

ANCEF[®]

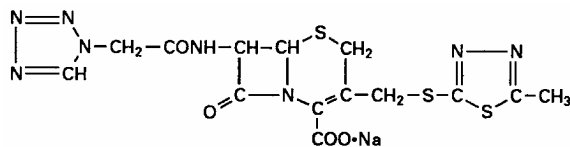
cefazolin for injection

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).

36 In synovial fluid, the level of ANCEF becomes comparable to that reached in serum at about
37 4 hours after drug administration.

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

40 ANCEF is excreted unchanged in the urine. In the first 6 hours approximately 60% of the drug
41 is excreted in the urine and this increases to 70% to 80% within 24 hours. ANCEF achieves peak
42 urine concentrations of approximately 2,400 mcg/mL and 4,000 mcg/mL respectively following
43 500-mg and 1-gram intramuscular doses.

44 In patients undergoing peritoneal dialysis (2 L/hr.), ANCEF produced mean serum levels of
45 approximately 10 and 30 mcg/mL after 24 hours' instillation of a dialyzing solution containing
46 50 mg/L and 150 mg/L, respectively. Mean peak levels were 29 mcg/mL (range 13 to
47 44 mcg/mL) with 50 mg/L (3 patients), and 72 mcg/mL (range 26 to 142 mcg/mL) with
48 150 mg/L (6 patients). Intraperitoneal administration of ANCEF is usually well tolerated.

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

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

55 *Staphylococcus aureus* (including penicillinase-producing strains)

56 *Staphylococcus epidermidis*

57 Methicillin-resistant staphylococci are uniformly resistant to cefazolin

58 Group A beta-hemolytic streptococci and other strains of streptococci (many strains of
59 enterococci are resistant)

60 *Streptococcus pneumoniae*

61 *Escherichia coli*

62 *Proteus mirabilis*

63 *Klebsiella species*

64 *Enterobacter aerogenes*

65 *Haemophilus influenzae*

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

69 **Disk Susceptibility Tests: Disk Diffusion Technique:** Quantitative methods that require
70 measurement of zone diameters give the most precise estimates of antibiotic susceptibility. One
71 such procedure¹ has been recommended for use with disks to test susceptibility to cefazolin.

72 Reports from a laboratory using the standardized single-disk susceptibility test¹ with a 30-mcg
73 cefazolin disk should be interpreted according to the following criteria:

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

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

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

81 For gram-positive isolates, a zone of 18 mm is indicative of a cefazolin-susceptible organism
82 when tested with either the cephalosporin-class disk (30 mcg cephalothin) or the cefazolin disk
83 (30 mcg cefazolin).

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

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

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

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

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

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

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

99 INDICATIONS AND USAGE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

137 (See [DOSAGE AND ADMINISTRATION.](#))

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

144 **CONTRAINDICATIONS**

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

147 **WARNINGS**

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

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

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

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

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

173 **PRECAUTIONS**

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

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

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

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

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

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

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

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

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

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

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

208 **Pregnancy: Teratogenic Effects:** Pregnancy Category B. Reproduction studies have been
209 performed in rats, mice, and rabbits at doses up to 25 times the human dose and have revealed no
210 evidence of impaired fertility or harm to the fetus due to ANCEF. There are, however, no
211 adequate and well-controlled studies in pregnant women. Because animal reproduction studies
212 are not always predictive of human response, this drug should be used during pregnancy only if
213 clearly needed.

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

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

219 **Pediatric Use:** Safety and effectiveness for use in premature infants and neonates have not
220 been established. See [DOSAGE AND ADMINISTRATION](#) for recommended dosage in
221 pediatric patients older than 1 month.

222 **Geriatric Use:** Of the 920 subjects who received ANCEF in clinical studies, 313 (34%) were
223 65 years and over, while 138 (15%) were 75 years and over. No overall differences in safety or
224 effectiveness were observed between these subjects and younger subjects. Other reported clinical
225 experience has not identified differences in responses between the elderly and younger patients,
226 but greater sensitivity of some older individuals cannot be ruled out.

