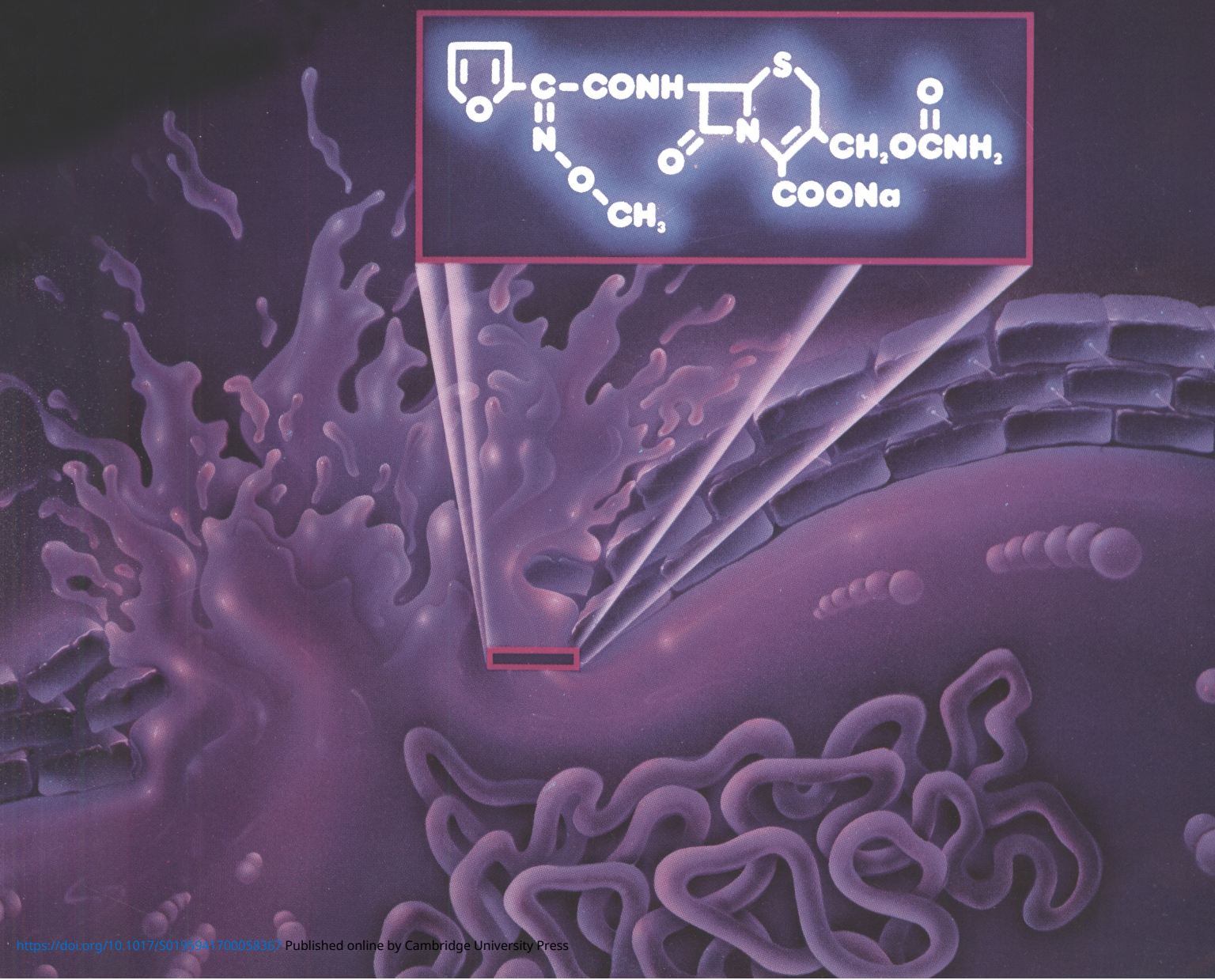
Introducing

New ZINACEF® 750 mg q8h IM/IV GLAXO

sterile cefuroxime sodium

From Glaxo, a pioneer in cephalosporin research



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New

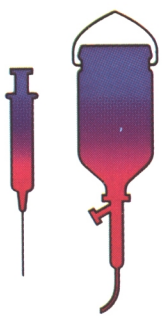
ZINACEF®

IM/IV q8h **GLAXO**

sterile cefuroxime sodium

Overall 98% of patients cured or improved in a range of serious infections due to susceptible organisms

- Meningitis
- Lower respiratory
- Skin and skin structure
- Urinary tract—complicated and uncomplicated
- Septicemia
- Uncomplicated and disseminated gonorrhea
- Prophylactic use may reduce the incidence of postoperative infections



- Used in over 1,000,000 patients worldwide; proven safe and effective in U.S. clinical trials
- Therapeutic doses provide antibacterial levels in a wide range of body fluids and tissues*
- Rapidly absorbed IM

