

HOSPITAL EPIDEMIOLOGY

Volume 10, Number 8 • August 1989

Special Update:

Fourth Consensus Conference on HIV Testing

Sponsored by the Association of State and Territorial Public Health Laboratories

The Official Journal of The Society of Hospital Epidemiologists of America

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INFECTION CONTROL

AND HOSPITAL EPIDEMIOLOGY

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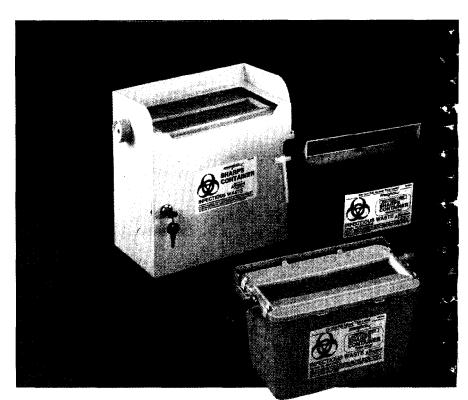
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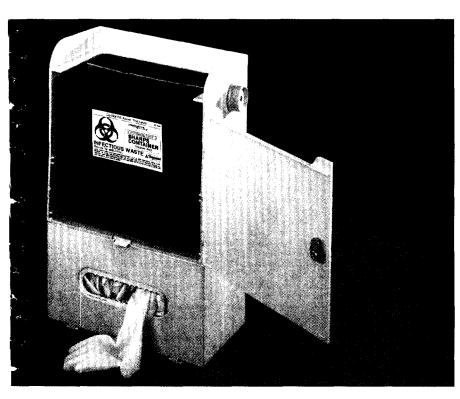
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(ciprofloxacin HCI/Miles) BRIEF SUMMARY

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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

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WARNINGS

WARNINGS CIPROFLOXACIN SHOULD NOT BE USED IN CHILDREN ADOLE SCENTS. OR PREGNANT WOMEN The oral adminis-tration 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 nalidxic acidi, clinoxacin, and norfloxacin also produced erosions of cartilage of weight-bearing joints and other signs of arthropathy immature animals of vanous species (SEE ANIMAL PHARMACOLOGY SECTIONIN FULL PRESCRIBING INFORMATION) PRECAUTIONS Concerch As with other quilippones ciprofloxed provide system (CNS) stimulation, which may

PRECAUTIONS General: As with other quinolones, ciprofloxacin may cause central nervous system (CNS) stimulation, which may lead to tremor, restlessness, lightheadedness, conflusion, and rarely to halucinations or convulsive seizures There-fore, ciprofloxacin should be used with caution in patients with known or suspected CNS disorders, such as severe cerebral arteriosclensis 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 consciousnes, tingking, pharyngealor facial edema, dyspena, urticara, 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 sun of howersensitivity or allerow.

reactions may require epinepinine and other energency measures opportunation and/or or operationation and a 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

Ciprofloxacin should be discontinued at the first appearance of a skin rash of any sign of other hypersensitivity reaction. Crystals of ciprofloxacin have been observedrarely in the urine of human subjects but more frequently in the urine of *laboratory* animals (SEE ANIMAL PHARMACOLOGY SECTION INFULL PRESCRIBING INFORMATION) Crystalluria related to ciprofloxacin should be been reported only rarely in man, because human urine is usually acidic Patients receiving ciprofloxacinshould be well hydrated, and alkalinity of the urine should be avoided Therecommended daily dogs should not be exceeded Alteration of the dosage regimen is necessary for patients with impairment of renal function (SEE DOSAGE AND ADMINISTRATION) and being and benafic and benafic As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto, particular consistent functions (SEE DOSAGE AND As with any usefuel duto.

ADMINISTRATION As with any potent drug, periodic assessment of organ system functions, including renal, hepatic, and hemato-poietic function, is advisable during prolonged therapy. Drug Interactions: As with other quinolones, concurrent administration of ciprofloxacin with theophyllinemay 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. Ournolones, including oprificazin, 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 ciproflox-acin resulting in serum and unne levels lower than desired; concurrent administration of these agents with ciproflox-acin should be avoided. Concomitant administration of the nonsteroidal anti-inflammatory drug fenbufen with a quinolone has been

Concomitant administration of the nonsteroidal anti-inflammatory drug tenbuten with a quinionitie has been reported to increase the risk of CNS stimulation and convolvies escures 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 nonsuscepti-ble organisms Repeated evaluation of the patient's condition and microbial susceptibility testing is essential if superinterious 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 dosings two hours after armeal Patients should also be advised that ciprofloxacin may be associated with whore sensitive reactions at uning the supering stime and the distribution the first should be advised that the first should be advised that into the satisfic scontaining magnesium or aluminum. Patients should be advised that ciprofloxacin may be associated with whore sensitive reactions: even following a stime dows a during the drive at the first should be in the first should be advised that ciprofloxacin may be associated with a stime at the sense following the stime at the drive at the first should be taken to the first should be advised that ciprofloxacin may be associated with an advise to drive the first should be advised that ciprofloxacin may be associated with a stime dows and to disconting the first should as being the stime at the first should be advised that ciprofloxacin may be associated with a stime dows and to disconting the first should be first should be advised that ciprofloxacin may be associated with a stime dows and to disconting the first should be advised that ciprofloxacin may be associated with a stime dows and the first should be advised that ciprofloxacin ma https://www.initial.com/second/action/or and/or a single dose, and to discontinue the drug at the first sign of a skin rash or other allergic reaction.

