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3 **PRESCRIBING INFORMATION**

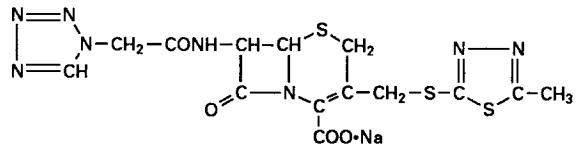
4 **ANCEF®**

5 **cefazolin for injection**

6 **DESCRIPTION**

7 Ancef (cefazolin for injection) is a semi-synthetic cephalosporin for parenteral administration. It
8 is the sodium salt of 3-{[(5-methyl-1,3,4-thiadiazol-2-yl)thio]-methyl}-8-oxo-7-[2-(1H-tetrazol-
9 1-yl) acetamido]-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylic acid.

10 Structural Formula:



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

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

21 **CLINICAL PHARMACOLOGY**

22 **Human Pharmacology:** After intramuscular administration of *Ancef* to normal volunteers, the
23 mean serum concentrations were 37 mcg/mL at 1 hour and 3 mcg/mL at 8 hours following a
24 500 mg dose, and 64 mcg/mL at 1 hour and 7 mcg/mL at 8 hours following a 1 gram dose.

25 Studies have shown that following intravenous administration of *Ancef* to normal volunteers,
26 mean serum concentrations peaked at approximately 185 mcg/mL and were approximately
27 4 mcg/mL at 8 hours for a 1 gram dose.

28 The serum half-life for *Ancef* is approximately 1.8 hours following I.V. administration and
29 approximately 2.0 hours following I.M. administration.

30 In a study (using normal volunteers) of constant intravenous infusion with dosages of 3.5 mg/kg
31 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.

32 Studies in patients hospitalized with infections indicate that Ancef (cefazolin for injection)
33 produces mean peak serum levels approximately equivalent to those seen in normal volunteers.

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

34 In synovial fluid, the *Ancef* level becomes comparable to that reached in serum at about 4 hours
35 after drug administration.

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

38 *Ancef* is excreted unchanged in the urine. In the first 6 hours approximately 60% of the drug is
39 excreted in the urine and this increases to 70% to 80% within 24 hours. *Ancef* achieves peak
40 urine concentrations of approximately 2400 mcg/mL and 4000 mcg/mL respectively following
41 500 mg and 1 gram intramuscular doses.

42 In patients undergoing peritoneal dialysis (2 l/hr.), *Ancef* produced mean serum levels of
43 approximately 10 and 30 mcg/mL after 24 hours' instillation of a dialyzing solution containing
44 50 mg/l and 150 mg/l, respectively. Mean peak levels were 29 mcg/mL (range 13-44 mcg/mL)
45 with 50 mg/l (three patients), and 72 mcg/mL (range 26-142 mcg/mL) with 150 mg/l (six
46 patients). Intraperitoneal administration of *Ancef* is usually well tolerated.

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

50 **Microbiology:** *In vitro* tests demonstrate that the bactericidal action of cephalosporins results
51 from inhibition of cell wall synthesis. *Ancef* (cefazolin for injection) is active against the
52 following organisms *in vitro* and in clinical infections:

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

54 *Staphylococcus epidermidis*

55 Methicillin-resistant staphylococci are uniformly resistant to cefazolin

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

58 *Streptococcus pneumoniae*

59 *Escherichia coli*

60 *Proteus mirabilis*

61 *Klebsiella species*

62 *Enterobacter aerogenes*

63 *Haemophilus influenzae*

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

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

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

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

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

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

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

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

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

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

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

94 The range of MIC's for the control strains are as follows:

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

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

97 **INDICATIONS AND USAGE**

98 *Ancef* (cefazolin for injection) is indicated in the treatment of the following serious infections
99 due to susceptible organisms:

100 RESPIRATORY TRACT INFECTIONS due to *Streptococcus pneumoniae*, *Klebsiella* species,
101 *Haemophilus influenzae*, *Staphylococcus aureus* (penicillin-sensitive and penicillin-resistant) and
102 group A beta-hemolytic streptococci.

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

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

108 URINARY TRACT INFECTIONS due to *Escherichia coli*, *Proteus mirabilis*, *Klebsiella* species
109 and some strains of enterobacter and enterococci.

110 SKIN AND SKIN STRUCTURE INFECTIONS due to *Staphylococcus aureus*
111 (penicillin-sensitive and penicillin-resistant), group A beta-hemolytic streptococci and other
112 strains of streptococci.

