**AF:LX**

**PRESCRIBING INFORMATION**

# ANCEF®

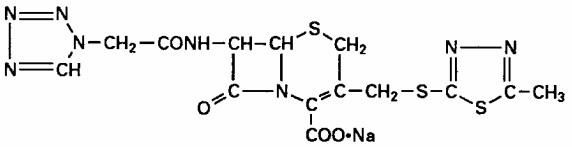
## cefazolin for injection

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ANCEF (cefazolin for injection) and other antibacterial drugs, ANCEF should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

## DESCRIPTION

ANCEF is a semi-synthetic cephalosporin for parenteral administration. It is the sodium salt of 3-{[(5-methyl-1,3,4-thiadiazol-2-yl)thio]-methyl}-8-oxo-7-[2-(1H-tetrazol-1-yl) acetamido]-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylic acid.

Structural Formula:




Each vial contains 48 mg of sodium/1 gram of cefazolin sodium.

ANCEF in lyophilized form is supplied in vials equivalent to 1 gram of cefazolin; in "Piggyback" Vials for intravenous admixture equivalent to 1 gram of cefazolin; and in Pharmacy Bulk Vials equivalent to 10 grams of cefazolin.

## CLINICAL PHARMACOLOGY

After intramuscular administration of ANCEF to normal volunteers, the mean serum concentrations were 37 mcg/mL at 1 hour and 3 mcg/mL at 8 hours following a 500-mg dose, and 64 mcg/mL at 1 hour and 7 mcg/mL at 8 hours following a 1-gram dose.

Studies have shown that following intravenous administration of ANCEF to normal volunteers, mean serum concentrations peaked at approximately 185 mcg/mL and were approximately 4 mcg/mL at 8 hours for a 1-gram dose.

The serum half-life for ANCEF is approximately 1.8 hours following IV administration and approximately 2.0 hours following IM administration.

In a study (using normal volunteers) of constant intravenous infusion with dosages of 3.5 mg/kg for 1 hour (approximately 250 mg) and 1.5 mg/kg the next 2 hours (approximately 100 mg), ANCEF produced a steady serum level at the third hour of approximately 28 mcg/mL.

Studies in patients hospitalized with infections indicate that ANCEF produces mean peak serum levels approximately equivalent to those seen in normal volunteers.

Bile levels in patients without obstructive biliary disease can reach or exceed serum levels by up to 5 times; however, in patients with obstructive biliary disease, bile levels of ANCEF are considerably lower than serum levels (< 1.0 mcg/mL).

In synovial fluid, the level of ANCEF becomes comparable to that reached in serum at about 4 hours after drug administration.

Studies of cord blood show prompt transfer of ANCEF across the placenta. ANCEF is present in very low concentrations in the milk of nursing mothers.

ANCEF is excreted unchanged in the urine. In the first 6 hours approximately 60% of the drug is excreted in the urine and this increases to 70% to 80% within 24 hours. ANCEF achieves peak urine concentrations of approximately 2,400 mcg/mL and 4,000 mcg/mL respectively following 500-mg and 1-gram intramuscular doses.

In patients undergoing peritoneal dialysis (2 L/hr.), ANCEF produced mean serum levels of approximately 10 and 30 mcg/mL after 24 hours' instillation of a dialyzing solution containing 50 mg/L and 150 mg/L, respectively. Mean peak levels were 29 mcg/mL (range 13 to 44 mcg/mL) with 50 mg/L (3 patients), and 72 mcg/mL (range 26 to 142 mcg/mL) with 150 mg/L (6 patients). Intraperitoneal administration of ANCEF is usually well tolerated.

Controlled studies on adult normal volunteers, receiving 1 gram 4 times a day for 10 days, monitoring CBC, SGOT, SGPT, bilirubin, alkaline phosphatase, BUN, creatinine, and urinalysis, indicated no clinically significant changes attributed to ANCEF.