Susceptible organisms

Gram-negative

● *Haemophilus influenzae* (including β-lactamase- and non-β-lactamase-producing strains) ● *Haemophilus parainfluenzae* ● *Neisseria gonorrhoeae* (including β-lactamase- and non-β-lactamase-producing strains) ● *Neisseria meningitidis* ● *Escherichia coli* ● *Klebsiella* sp (including *K. pneumoniae)* ● *Enterobacter* sp ● *Citrobacter* sp ● *Salmonella* sp ● *Shigella* sp ● *Proteus mirabilis* ● *Proteus inconstans* (formerly *Providencia)* ● *Providencia rettgeri* (formerly *Proteus rettgeri*) ● *Morganella morganii* (formerly *P. morganii*)

Gram-positive

● *Staphylococcus aureus* (both β-lactamase and non-β-lactamase producers) ● *Staphylococcus epidermidis* ● *Streptococcus pyogenes* (and other streptococci) ● *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*)

Anaerobes

● Gram-positive and gram-negative cocci (including *Peptococcus* and *Peptostreptococcus* sp) ● Gram-positive bacilli (including *Clostridium* sp) ● Gram-negative bacilli (including *Bacteroides* and *Fusobacterium* sp)

Pseudomonas, Campylobacter, Acinetobacter calcoaceticus (formerly *Mima* and *Herellea* species), most strains of *Serratia* and *Proteus vulgaris, Streptococcus faecalis,* methicillin-resistant staphylococci, *Clostridium difficile, Bacteroides fragilis* and *Listeria monocytogenes* are resistant to cefuroxime and most other cephalosporins.

Some strains of *M. morganii, E. cloacae* and *Citrobacter* species have been shown by *in vitro* tests to be resistant to cefuroxime and other cephalosporins.

Worth special note

- 750 mg q8h IM or IV 98% successful in most indicated infections
- ZINACEF provides savings in:
  - the amount of antibiotic needed
  - staff time involved in administration
  - IV sets, tubing, etc., used in IV reconstitution and administration

*Although a useful guide, *in vitro* activity and pharmacokinetic data do not necessarily correlate with clinical response.

See last page for brief summary of prescribing information.

Glaxo

Glaxo Inc., Research Triangle Park, NC 27709

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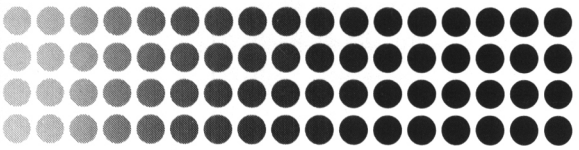

Introducing new ZINACEF® IM/IV q8h GLAXO sterile cefuroxime sodium

ZINACEF® (sterile cefuroxime sodium, Glaxo)
Brief Summary. Before prescribing, consult complete prescribing information.

INDICATIONS AND USAGE

ZINACEF® is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the diseases listed below:

1. **Lower Respiratory Infections,** including pneumonia caused by *Streptococcus pneumoniae* (formerly *Diplococcus pneumoniae*), *Haemophilus influenzae* (including ampicillin-resistant strains), *Klebsiella* species, *Staphylococcus aureus* (penicillinase and non-penicillinase producing), *Streptococcus pyogenes,* and *Escherichia coli.*
2. **Urinary Tract Infections** caused by *Escherichia coli* and *Klebsiella* species.
3. **Skin and Skin Structure Infections** caused by *Staphylococcus aureus* (penicillinase and non-penicillinase producing), *Streptococcus pyogenes, Escherichia coli, Klebsiella* species, and *Enterobacter* species.
4. **Septicemia** caused by *Staphylococcus aureus* (penicillinase and non-penicillinase producing), *Streptococcus pneumoniae, Escherichia coli, Haemophilus influenzae* (including ampicillin-resistant strains), and *Klebsiella* species.
5. **Meningitis** caused by *Streptococcus pneumoniae, Haemophilus influenzae* (including ampicillin-resistant strains), *Neisseria meningitidis,* and *Staphylococcus aureus* (penicillinase and non-penicillinase producing).
6. **Gonorrhea** Uncomplicated and disseminated gonococcal infections due to *Neisseria gonorrhoeae* (penicillinase and non-penicillinase producing strains) in both males and females.

Clinical microbiological studies in skin and skin structure infections frequently reveal the growth of susceptible strains of both aerobic and anaerobic organisms. ZINACEF has been used successfully in these mixed infections in which several organisms have been isolated. Appropriate cultures and susceptibility studies should be performed to determine the susceptibility of the causative organisms to ZINACEF. Therapy may be started while awaiting the results of these studies; however, once these results become available, the antibiotic treatment should be adjusted accordingly. In certain cases of confirmed or suspected gram-positive or gram-negative sepsis or in patients with other serious infections in which the causative organism has not been identified, ZINACEF may be used concomitantly with an aminoglycoside (see **PRECAUTIONS**). The recommended doses of both antibiotics may be given depending on the severity of the infection and the patient's condition.

