INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY

Volume 10, Number 8 • August 1989

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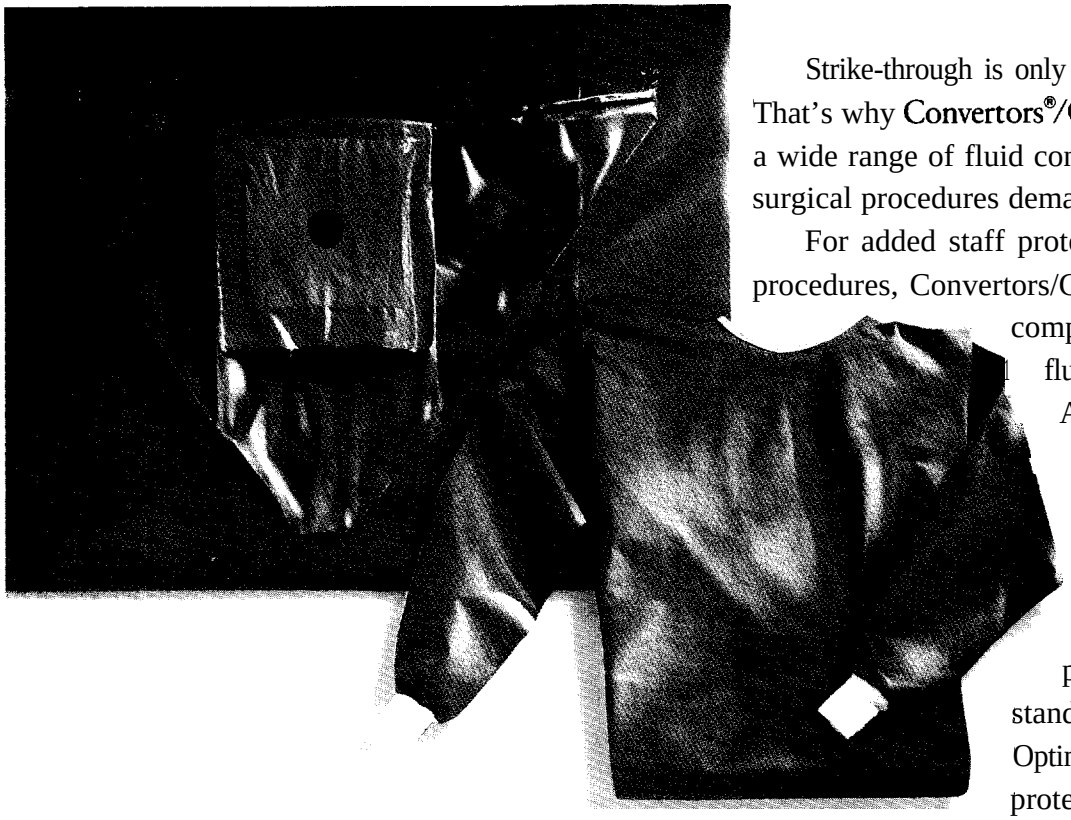
The Official Journal of The Society of Hospital Epidemiologists of America

The issue isn't just strike-through.

It's fluid control.



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VOLUME 10, NUMBER 8 AUGUST 1989

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Publisher: Infection Control and Hospital Epidemiology (ISSN-0899-823X) is published monthly by SLACK Incorporated 6900 Grove Road. Thorofare, New Jersey 08086 Telephone (609) 848-1000