**Microbiology:** In vitro tests demonstrate that the bactericidal action of cephalosporins results from inhibition of cell wall synthesis. ANCEF is active against the following organisms in vitro and in clinical infections:

*Staphylococcus aureus* (including penicillinase-producing strains)
*Staphylococcus epidermidis*
Methicillin-resistant staphylococci are uniformly resistant to cefazolin
Group A beta-hemolytic streptococci and other strains of streptococci (many strains of enterococci are resistant)
*Streptococcus pneumoniae*
*Escherichia coli*
*Proteus mirabilis*
*Klebsiella species*
*Enterobacter aerogenes*
*Haemophilus influenzae*

Most strains of indole positive Proteus (*Proteus vulgaris*), *Enterobacter cloacae*, *Morganella morganii*, and *Providencia rettgeri* are resistant. *Serratia, Pseudomonas, Mima, Herellea* species are almost uniformly resistant to cefazolin.

**Disk Susceptibility Tests: *Disk Diffusion Technique:*** Quantitative methods that require measurement of zone diameters give the most precise estimates of antibiotic susceptibility. One such procedure[1] has been recommended for use with disks to test susceptibility to cefazolin.

Reports from a laboratory using the standardized single-disk susceptibility test[1] with a 30-mcg cefazolin disk should be interpreted according to the following criteria:

Susceptible organisms produce zones of 18 mm or greater, indicating that the tested organism is likely to respond to therapy.

Organisms of intermediate susceptibility produce zones 15 to 17 mm, indicating that the tested organism would be susceptible if high dosage is used or if the infection is confined to tissues and fluids (e.g., urine), in which high antibiotic levels are attained.

Resistant organisms produce zones of 14 mm or less, indicating that other therapy should be selected.

For gram-positive isolates, a zone of 18 mm is indicative of a cefazolin-susceptible organism when tested with either the cephalosporin-class disk (30 mcg cephalothin) or the cefazolin disk (30 mcg cefazolin).

Gram-negative organisms should be tested with the cefazolin disk (using the above criteria), since cefazolin has been shown by in vitro tests to have activity against certain strains of Enterobacteriaceae found resistant when tested with the cephalothin disk. Gram-negative organisms having zones of less than 18 mm around the cephalothin disk may be susceptible to cefazolin.

Standardized procedures require use of control organisms. The 30-mcg cefazolin disk should give zone diameter between 23 and 29 mm for *E. coli* ATCC 25922 and between 29 and 35 mm for *S. aureus* ATCC 25923.

The cefazolin disk should not be used for testing susceptibility to other cephalosporins.

***Dilution Techniques:*** A bacterial isolate may be considered susceptible if the minimal inhibitory concentration (MIC) for cefazolin is not more than 16 mcg per mL. Organisms are considered resistant if the MIC is equal to or greater than 64 mcg per mL.

The range of MICs for the control strains are as follows:

*S. aureus* ATCC 25923, 0.25 to 1.0 mcg/mL

*E. coli* ATCC 25922, 1.0 to 4.0 mcg/mL

## INDICATIONS AND USAGE

ANCEF is indicated in the treatment of the following serious infections due to susceptible organisms:

**Respiratory Tract Infections:** Due to *S. pneumoniae, Klebsiella* species, *H. influenzae, S. aureus* (penicillin-sensitive and penicillin-resistant), and group A beta-hemolytic streptococci.

Injectable benzathine penicillin is considered to be the drug of choice in treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever.

ANCEF is effective in the eradication of streptococci from the nasopharynx; however, data establishing the efficacy of ANCEF in the subsequent prevention of rheumatic fever are not available at present.

**Urinary Tract Infections:** Due to *E. coli, P. mirabilis, Klebsiella* species, and some strains of enterobacter and enterococci.

**Skin and Skin Structure Infections:** Due to *S. aureus* (penicillin-sensitive and penicillin-resistant), group A beta-hemolytic streptococci, and other strains of streptococci.