Prevention The preoperative prophylactic administration of ZINACEF may prevent the growth of susceptible disease-causing bacteria and, thereby, may reduce the incidence of certain postoperative infections in patients undergoing surgical procedures (e.g. vaginal hysterectomy) that are classified as clean-contaminated or potentially contaminated procedures. Effective prophylactic use of antibiotics in surgery depends on the time of administration. ZINACEF should usually be given ½ to 1 hour before the operation to allow sufficient time to achieve effective antibiotic concentrations in the wound tissues during the procedure. The dose should be repeated intraoperatively if the surgical procedure is lengthy. Prophylactic administration is usually not required after the surgical procedure ends and should be stopped within 24 hours. In the majority of surgical procedures, continuing prophylactic administration of any antibiotic does not reduce the incidence of subsequent infections but will increase the possibility of adverse reactions and the development of bacterial resistance. The perioperative use of ZINACEF has also been effective during open heart surgery for surgical patients in whom infections at the operative site would present a serious risk. For these patients it is recommended that ZINACEF therapy be continued for at least 48 hours after the surgical procedure ends. If an infection is present, specimens for culture should be obtained for the identification of the causative organism and appropriate antimicrobial therapy should be instituted.

CONTRAINDICATIONS

ZINACEF® is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS

BEFORE THERAPY WITH ZINACEF® IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY, PARTICULARLY TO DRUGS. IF AN ALLERGIC REACTION TO ZINACEF OCCURS, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE EPINEPHRINE AND OTHER EMERGENCY MEASURES.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad-spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Treatment with broad-spectrum antibiotics alters normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro.*

Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte, and protein supplementation as indicated.

When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile.* Other causes of colitis should also be considered.

PRECAUTIONS

Although ZINACEF® rarely produces alterations in kidney function, evaluation of renal status during therapy is recommended, especially in seriously ill patients receiving the maximum doses. Cephalosporins should be given with caution to patients receiving concurrent treatment with potent diuretics as these regimens are suspected of adversely affecting renal function.

The total daily dose of ZINACEF should be reduced in patients with transient or persistent renal insufficiency (see **DOSAGE**), because high and prolonged serum antibiotic concentrations can occur in such individuals from usual doses.

As with other antibiotics, prolonged use of ZINACEF may result in overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection does occur during therapy, appropriate measures should be taken.

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Nephrotoxicity has been reported following concomitant administration of aminoglycoside antibiotics and cephalosporins.

Interference with Laboratory Tests A false positive reaction for glucose in the urine may occur with copper reduction tests (Benedict's or Fehling's solution or with Clinitest® tablets), but not with enzyme-based tests for glycosuria (e.g. Tes-Tape®). A false negative reaction may occur in the ferricyanide test for blood glucose. Cefuroxime does not interfere with the assay of serum and urine creatinine by the alkaline picrate method.

Carcinogenesis, Mutagenesis, and Impairment of Fertility Although no long-term studies in animals have been performed to evaluate carcinogenic potential, no mutagenic potential of cefuroxime was found in standard laboratory tests.

Reproductive studies revealed no impairment of fertility in animals.

Usage in Pregnancy Pregnancy Category B: Reproduction studies have been performed in mice and rabbits at doses up to 60 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cefuroxime. There are, however, no adequate well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers Since ZINACEF is excreted in human milk, caution should be exercised when ZINACEF is administered to a nursing woman.

Pediatric Use Safety and effectiveness in children below the age of 3 months have not been established. Accumulation of other members of the cephalosporin class in newborn infants (with resulting prolongation of drug half-life) has been reported.

ADVERSE REACTIONS

ZINACEF® is generally well tolerated. The most common adverse effects have been local reactions following intravenous administration. Other adverse reactions have been encountered only rarely.

Local Reactions Thrombophlebitis has occurred with intravenous administration in 1 in 60 patients.

Gastrointestinal Gastrointestinal symptoms occurred in 1 of 150 patients and included diarrhea (1 in 220 patients) and nausea (1 in 440 patients). Symptoms of pseudomembranous colitis can appear during or after antibiotic treatment.

Hypersensitivity Reactions Hypersensitivity reactions have been reported in less than 1% of the patients treated with ZINACEF and include rash (1 in 125). Pruritus and urticaria and positive Coombs test each occurred in less than 1 in 250 patients.

Blood A decrease in hemoglobin and hematocrit has been observed in 1 in 10 patients and transient eosinophilia in 1 in 14 patients. Less common reactions seen were transient neutropenia (less than 1 in 100 patients) and leukopenia (1 in 750 patients). A similar pattern and incidence was seen with other cephalosporins used in controlled studies.