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

232 **ADVERSE REACTIONS**

233 The following reactions have been reported:

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

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

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

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

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

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

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

249 **DOSAGE AND ADMINISTRATION**

250 **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

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

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

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

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

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

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

266 **Dosage Adjustment for Patients With Reduced Renal Function:** ANCEF may be used
 267 in patients with reduced renal function with the following dosage adjustments: Patients with a
 268 creatinine clearance of 55 mL/min. or greater or a serum creatinine of 1.5 mg % or less can be
 269 given full doses. Patients with creatinine clearance rates of 35 to 54 mL/min. or serum creatinine
 270 of 1.6 to 3.0 mg % can also be given full doses but dosage should be restricted to at least 8 hour
 271 intervals. Patients with creatinine clearance rates of 11 to 34 mL/min. or serum creatinine of 3.1
 272 to 4.5 mg % should be given $\frac{1}{2}$ the usual dose every 12 hours. Patients with creatinine clearance
 273 rates of 10 mL/min. or less or serum creatinine of 4.6 mg % or greater should be given $\frac{1}{2}$ the
 274 usual dose every 18 to 24 hours. All reduced dosage recommendations apply after an initial
 275 loading dose appropriate to the severity of the infection. Patients undergoing peritoneal dialysis:
 276 See [CLINICAL PHARMACOLOGY](#).

277 **Pediatric Dosage:** In pediatric patients, a total daily dosage of 25 to 50 mg per kg
 278 (approximately 10 to 20 mg per pound) of body weight, divided into 3 or 4 equal doses, is
 279 effective for most mild to moderately severe infections. Total daily dosage may be increased to
 280 100 mg per kg (45 mg per pound) of body weight for severe infections. Since safety for use in
 281 premature infants and in neonates has not been established, the use of ANCEF in these patients is
 282 not recommended.

Pediatric Dosage Guide					
Weight		25 mg/kg/day		25 mg/kg/day	
		Divided into 3 Doses		Divided into 4 Doses	
Lbs	Kg	Approximate Single Dose mg/q8h	Vol. (mL)	Approximate Single Dose mg/q6h	Vol. (mL)
			needed with dilution of 125 mg/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		50 mg/kg/day	
		Divided into 3 Doses		Divided into 4 Doses	
Lbs	Kg	Approximate Single Dose mg/q8h	Vol. (mL)	Approximate Single Dose mg/q6h	Vol. (mL)
			needed with dilution of 225 mg/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

284 In pediatric patients with mild to moderate renal impairment (creatinine clearance of 70 to
285 40 mL/min.), 60 percent of the normal daily dose given in equally divided doses every 12 hours
286 should be sufficient. In patients with moderate impairment (creatinine clearance of 40 to
287 20 mL/min.), 25 percent of the normal daily dose given in equally divided doses every 12 hours
288 should be adequate. Pediatric patients with severe renal impairment (creatinine clearance of 20 to
289 5 mL/min.) may be given 10 percent of the normal daily dose every 24 hours. All dosage
290 recommendations apply after an initial loading dose.

291 **RECONSTITUTION**

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

295 When reconstituted or diluted according to the instructions below, ANCEF is stable for
296 24 hours at room temperature or for 10 days if stored under refrigeration (5°C or 41°F).
297 Reconstituted solutions may range in color from pale yellow to yellow without a change in
298 potency.

299 **Single-Dose Vials:** For IM injection, IV direct (bolus) injection or IV infusion, reconstitute
300 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

301 **Pharmacy Bulk Vials:** Add Sterile Water for Injection, Bacteriostatic Water for Injection, or
302 Sodium Chloride Injection according to the table below. SHAKE WELL. Use promptly.
303 (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

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

308 **ADMINISTRATION**

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

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

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

- 318 Sodium Chloride Injection, USP
- 319 5% or 10% Dextrose Injection, USP
- 320 5% Dextrose in Lactated Ringer’s Injection, USP
- 321 5% Dextrose and 0.9% Sodium Chloride Injection, USP
- 322 5% Dextrose and 0.45% Sodium Chloride Injection, USP
- 323 5% Dextrose and 0.2% Sodium Chloride Injection, USP
- 324 Lactated Ringer’s Injection, USP
- 325 Invert Sugar 5% or 10% in Sterile Water for Injection
- 326 Ringer’s Injection, USP
- 327 5% Sodium Bicarbonate Injection, USP

328 **HOW SUPPLIED**

329 ANCEF

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

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

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

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

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

336 Before reconstitution protect from light and store at Controlled Room Temperature 20° to
337 25°C (68° to 77°F).

338 **REFERENCE**

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

342

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344 CLINITEST is a registered trademark of Miles, Inc.
345 CLINISTIX is a registered trademark of Bayer Corporation.
346



GlaxoSmithKline

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