113 BILIARY TRACT INFECTIONS due to *Escherichia coli*, various strains of streptococci,
114 *Proteus mirabilis*, *Klebsiella* species and *Staphylococcus aureus*.

115 BONE AND JOINT INFECTIONS due to *Staphylococcus aureus*.

116 GENITAL INFECTIONS (i.e., prostatitis, epididymitis) due to *Escherichia coli*, *Proteus*
117 *mirabilis*, *Klebsiella* species and some strains of enterococci.

118 SEPTICEMIA due to *Streptococcus pneumoniae*, *Staphylococcus aureus* (penicillin-sensitive
119 and penicillin-resistant), *Proteus mirabilis*, *Escherichia coli* and *Klebsiella* species.

120 ENDOCARDITIS due to *Staphylococcus aureus* (penicillin-sensitive and penicillin-resistant)
121 and group A beta-hemolytic streptococci.

122 Appropriate culture and susceptibility studies should be performed to determine susceptibility of
123 the causative organism to *Ancef*.

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

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

133 The prophylactic administration of *Ancef* should usually be discontinued within a 24-hour period
134 after the surgical procedure. In surgery where the occurrence of infection may be particularly

135 devastating (e.g., open-heart surgery and prosthetic arthroplasty), the prophylactic administration
136 of *Ancef* may be continued for 3 to 5 days following the completion of surgery.

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

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

140 **CONTRAINDICATIONS**

141 ANCEF (CEFAZOLIN FOR INJECTION) IS CONTRAINDICATED IN PATIENTS WITH
142 KNOWN ALLERGY TO THE CEPHALOSPORIN GROUP OF ANTIBIOTICS.

143 **WARNINGS**

144 BEFORE THERAPY WITH ANCEF IS INSTITUTED, CAREFUL INQUIRY SHOULD BE
145 MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS
146 HYPERSENSITIVITY REACTIONS TO CEFAZOLIN, CEPHALOSPORINS, PENICILLINS,
147 OR OTHER DRUGS. IF THIS PRODUCT IS GIVEN TO PENICILLIN-SENSITIVE
148 PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE
149 CROSS-HYPERSENSITIVITY AMONG BETA-LACTAM ANTIBIOTICS HAS BEEN
150 CLEARLY DOCUMENTED AND MAY OCCUR IN UP TO 10% OF PATIENTS WITH A
151 HISTORY OF PENICILLIN ALLERGY. IF AN ALLERGIC REACTION TO ANCEF
152 OCCURS, DISCONTINUE TREATMENT WITH THE DRUG. SERIOUS ACUTE
153 HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE
154 AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, IV FLUIDS, IV
155 ANTIHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES AND AIRWAY
156 MANAGEMENT, AS CLINICALLY INDICATED.

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

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

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

169 **PRECAUTIONS**

170 **General:** Prolonged use of Ancef (cefazolin for injection) may result in the overgrowth of
171 nonsusceptible organisms. Careful clinical observation of the patient is essential.

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

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

177 *Ancef*, as with all cephalosporins, should be prescribed with caution in individuals with a history
178 of gastrointestinal disease, particularly colitis.

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

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

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

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

191 **Carcinogenesis/Mutagenesis:** Mutagenicity studies and long-term studies in animals to
192 determine the carcinogenic potential of Ancef (cefazolin for injection) have not been performed.

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

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

202 **Nursing Mothers:** Ancef (cefazolin for injection) is present in very low concentrations in the
203 milk of nursing mothers. Caution should be exercised when *Ancef* is administered to a nursing
204 woman.

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

208 **ADVERSE REACTIONS**

209 The following reactions have been reported:

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

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

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

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

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

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

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

225 **DOSAGE AND ADMINISTRATION**

226 **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 + 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

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

228 **Perioperative Prophylactic Use**

229 To prevent postoperative infection in contaminated or potentially contaminated surgery,
230 recommended doses are:

231 a. 1 gram I.V. or I.M. administered $\frac{1}{2}$ hour to 1 hour prior to the start of surgery.

232 b. For lengthy operative procedures (e.g., 2 hours or more), 500 mg to 1 gram I.V. or I.M.
233 during surgery (administration modified depending on the duration of the operative
234 procedure).

235 c. 500 mg to 1 gram I.V. or I.M. every 6 to 8 hours for 24 hours postoperatively.

236 It is important that (1) the preoperative dose be given just ($\frac{1}{2}$ to 1 hour) prior to the start of
237 surgery so that adequate antibiotic levels are present in the serum and tissues at the time of initial
238 surgical incision; and (2) *Ancef* be administered, if necessary, at appropriate intervals during
239 surgery to provide sufficient levels of the antibiotic at the anticipated moments of greatest
240 exposure to infective organisms.

