infection (intestinal or GU tract, perineum, or axilla) (off-label use)
- Traveler's diarrhea, uncomplicated (empiric therapy) (off-label dose)
- Tularemia (Francisella tularensis) (off-label use)
- Urinary tract infection (UTI)

Dosing: Adult

Note: Extended-release tablets and immediate-release formulations are not interchangeable. Unless otherwise specified, oral dosing reflects the use of immediate-release formulations.

Anthrax: Note:

- Inhalational exposure (postexposure prophylaxis): Oral: 500 mg/ BID for 60 days /IV: 400 mg/ BID for 60 days
- Cutaneous (without systemic involvement) (empiric therapy) (off-label use): Oral: 500 mg/ BID for 7 to 10 days after naturally acquired infection; 60 days following biological weapon-related event
- Note: Patients with cutaneous lesions of the head or neck or extensive edema should be treated for systemic involvement.
- Systemic (meningitis excluded) (off-label use): IV: 400 mg/TID in combination with other appropriate agents for 2 weeks until clinically stable.
- Meningitis (off-label use): IV: 400 mg/ TID in combination with other appropriate agents for 2 to 3 weeks until clinically stable.

Note: Following the course of IV combination therapy for systemic anthrax infection (including meningitis), patients exposed to aerosolized spores require oral monotherapy to complete a total antimicrobial course of 60 days.

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Bite wound infection, prophylaxis or treatment (animal and human bites) (alternative agent) (off-label use)

- Note: Use in combination with an appropriate agent for anaerobes.
- Oral: 500 to 750 mg/BID
- IV: 400 mg/ BID
- Duration of therapy: 3 to 5 days for prophylaxis; duration of treatment for established infection varies based on patient-specific factors

Cat scratch disease, lymphadenitis (nondisseminated) (alternative agent) (off-label use)

- Oral: 500 mg/ BID

- **Chancroid (alternative agent) (off-label use)**
- Oral: 500 mg/ BID for 3 days

Cholera (Vibrio cholerae) (alternative agent) (off-label use)

- Oral: 1 g as a single dose

Diabetic foot infections (off-label use)

- Note: When used as empiric therapy, must be used in combination with other appropriate agents.
- Moderate: Oral: 500 mg /BID (750 mg/ BID if Pseudomonas aeruginosa is suspected)
- Moderate to severe: IV: 400 mg /BID (400 mg/ TID if P. aeruginosa is suspected)

Endocarditis due to HACEK organisms (alternative agent) (off-label use)

- Oral: 500 mg/ BID for 4 weeks (native valve) or 6 weeks (prosthetic valve)
- IV: 400 mg / BID for 4 weeks (native valve) or 6 weeks (prosthetic valve)

Granuloma inguinale (donovanosis) (alternative agent) (off-label use

- Oral: 750 mg/ BID for at least 3 weeks (and until lesions have healed)
- Note: If symptoms do not improve within the first few days of therapy, another agent (eg, aminoglycoside) can be added.

Hematopoietic cell transplant (HCT) antibacterial prophylaxis (off-label use)

- Oral: 500 mg/BID; begin at the time of stem cell infusion and continue until recovery of neutropenia or until initiation of empiric antibiotic therapy for febrile neutropenia

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Intra-abdominal infections (including perforated appendix, appendiceal abscess, acute diverticulitis, acute cholecystitis), community-acquired

- Note: For empiric therapy, use in combination with metronidazole.
- Oral: 500 mg/ BID
- IV: 400 mg/ BID
- Duration of therapy: Duration depends on whether source of infection has been controlled. Guidelines recommend treatment duration of 4 to 7 days.

Meningitis, bacterial (community-acquired or health care-associated) (alternative agent) (off-label use)

- IV: 400 mg every 8 to 12 hours; for empiric therapy, must be used in combination with other appropriate agents.