**Biliary Tract Infections:** Due to *E. coli,* various strains of streptococci, *P. mirabilis, Klebsiella* species, and *S. aureus.*

**Bone and Joint Infections:** Due to *S. aureus*.

**Genital Infections:** (i.e., prostatitis, epididymitis) due to *E. coli*, *P. mirabilis*, *Klebsiella* species, and some strains of enterococci.

**Septicemia:** Due to *S. pneumoniae*, *S. aureus* (penicillin-sensitive and penicillin-resistant), *P. mirabilis*, *E. coli*, and *Klebsiella* species.

**Endocarditis:** Due to *S. aureus* (penicillin-sensitive and penicillin-resistant) and group A beta-hemolytic streptococci.

**Perioperative Prophylaxis:** The prophylactic administration of ANCEF preoperatively, intraoperatively, and postoperatively may reduce the incidence of certain postoperative infections in patients undergoing surgical procedures which are classified as contaminated or potentially contaminated (e.g., vaginal hysterectomy, and cholecystectomy in high-risk patients such as those older than 70 years , with acute cholecystitis, obstructive jaundice, or common duct bile stones).

The perioperative use of ANCEF may also be effective in surgical patients in whom infection at the operative site would present a serious risk (e.g., during open-heart surgery and prosthetic arthroplasty).

The prophylactic administration of ANCEF should usually be discontinued within a 24-hour period after the surgical procedure. In surgery where the occurrence of infection may be particularly devastating (e.g., open-heart surgery and prosthetic arthroplasty), the prophylactic administration of ANCEF may be continued for 3 to 5 days following the completion of surgery.

If there are signs of infection, specimens for cultures should be obtained for the identification of the causative organism so that appropriate therapy may be instituted.

(See DOSAGE AND ADMINISTRATION.)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ANCEF and other antibacterial drugs, ANCEF should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

## CONTRAINDICATIONS

ANCEF IS CONTRAINDICATED IN PATIENTS WITH KNOWN ALLERGY TO THE CEPHALOSPORIN GROUP OF ANTIBIOTICS.

## WARNINGS

BEFORE THERAPY WITH ANCEF IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEFAZOLIN, CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-HYPERSENSITIVITY AMONG BETA-LACTAM ANTIBIOTICS HAS BEEN

CLEARLY DOCUMENTED AND MAY OCCUR IN UP TO 10% OF PATIENTS WITH A HISTORY OF PENICILLIN ALLERGY. IF AN ALLERGIC REACTION TO ANCEF OCCURS, DISCONTINUE TREATMENT WITH THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, IV FLUIDS, IV ANTIHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED.

**Pseudomembranous colitis has been reported with nearly all antibacterial agents, including cefazolin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.**

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of "antibiotic-associated colitis."

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an oral antibacterial drug clinically effective against *C. difficile* colitis.

## PRECAUTIONS

**General:** Prolonged use of ANCEF may result in the overgrowth of nonsusceptible organisms. Careful clinical observation of the patient is essential.

When ANCEF is administered to patients with low urinary output because of impaired renal function, lower daily dosage is required (see DOSAGE AND ADMINISTRATION).

As with other β-lactam antibiotics, seizures may occur if inappropriately high doses are administered to patients with impaired renal function (see DOSAGE AND ADMINISTRATION).

ANCEF, as with all cephalosporins, should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Cephalosporins may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

Prescribing ANCEF in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

**Drug Interactions:** Probenecid may decrease renal tubular secretion of cephalosporins when used concurrently, resulting in increased and more prolonged cephalosporin blood levels.

**Drug/Laboratory Test Interactions:** A false positive reaction for glucose in the urine may occur with Benedict's solution, Fehling's solution or with CLINITEST® tablets, but not with enzyme-based tests such as CLINISTIX®.

Positive direct and indirect antiglobulin (Coombs) tests have occurred; these may also occur in neonates whose mothers received cephalosporins before delivery.