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

Dosage Adjustment for Patients with Reduced Renal Function

244 *Ancef* may be used in patients with reduced renal function with the following dosage
245 adjustments: Patients with a creatinine clearance of 55 mL/min. or greater or a serum creatinine
246 of 1.5 mg % or less can be given full doses. Patients with creatinine clearance rates of 35 to
247 54 mL/min. or serum creatinine of 1.6 to 3.0 mg % can also be given full doses but dosage
248 should be restricted to at least 8 hour intervals. Patients with creatinine clearance rates of 11 to
249 34 mL/min. or serum creatinine of 3.1 to 4.5 mg % should be given $\frac{1}{2}$ the usual dose every
250 12 hours. Patients with creatinine clearance rates of 10 mL/min. or less or serum creatinine of
251 4.6 mg % or greater should be given $\frac{1}{2}$ the usual dose every 18 to 24 hours. All reduced dosage
252 recommendations apply after an initial loading dose appropriate to the severity of the infection.
253 Patients undergoing peritoneal dialysis: See [Human Pharmacology](#).

Pediatric Dosage

254 In pediatric patients, a total daily dosage of 25 to 50 mg per kg (approximately 10 to 20 mg per
255 pound) of body weight, divided into three or four equal doses, is effective for most mild to
256 moderately severe infections. Total daily dosage may be increased to 100 mg per kg (45 mg per
257 pound) of body weight for severe infections. Since safety for use in premature infants and in
258 neonates has not been established, the use of *Ancef* (cefazolin for injection) in these patients is
259 not recommended.

Pediatric Dosage Guide		
	25 mg/kg/Day	25 mg/kg/Day
Weight	Divided into 3 Doses	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

262

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

263 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.

270 RECONSTITUTION

271 Preparation of Parenteral Solution

272 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.

275 When reconstituted or diluted according to the instructions below, Ancef (cefazolin for injection)
276 is stable for 24 hours at room temperature or for 10 days if stored under refrigeration (5°C or
277 41°F). Reconstituted solutions may range in color from pale yellow to yellow without a change
278 in potency.

279 Single-Dose Vials

280 For I.M. injection, I.V. direct (bolus) injection or I.V. infusion, reconstitute with Sterile Water
281 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

282 Pharmacy Bulk Vials

283 Add Sterile Water for Injection, Bacteriostatic Water for Injection or Sodium Chloride Injection
284 according to the table below. SHAKE WELL. Use promptly. (Discard vial within 4 hours after
285 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

286 "Piggyback" Vials

287 Reconstitute with 50 to 100 mL of Sodium Chloride Injection or other I.V. solution listed under
288 ADMINISTRATION. When adding diluent to vial, allow air to escape by using a small vent
289 needle or by pumping the syringe. SHAKE WELL. Administer with primary I.V. fluids, as a
290 single dose.

291 ADMINISTRATION

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

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

299 Intermittent or continuous infusion: Dilute reconstituted *Ancef* in 50 to 100 mL of one of the
300 following solutions:

301 Sodium Chloride Injection, USP

302 5% or 10% Dextrose Injection, USP
303 5% Dextrose in Lactated Ringer's Injection, USP
304 5% Dextrose and 0.9% Sodium Chloride Injection, USP
305 5% Dextrose and 0.45% Sodium Chloride Injection, USP
306 5% Dextrose and 0.2% Sodium Chloride Injection, USP
307 Lactated Ringer's Injection, USP
308 Invert Sugar 5% or 10% in Sterile Water for Injection
309 Ringer's Injection, USP
310 5% Sodium Bicarbonate Injection, USP

311 HOW SUPPLIED

312 Ancef (cefazolin for injection)
313 Each vial contains cefazolin sodium equivalent to 1 gram of cefazolin.
314 NDC 0007-3130-16 (package of 25 vials)
315 Each vial contains cefazolin sodium equivalent to 1 gram of cefazolin.
316 NDC 0007-3137-05 (package of 10 "piggyback" vials)
317 Each vial contains cefazolin sodium equivalent to 10 grams of cefazolin.
318 NDC 0007-3135-05 (package of 10 pharmacy bulk vials)
319 As with other cephalosporins, *Ancef* tends to darken depending on storage conditions; within the
320 stated recommendations, however, product potency is not adversely affected.
321 Before reconstitution protect from light and store at Controlled Room Temperature 20° to 25°C
322 (68° to 77°F).

323 REFERENCE

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

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