INFECTION CONTROL AND
HOSPITAL EPIDEMIOLOGY
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**Special Update:**

# Hospital Epidemiology: New Challenges and Controversies

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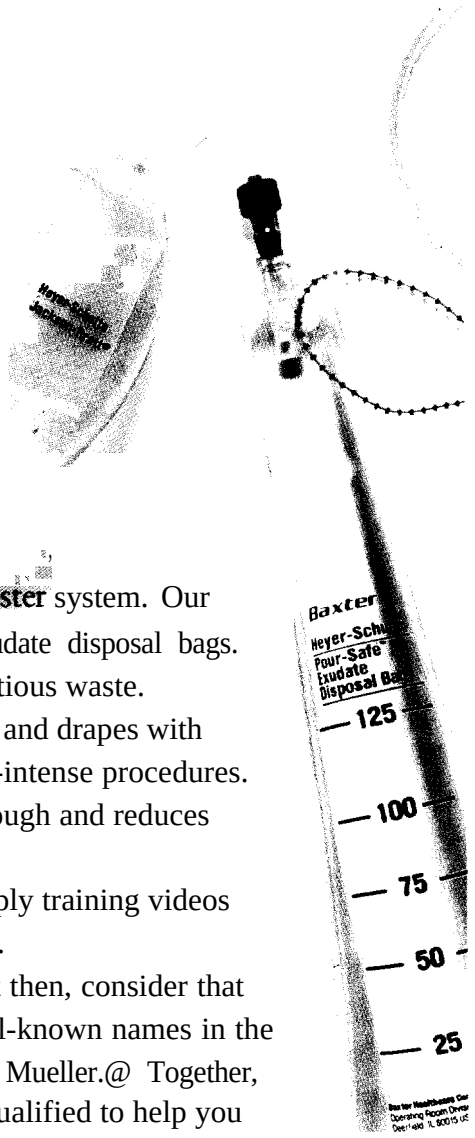
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**Topics in Long-Term Care**
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- For treatment of infections in the:
  -lower respiratory **tract**† – urinary **tract**†
  -skin/skin structure? -bones and joints?
- Convenient ***B.I.D.*** dosage-250 mg, 500 mg and 750 mg tablets

**In vitro* activity does not necessarily imply a correlation with *in vivo* results.
†**Due to susceptible strains of indicated pathogens. See indicated organisms in Brief Summary.**

**CIPRO" SHOULD NOT BE USED IN CHILDREN, ADOLESCENTS, OR PREGNANT WOMEN.**

A historyof hypersensitivity to ciprofloxacin is a contraindication to its use. A history of hypersensitivity to other quinolones may also contraindicate the use of ciprofloxacin.

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# Cipro® TABLETS (ciprofloxacin HCl/Miles)

# CONVENIENT *B.I.D.* DOSAGE

## Dosage guidelines

## Mild/Moderate Infections*: 500 mg q12h

## Severe/Complicated Infections*: 750 mg q12h

**CIPRO®** TABLETS
(ciprofloxacin **HCl/Miles)**

BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Cipro® is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below

Lower Respiratory **Infections** caused by *Escherichia coli Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Pseudomonas aeruginosa, Haemophilus influenzae Haemophilus parainfluenzae* and *Streptococcus pneumoniae*

Skin and Skin **Structure** Infections caused by *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis Proteus vulgans, Providencia stuartii. Morganella morganii Citrobacter freundii, Pseudomonas aeruginosa, Staphylococcus aureus. Staphylococcus epidermidis* and *Streptococcus pyogenes*

Bone and Joint **Infections** caused by *Enterobacter cloacae, Serratia marcescens,* and *Pseudomonas aeruginosa*

*Urinary* Tract Infections caused by *Escherichia coli. Klebsiella pneumoniae Enterobacter cloacae, Serratia marcescens, Proteus mirabilis, Providencia rettgeri, Morganella morganii. Citrobacter diversus Citrobacter freundii, Pseudomonas aeruginosa. Staphylococcus epidermidis* and *Streptococcus faecalis*