Meningococcal meningitis prophylaxis (off-label use)

- Oral: 500 mg as a single dose

Neutropenia (chemotherapy-induced), antibacterial prophylaxis in high-risk patients anticipated to have an ANC ≤100 cells/mm for >7 days (off-label use):

- Oral: 500 mg/ BID ; some clinicians will provide antibacterial prophylaxis if ANC is anticipated to be <500 cells/mm for >7 days.

Neutropenic fever, low-risk cancer patients (empiric therapy) (off-label use)

- Oral: 750 mg/ BID until afebrile and neutropenia has resolved; use in combination with amoxicillin and clavulanate.
- Note: Avoid in patients who have received fluoroquinolone prophylaxis

Osteomyelitis

- Oral:
- Treatment: 500 to 750 mg/ BID ; when treating P. aeruginosa, 750 mg/ BID
- Chronic suppression in presence of retained infected orthopedic hardware: 250 to 500 mg/ BID
- IV: 400 mg/ BID; when treating P. aeruginosa, 400 mg/ TID

Peritoneal dialysis catheter, exit-site or tunnel infection (off-label use)

- Oral: 250 mg/ BID
- When used for empiric therapy, must be used in combination with other appropriate agents

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- **Peritonitis, spontaneous bacterial** (prevention), high-risk patients (eg, hospitalized patients with Child-Pugh class B or C cirrhosis and active GI bleeding) (alternative agent) (off-label use)
- Oral: 500 mg/ BID ; total duration of therapy is 7 days (parenteral and oral) IV (alternative for non-functional GI tract): 400 mg BID ; total duration of therapy is 7 days (parenteral and oral)
- Long-term secondary SBP prophylaxis: Oral: 500 mg once daily

Plague (Yersinia pestis) infection (alternative agent)

- Note: Consult public health officials for event-specific recommendations:
- Postexposure prophylaxis: Oral: 500 mg/ BID for 7 days
- Treatment: Note: Duration of therapy is 10 to 14 days
- Oral: 500 to 750 mg/ BID
- IV: 400 mg every 8 to 12 hours

Pneumonia, community-acquired, as a component of empiric therapy for P. aeruginosa coverage (hospitalized patient) (off-label use)

- Note: For empiric therapy, must be used in combination with other appropriate agents.
- Oral: 750 mg /BID for 5 to 7 days
- IV: 400 mg / TID for 5 to 7 days

Pneumonia, hospital-acquired (nosocomial) (including ventilator-associated), as a component of empiric therapy for P. aeruginosa coverage

- Note: For empiric therapy, must be used in combination with other appropriate agents.
- Oral: 750 mg /BID for 7 days
- IV: 400 mg/ TID for 7 days

Prostatitis (acute bacterial) (off-label use)

- Note: When used for empiric therapy, must be used in combination with other appropriate agents.
- Oral: 500 mg BID
- IV: 400 mg/ BID
- Duration of therapy: 6 weeks

Prostatitis (chronic bacterial)

- Oral: 500 mg/ BID for ≥6 weeks
- IV: 400 mg /BID for ≥6 weeks

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Prosthetic joint infection (off-label use)
Note: Alternative agent for certain pathogens.
Treatment:
Gram-negative bacilli
Oral: 750 mg/ BID
IV: 400 mg/ BID
Staphylococci: Oral: 750 mg / BID.
Note: For use in combination with rifampin, following pathogen-specific IV therapy in patients undergoing 1-stage exchanges or debridement with retention of prosthesis.
Chronic suppressive therapy (for P. aeruginosa): Oral: 250 to 500 mg/ BID

Salmonella species, GI infection
Nontyphoidal, severe (nonbacteremic) illness or any severity in patients at high risk for invasive disease: Oral: 500 mg/ BID for 3 to 7 days.
Note: Immunosuppressed patients require longer duration of treatment (eg, weeks to months)

Typhoid fever (Salmonella typhi and paratyphi): Severe disease or mild to moderate infection in patients at high risk of developing invasive disease
Oral: 500 mg /BID for 7 to 10 days
IV: 400 mg/ BID for 7 to 10 days