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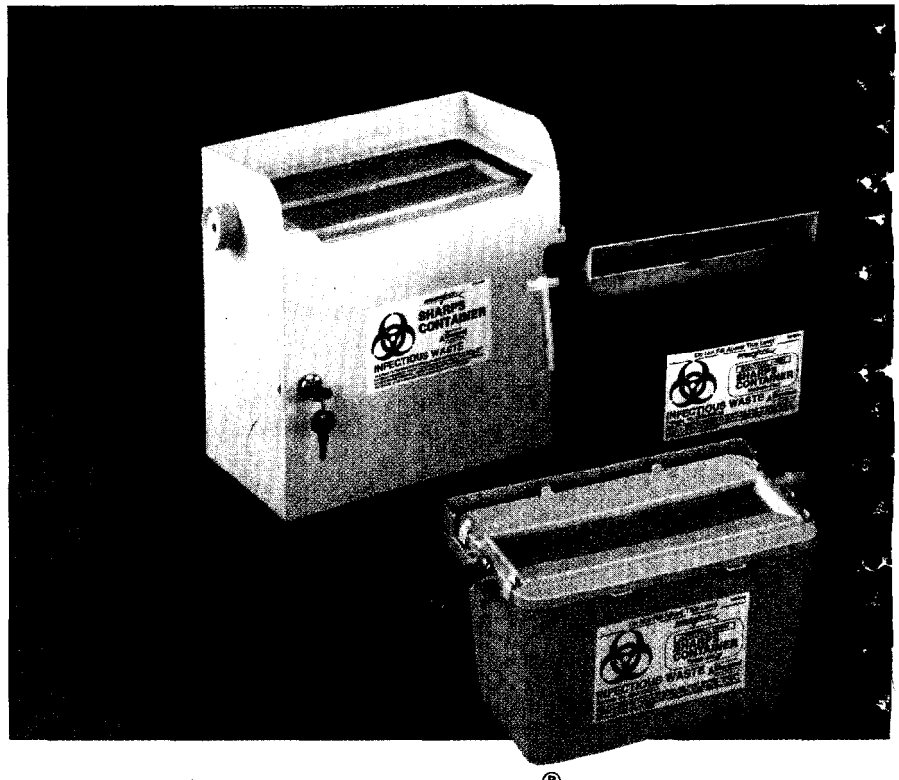

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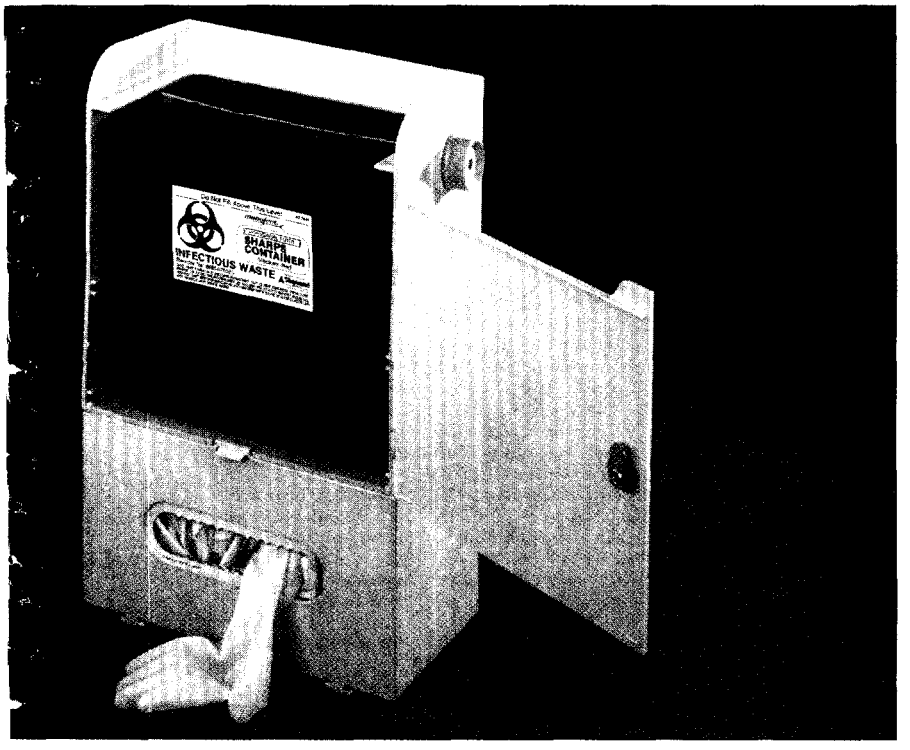

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  - **lower respiratory tract†**
  - **urinary tract†**
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- **Convenient *B.I.D.* dosage – 250 mg, 500 mg and 750 mg tablets**