Gprofloxacin 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_mCell HOPRT Test (Negative) Syrian Hamster Embry Cell Transformation Assay (Negative) Saccharomyces cerevisae Point Mutation Assay (Negative) Saccharomyces cerevisae Point Mutation Assay (Negative) Saccharomyces cerevisae Apoint Mutation Assay (Negative) Rat Hepatoryte DNA Repair Assay (Positive) Thus, two of the eight tests were positive, but the results of the following three *in vivo* test systems gavenegative results. Ciprofloxacin may cause dizziness or lightheadedness; therefore patients should know how they react to this drug

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 6 times the usual rlaip 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 terato-genicity was observed at letther dose After intravenous administration, at doses up to 20 mg/kg no maternal toxicity was produced, and no embryotoxicity or teratogenenity was observed at letter dose After Intravenous administration, at doses up to 20 mg/kg no maternal toxicity or teratogenenity was observed at letters. 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 the milk of lactuting rats and that other drugs of this class are excreted in human milk Because of this and because of the potential for senous adverse reactions from ciprofloxacin in nursing infants a derision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

decision and use matter. Pediatric Use: Patients under the age of 18 were not included in the clinical trials of ciprofloxacin because ciproflox-acin as well as other quinolones causes arthropathy in immature animals Ciprofloxacin should not be used in children or adolescents (SEE WARNINGS) ADVERSE REACTIONS

ADVERSE REACTONS 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 accurred 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 quinciones are italicized The most frequently reported events, drug related or not, were nausea (5 2%), *diarrhea* (2 3%), *vomiting* (2 0%), addominal pain/discomfort (1 7%), headache (1 2%), restlessness (1 1%), and rash (1 1%) Additional events that occurred mises than 1% of ciprofloxacin pourses are listed below COSTONUTSETINAL. (See above 1 cound ead more and execting in the prior and execting in eader and additional events that occurred mises than 1% of ciprofloxacin pourses are listed below

GASTROINTESTINAL (See above), painful oral mucosa, oral candidiasis, dysphagia intestinal perforation, gastrointestinal bleeding CENTRAL NERVOUS SYSTEM (See above), dizziness, lightheadedness, insomma, nightmares, hallucinations

Berning Herrick Herrick and State nodosum

nodosum Allergic reactons ranging from urticana to anaphylactic reactions have been reported (SEE PRECAUTIONS) SPECIAL SENSES: blurred vision, disturbed vision (change in color perception overbrightness of lights), decreased visual acutly diplopia eye par," tinnitis, hearing loss, bad taste MUSCULOSKELTAL, join or back pain joint stiffness, achiness, neck or chest pain, flare-up of gout RENAL/UROGENITAL: interstitial nephritis nephritis, renal failure, polyuria, urnary retention, urethral bleeding, vagmits acidosis CARDIOVASCULAR palpitations, atriai flutter, ventricular ectopy, syncope, hypertension, angina pectoris, myocardial infarction cardiopulmonary arrest, cerebral thrombosis

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

Most of the adverse events reported were described as only mild or moderate in severity, abated soon after the

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 investiga-tors to berelated to elevated plasma levels of theophylline possibly as a result of a drug interaction with ciprofloxacin. Other adverse events reported in the postmarkeling phase include anaphylactoid reactions. Stevens-Johnson syndrome exfoilative dermatitis, toxic epidermal necrolysis, hepatic necrosis, postural hypotension, possible exac-erbation of myasthenia gravis, confusion, of xysphasia, nystagruus, pseudomembranous colits, dyspepsia, flatilence, and constipation Also reported were agranulocytosis, elevation of serum triglycerides serum cholesterol, blood glucoses, serum potassum prolongation of prothromotin time albumnuria; candiduria, vaginal candidasis; and renal calculi (SEE PRECAUTIONS)

rse Laboratory Changes: Changes in laboratory parameters listed as adverse events without regard to drug relations

Hepatic - Elevations of ALT (SGPT) (1.9%) AST (SGOT) (1.7%) alkaline phosphatase (0.8%), LDH (0.4%), serum bilirubin (0 3%)

Cholestatic jaunice has been reported Hematologic—eosinophilia (0.6%), leukopenia (0.4%), decreased blood platelets (0.1%), elevated blood platelets (0.1%), pancytopenia (0.1%)

Piertartiologic – evolutionima (to 9%), reactivity (to 9%), electrosed blood platelets (b 1%), elevated blood platelets (0 1%), plancytopenia (0 1%), BUN (0 9%). CRYSTALLURIA, CYLUNDRURIA, 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 unc acid decrease in hemoglobin, anema, 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 hemodiallysis or peritoneal dialysis OOSAGE AND **ADMINISTRATION** The usual adult dosage for patients with unnary tract infections is 250 mg every 12 hours. For patients with complicated by organisms on highly susceptible, 500 mg may be administered every 12 hours Lower respiratory tract infections, skin and skinstructure infections, and bone and joint infections may be treated with 500 mg every 12 hours. For more severe or complicated infections, ad osage of 750 mg may be given every 12 hours.

The recommended dosage for infectious diarrhea is 500 mg 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 ADMINIS-TRATION SECTION IN FULL PRESCRIBING INFORMATION) HOW SUPPLIED Cipro®(ciprofloxacin HCI/Miles) is available as tablets of 250 mg, 500 mg, and 750 mg in bottles of 50, and in Unit-Dose backages 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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