**Infectious** Diarrhea caused by *Escherichia coli* (enterotoxigenic strains), *Campylobacter jejuni Shigella flexneri,** and *Shigella sonnei** when antibacterial therapy is indicated

*Efficacy for this organism in this organ system was studied in fewer than 10 infections

CONTRAINDICATIONS

A history of hypersensitivity to ciprofloxacl" is a contraindication to its "se A history of hypersensitivity to other quinolones may also contraindicate the use of ciprofloxacin

**WARNINGS**

CIPROFLOXACIN SHOULD NOT BE USED IN CHILOREN. AOOLESCENTS, OR PREGNANT WOMEN The oral administration of ciprofloxacin caused lameness i" immature dogs Histopathological examination of the weight-bearing joints of these dogs revealed permanent lesions of the cartilage Related drugs such as nalidixic acid, cinoxacin, and norfloxacin also produced erosions of cartilage of weight-bearing joints and other signs of arthropathy in immature animals of various spew (SEE ANIMAL PHARMACOLOGY SECTION IN FULL PRESCRIBING INFORMATION)

PRECAUTIONS

General: As with other quinolones clprofloxacl" may cause central nervous system (CNS) stimulation, which may lead to tremor, restlessness, lightheadedness, confusion, and rarely to hallucinations or convulsive seizures Therefore. ciprofloxacin should be used with caution i" patients with know" or suspected CNS disorders, such as severe cerebral arteriosclerosisor epilepsy. or other factors whichpredispose to seizures (SEE ADVERSE REACTIONS).

Anaphylactic reactions following the first dose have bee" reported i" patients receiving therapy with quinolones Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling pharyngeal or facial edema dyspnea, urticaria, and itching Only a few patients had a history of hypersensitivity reaction Anaphylactic reactions may require epinephrine and other emergency measures Ciprofloxacin should be discontinued at the first sign of hypersensitivity or allergy

Sever'e hypersensitivity reactions characterized by rash fever, eosinophilia jaundice, and hepatic necrosis with fatal outcome have bee" reported rarely (less than one per million prescriptions) i" patients receiving ciprofloxacin along with other drugs The possibility that these reactions were related to ciprofloxacin cannot be excluded Ciprofloxacin should be discontinued at the first appearance of a skin rash or any sign of other hypersensitivity reaction

Crystals of clprofloxacl" have bee" observed rarely in the urine of human subjects but more frequently i" the urine of laboratory animals (SEE ANIMAL PHARMACOLOGY SECTION IN FULL PRESCRIBING INFORMATION). Crystalluria related to ciprofloxacin has been reported only rarely i" ma" because human urine is usually acidic Patients receiving ciprofloxacin should be well hydrated. and alkalinity of the urine should be avoided. The recommended daily dose should "of be exceeded

Alteration of the dosage regimen is necessary for patients with impairment of renal function (SEE DOSAGE AN0 ADMINISTRATION)

As with any potent drug. periodic assessment of organ system functions, including renal. hepatic. and hematopoietic function. is advisable during prolonged therapy

Drug **Interactions:** As with other quinolones, concurrent administrationof ciprofloxacin with theophylline may lead to elevated plasma concentrations of theophylline and prolongation of its elimination half-life This may result in increased risk of theophylline-related adverse reactions If concomitant use cannot be avoided, plasma levels of theophylline should be monitored and dosage adiustments made as appropriate

Quinolones including ciprofloxacin have also been shown to interfere with the metabolism of caffeine This may lead to reduced *clearance* of caffeine and a prolongation of its plasma half-life

Antacids containing magnesium hydroxide or aluminum hydroxide may interfere with the absorption of ciprofloxacin resulting i" serum and urine levels lower than dewed. concurrent administration of these agents with ciprofloxacin should be avoided

Concomitant administration of the nonsteroidal anti-inflammatory drug fenbufen with a quinolone has been reported to increase the risk of CNS stimulation and convulsive seizures.