*In ***vitro*** activity does not **necessarily** imply a correlation with *in* ***vivo*** results

†**Due to susceptible stralns of indicated pathogens. Sea indicated organisms in Brief Summary.**

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

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

WARNINGS

CIPROFLOXACIN SHOULD NOT BE USED IN CHILDREN ADOLESCENTS, OR PREGNANT WOMEN The oral administration of ciprofloxacin caused lameness in 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 species (SEE ANIMAL PHARMACOLOGY SECTION IN FULL PRESCRIBING INFORMATION)

PRECAUTIONS

General: As with other quinolones, ciprofloxacin 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 in patients with known or suspected CNS disorders, such as severe cerebral arteriosclerosis or epilepsy, or other factors which predispose to seizures (SEE ADVERSE REACTIONS)

Anaphylactic reactions following the first dose have been reported in 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

Severe hypersensitivity reactions characterized by rash fever, eosinophilia, jaundice, and hepatic necrosis with fatal outcome have been reported rarely (less than one per million prescriptions) in 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 ciprofloxacin have been observed rarely in the urine of human subjects but more frequently in the urine of *laboratory* animals (SEE ANIMAL PHARMACOLOGY SECTION IN FULL PRESCRIBING INFORMATION) Crystalluria related to ciprofloxacin has been reported only rarely in man, 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 not be exceeded

Alteration of the dosage regimen is necessary for patients with impairment of renal function (SEE DOSAGE AND 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 administration of 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 adjustments 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 in serum and urine levels lower than desired; 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 an increase in *the level of* ciprofloxacin in 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 in 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 taken with or without meals The preferred time of dosing is two hours after a meal Patients should also be advised to drink fluids liberally and not take antacids containing magnesium or aluminum Patients should be advised that ciprofloxacin may be associated with hypersensitivity reactions, even following a single dose, and to 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 an automobile or machinery or engage in activities requiring mental alertness or coordination

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

Carcinogenesis, Mutagenesis, Impairment of Fertility: Eight *in vitro* mutagenicity tests have *been* conducted with ciprofloxacin 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 in rats and mice have been completed. After daily oral dosing for up to 2 years, there is no evidence that ciprofloxacin had any carcinogenic or tumorigenic effects in 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 In rabbits, as with most antimicrobial agents, ciprofloxacin (30 and 100 mg/kg orally) produced gastrointestinal disturbances resulting in maternal weight loss and an 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 is excreted in human milk; however, it is known that ciprofloxacin is excreted in the milk of lactating rats and that other drugs of this class are excreted in human milk Because of this and because of the potential for serious adverse reactions from ciprofloxacin in nursing infants a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Patients under the age of 18 were not included in 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 an adverse event in 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* (1 1%)

Additional events that occurred in less 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 nodosum

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

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 nephritis, 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 in severity, 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 coltis, dyspepsia, flatulence, and constipation Also reported were agranulocytosis; elevation of serum triglycerides serum cholesterol, blood glucose, serum potassium prolongation of prothrombin time; albuminuria; candiduria, vaginal candidiasis; and renal calculi (SEE PRECAUTIONS)

Adverse **Laboratory Changes:** Changes in 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%), LDH (0 4%), serum bilirubin (0 3%)

Cholestatic jaundice has *been* reported

Hematologic—eosinophilia (0 6%), leukopenia (0 4%), decreased blood platelets (0 1%), elevated blood platelets (0 1%), pancytopenia (0 1%)

Renal—Elevations of Serum creatinine (1.1%), BUN (0 9%).

CRYSTALLURIA, CYLINDRURIA, AND HEMATURIA HAVE BEEN REPORTED

Other changes occurring in less than 0 1% of courses were Elevation of serum gammaglutamyl transferase elevation of serum amylase, reduction in blood glucose elevated uric acid decrease in hemoglobin, anemia, bleeding diathesis, increase in blood monocytes, and leukocytosis

OVERWSAGE

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

OOSAGE 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 modification of 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 in bottles of 50, and in Unit-Dose packages of 100 (SEE FULL PRESCRIBING INFORMATION FOR COMPLETE DESCRIPTION)

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

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