**Information for Patients:** Patients should be counseled that antibacterial drugs including ANCEF, should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When ANCEF is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may: (1) decrease the effectiveness of the immediate treatment, and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by ANCEF or other antibacterial drugs in the future.

**Carcinogenesis/Mutagenesis:** Mutagenicity studies and long-term studies in animals to determine the carcinogenic potential of ANCEF have not been performed.

**Pregnancy: *Teratogenic Effects:*** Pregnancy Category B. Reproduction studies have been performed in rats, mice, and rabbits at doses up to 25 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to ANCEF. There are, however, no adequate and 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.

**Labor and Delivery:** When cefazolin has been administered prior to caesarean section, drug levels in cord blood have been approximately one quarter to one third of maternal drug levels. The drug appears to have no adverse effect on the fetus.

**Nursing Mothers:** ANCEF is present in very low concentrations in the milk of nursing mothers. Caution should be exercised when ANCEF is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness for use in premature infants and neonates have not been established. See DOSAGE AND ADMINISTRATION for recommended dosage in pediatric patients older than 1 month.

**Geriatric Use:** Of the 920 subjects who received ANCEF in clinical studies, 313 (34%) were 65 years and over, while 138 (15%) were 75 years and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (see PRECAUTIONS, General and DOSAGE and ADMINISTRATION).

## ADVERSE REACTIONS

The following reactions have been reported:

**Gastrointestinal:** Diarrhea, oral candidiasis (oral thrush), vomiting, nausea, stomach cramps, anorexia, and pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment (see WARNINGS). Nausea and vomiting have been reported rarely.

**Allergic:** Anaphylaxis, eosinophilia, itching, drug fever, skin rash, Stevens-Johnson syndrome.

**Hematologic:** Neutropenia, leukopenia, thrombocytopenia, thrombocythemia.

**Hepatic:** Transient rise in SGOT, SGPT, and alkaline phosphatase levels has been observed. As with other cephalosporins, reports of hepatitis have been received.

**Renal:** As with other cephalosporins, reports of increased BUN and creatinine levels, as well as renal failure, have been received.

**Local Reactions:** Rare instances of phlebitis have been reported at site of injection. Pain at the site of injection after intramuscular administration has occurred infrequently. Some induration has occurred.

**Other Reactions:** Genital and anal pruritus (including vulvar pruritus, genital moniliasis, and vaginitis).

## DOSAGE AND ADMINISTRATION

**Usual Adult Dosage:**

| Type of Infection | Dose | Frequency |
|---|---|---|
| Moderate to severe infections | 500 mg to 1 gram | every 6 to 8 hrs. |
| Mild infections caused by susceptible gram-positive cocci | 250 mg to 500 mg | every 8 hours |
| Acute, uncomplicated urinary tract infections | 1 gram | every 12 hours |
| Pneumococcal pneumonia | 500 mg | every 12 hours |
| Severe, life-threatening infections (e.g., endocarditis, septicemia)* | 1 gram to 1.5 grams | every 6 hours |

*In rare instances, doses of up to 12 grams of ANCEF per day have been used.

**Perioperative Prophylactic Use:** To prevent postoperative infection in contaminated or potentially contaminated surgery, recommended doses are:

a. 1 gram IV or IM administered $^1/_2$ hour to 1 hour prior to the start of surgery.
b. For lengthy operative procedures (e.g., 2 hours or more), 500 mg to 1 gram IV or IM during surgery (administration modified depending on the duration of the operative procedure).
c. 500 mg to 1 gram IV or IM every 6 to 8 hours for 24 hours postoperatively.

It is important that (1) the preoperative dose be given just ($^1/_2$ to 1 hour) prior to the start of surgery so that adequate antibiotic levels are present in the serum and tissues at the time of initial surgical incision; and (2) ANCEF be administered, if necessary, at appropriate intervals during

surgery to provide sufficient levels of the antibiotic at the anticipated moments of greatest exposure to infective organisms.