Probenecid interferes with the renal tubular secretion of ciprofloxacin and produces a" increase i" the level of ciprofloxacin i" the serum This should be considered if patients are receiving both drugs concomitantly

As with other broad-spectrum antibiotics, prolonged use of ciprofloxacin may result i" overgrowth of nonsusceptible organisms Repeated evaluation of the patient's condition and microbial susceptibility testing is essential If superinfection occurs during therapy appropriate measures should be taken

**Information for Patients:** Patients should be advised that ciprofloxacin may be take" with or without meals The preferred time of dosing is two hours after a meal Patients should also be advised to drink fluidsliberally and "of take antacids containing magnesium or aluminum Patients should be advised that ciprofloxacin may be associated with hypersensitivity reactions, even following a single dose. and lo discontinue the drug at the first sign of a skin rash or other allergic reaction

Ciprofloxacin may cause dizziness or lightheadedness; therefore patients should know how they react to this drug before they operate a" automobile or machinery or engage i" activities requiring mental alertness or coordination

Patients should be advised that clprofloxacl" may increase the effects of theophylline and caffeine

**Carcinogenesis,** Mutagenesis, Impairment **of Fertility:** Eight *in vitro* mutagenicity tests have been conducted with clprofloxacl" and the test results are listed below

- Salmonella/Microsome Test (Negative)
- *E coli* DNA Repair Assay (Negative)
- Mouse Lymphoma Cell Forward Mutation Assay (Positive)
- Chinese Hamster $V_{79}$ Cell HGPRT Test (Negative)
- Syrian Hamster Embryo Cell Transformation Assay (Negative)
- *Saccharomyces cerevisiae* Point Mutation Assay (Negative)
- *Saccharomyces cerevisiae* Mitotic Crossover and Gene Conversion Assay (Negative)
- Rat Hepatocyte DNA Repair Assay (Positive)

Thus. two of the eight tests were positive, but the results of the following three *in vivo* test systems gave negative results

- Rat Hepatocyte DNA Repair Assay
- Micronucleus Test (Mice)
- Dominant Lethal Test (Mice)

Long-term carcinogenicity studies i" rats and mice have been completed Affer daily oral dosing for up to 2 years there is no evidence that ciprofloxacin had any carcinogenic or tumorigenic effects i" these species

Pregnancy-Pregnancy **Category** C: Reproduction studies have been performed in rats and mice at doses up to 6 times the usual daily human dose and have revealed no evidence of impaired fertility or harm to the fetus due to ciprofloxacin i" rabbits. as with most antimicrobial agents, ciprofloxacin (30 and 100 mglkg orally) produced gastrointestinal disturbances resulting i" maternal weight loss and a" increased incidence of abortion No teratogenicity was observed at either dose After intravenous administration at doses up to 20 mg/kg, no maternal toxicity was produced. and no embryotoxicity or teratogenicity was observed There are, however. no adequate and well-controlled studies in pregnant women SINCE CIPROFLOXACIN. LIKE OTHER DRUGS IN ITS CLASS. CAUSES ARTHROPATHY IN IMMATURE ANIMALS, IT SHOULD NOT BE USED IN PREGNANT WOMEN (SEE WARNINGS)

Nursing Mothers: It is not known whether ciprofloxacin 15 excreted i" human milk, however, it is known that ciprofloxacin is excreted i" the milk of lactating rats and that other drugs of this class are excreted i" human milk Because of this and because of the potential for serious adverse reactions from ciprofloxacin i" nursing infants, a decision should be made to discontinue nursing or to discontinue the drug, takingjnto account the importance of the drug to the mother