Hepatic Transient rise in SGOT and SGPT (1 in 25 patients), alkaline phosphatase (1 in 50 patients), LDH (1 in 75 patients) and bilirubin (1 in 500 patients) levels have been noted.

Kidney Elevations in serum creatinine and/or blood urea nitrogen and a decreased creatinine clearance have been observed, but their relationship to cefuroxime is unknown.

DOSAGE AND ADMINISTRATION

Adults The usual adult dosage range for ZINACEF® (sterile cefuroxime sodium, Glaxo) is 750 mg to 1.5 g every 8 hours, usually for 5-10 days. In uncomplicated urinary tract infections, skin and skin structure infections, disseminated gonococcal infections, and uncomplicated pneumonia, a 750 mg dose every 8 hours is recommended. In severe or complicated infections, a 1.5 g dose every 8 hours is recommended. In life-threatening infections or infections due to less susceptible organisms, 1.5 g every 6 hours may be required. In bacterial meningitis, the dose should not exceed 3.0 g every 8 hours. The recommended dose for uncomplicated gonococcal infection is 1.5 g intramuscularly given as a single dose at two different sites together with 1.0 g of oral probenecid. For preventive use for clean-contaminated or potentially contaminated surgical procedures a 1.5 g dose administered intravenously just prior to surgery (approximately ½ to 1 hour before the initial incision) is recommended. Thereafter, give 750 mg intravenously or intramuscularly every 8 hours when the procedure is prolonged.

For preventive use during open heart surgery a 1.5 g dose administered intravenously at the induction of anesthesia and every 12 hours thereafter for a total of 6.0 g is recommended.

Impaired Renal Function When renal function is impaired, a reduced dosage must be employed. Dosage should be determined by the degree of renal impairment and the susceptibility of the causative organism. See full prescribing information for dosage in patients with impaired renal function.

HOW SUPPLIED

ZINACEF® (sterile cefuroxime sodium, Glaxo) is a dry white to off-white powder supplied in vials and infusion bottles.

Each vial contains cefuroxime sodium equivalent to 750 mg or 1.5 g cefuroxime. ZINACEF in the dry state should be stored at controlled room temperature and protected from light.

NDC 0173-0352-30	750 mg Vials (10 singles)
NDC 0173-0352-31	750 mg Vials (Tray of 25)
NDC 0173-0354-34	1.5 g Vials (10 singles)
NDC 0173-0354-35	1.5 g Vials (Tray of 25)
NDC 0173-0355-36	1.5 g Infusion Pack (10 singles)

Manufactured for Glaxo Inc., Research Triangle Park, NC 27709
by Glaxo Operations UK Ltd., Greenford, England

Sept. 1983

Glaxo
Glaxo Inc., Research Triangle Park, NC 27709

ZIN-0011-0025-1083

Patients aren't the only people who need protection . . .

Nurses need protection, too. Think about it.

Your nurses are expected to wash their hands before every patient contact. For some, this could mean as many as twenty or thirty hand washings on a single shift. Results?...drying and irritation. Roughened hands that afford more hiding places for pathogens. In effect, a potentially serious breakdown in the control of infections.

That's why you should consider the EpiCare™ Professional Skin Care System. A complete line of pure, natural soaps, combined with soothing moisturizers and emollients. Each designed to protect skin from the drying and irritation caused by repeated washings.

Specifically formulated for health care users, EpiCare Antiseptic Lotion Soap contains a unique, synergistic combination of two broad spectrum biocidal ingredients, PCMX and Triclosan. In addition to rapid biocidal activity, this combination of antiseptics has demonstrated hours of residual bacteriostatic action—even after rinsing.

Plus a unique dispenser developed for performance and durability, and engineered to prevent contamination. Each product is available in hermetically sealed, disposable cartridges with an integral dispensing nozzle —a unique combination designed to prevent bacterial contamination.

For complete technical information, call your local Airwick Professional Products representative. We've been serving health care for more than 35 years. EpiCare...because protecting your nurses may be the best way to protect your patients.

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The Solutions

Years of research and clinical experience confirm the efficacy of CIDEX* Solutions and their safety on instruments of all kinds. No other solutions provide a comparable range of benefits.

Only CIDEX Solutions offer you a 14-day solution, a 28-day solution and a machine concentrate to best fit your needs.

The Systems

Save time, minimize handling and risk of equipment damage, maximize efficiency with the right CIDEX Sterilizing/Disinfecting Tray or Bucket System for *your* job.

The Proof

The two-minute EFFECTIVENESS TEST KITS add a special dimension of safety to your total patient care system.

SURGIKOS

SURGIKOS, INC., ARLINGTON, TEXAS 76010

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