In surgery where the occurrence of infection may be particularly devastating (e.g., open-heart surgery and prosthetic arthroplasty), the prophylactic administration of ANCEF may be continued for 3 to 5 days following the completion of surgery.

**Dosage Adjustment for Patients With Reduced Renal Function:** ANCEF may be used in patients with reduced renal function with the following dosage adjustments: Patients with a creatinine clearance of 55 mL/min. or greater or a serum creatinine of 1.5 mg % or less can be given full doses. Patients with creatinine clearance rates of 35 to 54 mL/min. or serum creatinine of 1.6 to 3.0 mg % can also be given full doses but dosage should be restricted to at least 8 hour intervals. Patients with creatinine clearance rates of 11 to 34 mL/min. or serum creatinine of 3.1 to 4.5 mg % should be given $^1/_2$ the usual dose every 12 hours. Patients with creatinine clearance rates of 10 mL/min. or less or serum creatinine of 4.6 mg % or greater should be given $^1/_2$ the usual dose every 18 to 24 hours. All reduced dosage recommendations apply after an initial loading dose appropriate to the severity of the infection. Patients undergoing peritoneal dialysis: See CLINICAL PHARMACOLOGY.

**Pediatric Dosage:** In pediatric patients, a total daily dosage of 25 to 50 mg per kg (approximately 10 to 20 mg per pound) of body weight, divided into 3 or 4 equal doses, is effective for most mild to moderately severe infections. Total daily dosage may be increased to 100 mg per kg (45 mg per pound) of body weight for severe infections. Since safety for use in premature infants and in neonates has not been established, the use of ANCEF in these patients is not recommended.

**Pediatric Dosage Guide**

| **Weight** | | **25 mg/kg/day Divided into 3 Doses** | | **25 mg/kg/day Divided into 4 Doses** | |
|---|---|---|---|---|---|
| Lbs | Kg | Approximate Single Dose mg/q8h | Vol. (mL) needed with dilution of 125 mg/mL | Approximate Single Dose mg/q6h | Vol. (mL) needed with dilution of 125 mg/mL |
| 10 | 4.5 | 40 mg | 0.35 mL | 30 mg | 0.25 mL |
| 20 | 9.0 | 75 mg | 0.60 mL | 55 mg | 0.45 mL |
| 30 | 13.6 | 115 mg | 0.90 mL | 85 mg | 0.70 mL |
| 40 | 18.1 | 150 mg | 1.20 mL | 115 mg | 0.90 mL |
| 50 | 22.7 | 190 mg | 1.50 mL | 140 mg | 1.10 mL |

| Weight | | 50 mg/kg/day Divided into 3 Doses | | 50 mg/kg/day Divided into 4 Doses | |
|---|---|---|---|---|---|
| Lbs | Kg | Approximate Single Dose mg/q8h | Vol. (mL) needed with dilution of 225 mg/mL | Approximate Single Dose mg/q6h | Vol. (mL) needed with dilution of 225 mg/mL |
| 10 | 4.5 | 75 mg | 0.35 mL | 55 mg | 0.25 mL |
| 20 | 9.0 | 150 mg | 0.70 mL | 110 mg | 0.50 mL |
| 30 | 13.6 | 225 mg | 1.00 mL | 170 mg | 0.75 mL |
| 40 | 18.1 | 300 mg | 1.35 mL | 225 mg | 1.00 mL |
| 50 | 22.7 | 375 mg | 1.70 mL | 285 mg | 1.25 mL |

In pediatric patients with mild to moderate renal impairment (creatinine clearance of 70 to 40 mL/min.), 60 percent of the normal daily dose given in equally divided doses every 12 hours should be sufficient. In patients with moderate impairment (creatinine clearance of 40 to 20 mL/min.), 25 percent of the normal daily dose given in equally divided doses every 12 hours should be adequate. Pediatric patients with severe renal impairment (creatinine clearance of 20 to 5 mL/min.) may be given 10 percent of the normal daily dose every 24 hours. All dosage recommendations apply after an initial loading dose.