Pediatric Use: Patients under the age of 18 were not included i" the clinical trials of ciprofloxacin because ciprofloxacin as well as other quinolones causes arthropathy in immature animals Ciprofloxacin should not be used in children or adolescents (SEE WARNINGS)

ADVERSE REACTIONS

Ciprofloxacin is generally well tolerated During clinical investigation 2 799 patients received 2,868 courses of the drug Adverse events that were considered likely to be drug related occurred in 7 3% of courses, possibly related in 9 2% and remotely related in 3 0% Ciprofloxacin was discontinued because of a" adverse event i" 3 5% of courses, primarily involving the gastrointestinal system (1 5%), skin (0 6%), and central nervous system (0 4%) Those events typical of quinolones are italicized

The most frequently reported events. drug related or not, were nausea (5 2%) diarrhea (2 3%). *vomiting (2 0%). abdominal pain/discomfort* (1 7%) *headache* (1 2%), *restlessness* (1 1%), and *rash* ll 1%)

Additional events that occurred i" fess than 1% of ciprofloxacin courses are listed below

GASTROINTESTINAL: *(See above)* painful oral mucosa oral candidiasis dysphagia intestinal perforation, gastrointestinal bleeding

CENTRAL NERVOUS SYSTEM (See *above), dizziness, lightheadedness, insomnia, nightmares. hallucinations, manic reaction irritability, tremor. ataxia, convulsive seizures, lethargy drowsiness, weakness. malaise, anorexia phobia, depersonalization, depression, paresthesia*

SKIN/HYPERSENSITIVITY: *(See above), pruritus, urticaria, photosensitivity, flushing, fever, chills, angioedema* edema *of the* face, *neck, lips, conjunctivae* or *hands. cutaneous* candidiasis hyperpigmentation, erythema "odasum.

Allergic reactions ranging from urticaria to anaphylactic reactions have been reported (SEE PRECAUTIONS1

SPECIAL SENSES *blurred vision disturbed vision (change in color perception overbrightness of lights), decreased visual acuity, diplopia, eye* pa,", *tinnitus, hearing loss. bad taste*

MUSCULOSKELETAL *joint* or *back pain, joint stiffness,* achiness, neck or chest pain, flare-up of gout.

RENAL/UROGENITAL *interstitial nephritis, nephrits, renal failure,* polyuria, urinary retention, urethral bleeding, vaginitis, acidosis

CARDIOVASCULAR palpitations, atrial flutter ventricular ectopy syncope, hypertension, angina pectoris, myocardial infarction, cardiopulmonary arrest cerebral thrombosis

RESPIRATORY epistaxis, laryngeal or pulmonary edema, hiccough hemoptysis, dyspnea, bronchospasm, pulmonary embolism

Most of the adverse events reported were described as only mild or moderate i" seventy, abated soon after the drug was discontinued, and required no treatment

In several Instances nausea vomiting, tremor. restlessness agitation, or palpitations were judged by investigators to be related to elevated plasma levels of theophylline possibly as a result of a drug interaction with ciprofloxacin.

Other adverse events reported in the postmarketing phase include anaphylactoid reactions, Stevens-Johnson syndrome. exfoliative dermatitis, toxic epidermal necrolysis, hepatic necrosis, postural hypotension, possible exacerbation of myasthenia gravis, confusion, dysphasia nystagmus, pseudomembranous colitis dyspepsia flatulence. and constipation Also reported were agranulocytosis elevation of serum tgjglvcerides serum cholesterol. blood glucose serum potassium; prolongation of prothrombin time albuminuria; candiduria, vaginal candidiasis; and *renal* calculi (SEE PRECAUTIONS)

Adverse Laboratory Changes: Changes i" laboratory parameters listed as adverse events without regard to drug relationship

Hepatic—Elevations of: ALT (SGPT) (1 9%), AST (SGOT) (1 7%), alkaline phosphatase (0.8%) LOH (0 4%). serum bilirubin (0 3%)

Cholestatic jaundice has bee" reported.