Septic arthritis (without prosthetic material) (alternative agent)
Note: Use in combination with an aminoglycoside for initial treatment if P. aeruginosa suspected
Oral: 500 to 750 mg/ BID
IV: 400 mg/ BID

Shigella GI infection (off-label dose)
Oral: 500 mg/ BID or 750 mg once daily for 3 days; the duration should be extended to 5 to 7 days for those with S. dysenteriae type 1 infection or HIV coinfection

Surgical (preoperative) prophylaxis (alternative agent) (off-label use)
Note: Use in combination with other appropriate agents may be warranted (procedure-dependent).
IV: 400 mg within 120 minutes prior to surgical

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Traveler's diarrhea, uncomplicated (empiric therapy) (off-label dose)

Oral: 500 mg/ BID for 3 days or 750 mg as a single dose.

If symptoms not resolved after 24 hours following single-dose therapy, continue with 500 mg BID for 2 more days. The 3-day therapy course is recommended in patients with fever or dysentery; enteric infection due to Shigella dysenteriae is an exception as a 5-day treatment duration appears to be superior to single-dose or 3-day regimens. Adjunctive loperamide may be considered in patients receiving antibiotic therapy, in particular for immunocompetent adults with acute watery diarrhea.

Note: Fluoroquinolone resistance is increasing; azithromycin may be preferred, particularly in regions such as Southeast Asia or India with a high prevalence of Campylobacter

Tularemia (Francisella tularensis) (off-label use)

Note: Consult public health officials for eventspecific recommendations.

Mild disease or postexposure prophylaxis: Oral: 500 or 750 mg / BID

Urinary tract infection (UTI):

Cystitis, acute uncomplicated

Note: Use for uncomplicated urinary tract infections is discouraged due to significant E. coli resistance and safety issues; reserve for clinical situations where other appropriate treatment options cannot be used.

Oral, immediate release: 250 mg/ BID for 3 days

Oral, extended release: 500 mg every 24 hours for 3 days

UTI, complicated (including pyelonephritis)

Note: If the prevalence of fluoroquinolone resistance is >10%, an initial dose of a long-acting parenteral antimicrobial, such as ceftriaxone, or a consolidated 24-hour dose of an aminoglycoside is recommended for outpatients.

Oral, immediate release: 500 mg/ BID for 5 to 7 days

Oral, extended release: 1,000 mg every 24 hours for 5 to 7 days

IV (inpatient): 400 mg/ BID for a total of 5 to 7 days

Products

- Ciprofloxacin is available as a concentrate in 20- and 40-mL vials.
- Each milliliter of solution contains 10 mg of ciprofloxacin, with lactic acid as a solubilizer and hydrochloric acid to adjust the pH.

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Administration

- Ciprofloxacin is administered at a concentration of 1 to 2 mg/mL by IV infusion into a large vein slowly over 60 minutes.
- When given intermittently through a Y-site, the primary solution should be discontinued temporarily.

Stability & Compatibility Information

- Ciprofloxacin is a clear, colorless to slightly yellow solution.
- It should be stored between 5 and 25 °C (bags) or 30 °C (vials) and protected from light, temperatures over 40 °C, and freezing.
- pH Effects: Ciprofloxacin in aqueous solution is stated to be stable for up to 14 days at room temperature in the pH range of 1.5 to 7.5 (please see table 1-2).
- Light Effects: Ciprofloxacin undergoes slow degradation when exposed to natural daylight.

Infusion Solutions

- Ciprofloxacin in concentrations between 0.5 and 2 mg/mL in dextrose 5%, dextrose 10%, dextrose 5% inbsodium chloride 0.225%, dextrose 5% in sodium chloride 0.45%, Ringer's injection, lactated, or sodium chloride 0.9% is stable for 14 days at room temperature or under refrigeration .

solution	compatible	incompatible
Dextrose 5% & 10%	*	
Ringer's injection, lactated	*	
Ringer's injection	*	
Sodium chloride 0.9%	*	
Dextrose 5% in sodium chloride 0.9%	*	

References

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