## RECONSTITUTION

**Preparation of Parenteral Solution:** Parenteral drug products should be SHAKEN WELL when reconstituted, and inspected visually for particulate matter prior to administration. If particulate matter is evident in reconstituted fluids, the drug solutions should be discarded.

When reconstituted or diluted according to the instructions below, ANCEF is stable for 24 hours at room temperature or for 10 days if stored under refrigeration (5°C or 41°F). Reconstituted solutions may range in color from pale yellow to yellow without a change in potency.

**Single-Dose Vials:** For IM injection, IV direct (bolus) injection or IV infusion, reconstitute with Sterile Water for Injection according to the following table. SHAKE WELL.

| Vial Size | Amount of Diluent | Approximate Concentration | Approximate Available Volume |
|---|---|---|---|
| 1 gram | 2.5 mL | 330 mg/mL | 3.0 mL |

**Pharmacy Bulk Vials:** Add Sterile Water for Injection, Bacteriostatic Water for Injection, or Sodium Chloride Injection according to the table below. SHAKE WELL. Use promptly. (Discard vial within 4 hours after initial entry.)

| Vial Size | Amount of Diluent | Approximate Concentration | Approximate Available Volume |
|---|---|---|---|
| 10 grams | 45 mL | 1 gram/5 mL | 51 mL |
| | 96 mL | 1 gram/10 mL | 102 mL |

**"Piggyback" Vials:** Reconstitute with 50 to 100 mL of Sodium Chloride Injection or other IV solution listed under ADMINISTRATION. When adding diluent to vial, allow air to escape by using a small vent needle or by pumping the syringe. SHAKE WELL. Administer with primary IV fluids, as a single dose.

## ADMINISTRATION

**Intramuscular Administration:** Reconstitute vials with Sterile Water for Injection according to the dilution table above. Shake well until dissolved. ANCEF should be injected into a large muscle mass. Pain on injection is infrequent with ANCEF.

**Intravenous Administration:** Direct (bolus) injection: Following reconstitution according to the above table, further dilute vials with approximately 5 mL Sterile Water for Injection. Inject the solution slowly over 3 to 5 minutes, directly or through tubing for patients receiving parenteral fluids (see list below).

Intermittent or continuous infusion: Dilute reconstituted ANCEF in 50 to 100 mL of 1 of the following solutions:

Sodium Chloride Injection, USP
5% or 10% Dextrose Injection, USP
5% Dextrose in Lactated Ringer's Injection, USP
5% Dextrose and 0.9% Sodium Chloride Injection, USP
5% Dextrose and 0.45% Sodium Chloride Injection, USP
5% Dextrose and 0.2% Sodium Chloride Injection, USP
Lactated Ringer's Injection, USP
Invert Sugar 5% or 10% in Sterile Water for Injection
Ringer's Injection, USP
5% Sodium Bicarbonate Injection, USP

## HOW SUPPLIED

ANCEF

Each vial contains cefazolin sodium equivalent to 1 gram of cefazolin.

NDC 0007-3130-16 (package of 25 vials)

Each vial contains cefazolin sodium equivalent to 1 gram of cefazolin.

NDC 0007-3137-05 (package of 10 "piggyback" vials)

As with other cephalosporins, ANCEF tends to darken depending on storage conditions; within the stated recommendations, however, product potency is not adversely affected.

Before reconstitution protect from light and store at Controlled Room Temperature 20° to 25°C (68° to 77°F).

## REFERENCE

1. Bauer, A.W.; Kirby, W.M.M.; Sherris, J.C., and Turck, M.: Antibiotic Testing by a Standardized Single Disc Method, Am. J. Clin. Path. 45:493, 1966. Standardized Disc Susceptibility Test, Federal Register 39:19182-19184, 1974.

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Month Year AF:LX