Hematologic—eosinophilia (0 6%), leukopenia (0 4%), decreased blood platelets (0.1%). elevated blood platelets (0.1%) pancytopenia (0.18)

Renal—Elevations of Serum creatinine (1 1%). BUN (0 9%)

CRYSTALLURIA. CYLINDRURIA, AND HEMATURIA HAVE BEEN REPORTED.

Other changes occurring i" less than 0.1% of courses were Elevation of serum gammaglutamyl transferase, elevation of serum amylase reduction i" blood glucose. elevated uric acid, decrease in hemoglobin, anemia, bleeding diathesis, increase in blood monocytes, and leukocytosis

**OVERDOSAGE**

Information on overdosage in humans is not available In the event of acute overdosage. the stomach should be emptied by inducing vomiting or by gastric lavage The patient should be carefully observed and given supportive treatment Adequate hydration must be maintained Only a small amount of ciprofloxacin (< 10%) is removed from the body after hemodialysis or peritoneal dialysis

DOSAGE AND ADMINISTRATION

The usual adult dosage for patients with urinary tract infections is 250 mg every 12 hours. For patients with complicated infections caused by organisms not highly susceptible. 500 mg may be administered every 12 hours

Lower respiratory tract infections, skin and skin structure infections, and bone and joint infections may be treated with 500 mg every 12 hours For more severe or complicated infections a dosage of 750 mg may be given every 12 hours

The recommended dosage for infectious diarrhea is 500 mg every 12 hours

In patients with renal impairment, some modificationof dosage is recommended (SEE DOSAGE AND ADMINISTRATION SECTION IN FULL PRESCRIBING INFORMATION).

HOW SUPPLIED

Cipro® (ciprofloxacin HCl/Miles) is available as tablets of 250 mg 500 mg, and 750 mg i" bottles of 50, and i" Unit-Dose packages of 100 (SEE FULL PRESCRIBING INFORMATION FOR COMPLETE DESCRIPTION)

*Due to susceptible **strains of** indicated pathogens. **See** indicated organisms in Prescribing **Information.**

For further information, contact the Miles Information Service:
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EDITORIAL

**Challenges and Controversies** 239
Richard A. Garibaldi, MD; Richard P. Wenzel, MD, MSc

PROGRAM SUMMARIES

**AIDS**

**Risk of HIV Infection to Health Care Workers** 241
William Schaffner, MD

**Serologic Testing for the Human Immunodeficiency Virus—To Screen or Not to Screen** 243
Dennis G. Maki, MD

**Understanding the Pathogenesis of HIV Infection** 248
Donald A. Goldmann, MD; Thomas F. Zuck, MD

**Expanding Roles of Hospital Epidemiology**

**Pharmacoepidemiology** 253
John P. Burke, MD; Hugh H. Tilson, MD, MPH; Richard Platt, MD

**Quality Assurance** 255
Richard P. Wenzel, MD, MSc

**Severity of Illness Indicators** 257
Peter A. Gross, MD

**Employee Health—Chemical Exposure in the Health Care Setting** 261
William A. Rutala, PhD, MPH; Bruce H. Hamory, MD

**Infection Control**

**New Problem Organisms for Infection Control** 267
John E. McGowan, Jr., MD

**Opportunistic Fungal Infections—The Increasing Importance of *Candida* Species** 270
Michael A. Pfaller, MD

**The Immunocompromised Host** 274
Lowell S. Young, MD

**The Future of Hospital Epidemiology** 276
Calvin M. Kunin, MD

SPECIAL SECTIONS

**Topics in Clinical Microbiology: *Candida tropicalis*** 280
Michael S. Gelfand, MD

DEPARTMENTS

**Information for Authors** 238
**Calendar of Events** 284
***SHEA Newsletter*** 285
**Classified Marketplace** 287

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