CEFAZOLIN FOR INJECTION USP and Dextrose Injection USP

Rx only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefazolin for Injection USP and Dextrose Injection USP and other antibacterial drugs, Cefazolin for Injection USP and Dextrose Injection USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

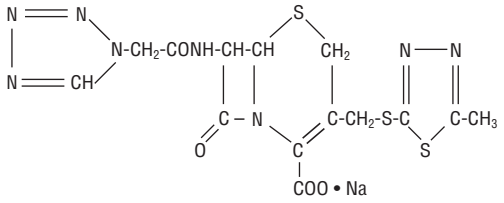
DESCRIPTION

Cefazolin for Injection USP and Dextrose Injection USP is a sterile, nonpyrogenic, single use, packaged combination of Cefazolin Sodium USP (lyophilized) and sterile iso-osmotic diluent in the DUPLEX sterile container. The DUPLEX Container is a flexible dual chamber container.

After reconstitution the approximate osmolality for Cefazolin for Injection USP and Dextrose Injection USP is 290 mOsmol/kg.

The drug chamber is filled with sterile lyophilized Cefazolin Sodium USP, a semi-synthetic cephalosporin and has the following IUPAC nomenclature: Sodium (6*R*,-7*R*)-3-[[(5-methyl-1,3,4-thiadiazol-2-yl)thio]methyl]-8-oxo-7-[2-(1*H*-tetrazol-1-yl)acetamido]-5-thia-1-azabicyclo-[4.2.0]oct-2-ene-2-carboxylate.

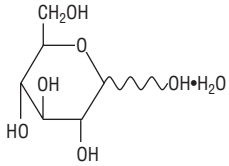
Cefazolin Sodium USP has the following structural formula:



The sodium content is 48 mg/g of cefazolin sodium.

The diluent chamber contains Dextrose Injection USP, an iso-osmotic diluent using Hydrous Dextrose USP in Water for Injection USP. Dextrose Injection USP is sterile, nonpyrogenic, and contains no bacteriostatic or antimicrobial agents.

Hydrous Dextrose USP has the following structural (molecular) formula:



The molecular weight of Hydrous Dextrose USP is 198.17

Cefazolin Sodium USP is supplied as a lyophilized form equivalent to either 500 mg or 1 g of cefazolin. Dextrose hydrous USP has been added to the diluent to adjust osmolality (approximately 2.4 g and 2 g to 500 mg and 1 g dosages, respectively).

After removing the peelable foil strip, activating the seals, and thoroughly mixing, the reconstituted drug product is intended for single intravenous use.

The DUPLEX Container is Latex-free, PVC-free, and DEHP-free.

The DUPLEX dual chamber container is made from a specially formulated material. The product (diluent and drug) contact layer is a mixture of thermoplastic rubber and a polypropylene ethylene copolymer that contains no plasticizers. The safety of the container system is supported by USP biological evaluation procedures.

CLINICAL PHARMACOLOGY

Studies have shown that following intravenous administration of cefazolin 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 cefazolin is approximately 1.8 hours following IV 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), cefazolin produced a steady serum level at the third hour of approximately 28 mcg/mL.

Studies in patients hospitalized with infections indicate that cefazolin 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 five times; however, in patients with obstructive biliary disease, bile levels of cefazolin are considerably lower than serum levels (< 1.0 mcg/mL).

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

Studies of cord blood show prompt transfer of cefazolin across the placenta. Cefazolin is present in very low levels in the milk of nursing mothers.

Cefazolin 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.

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 cefazolin.

Microbiology

In vitro tests demonstrate that the bactericidal action of cephalosporins results from inhibition of cell wall synthesis. Cefazolin 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* and *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

Cefazolin for Injection USP and Dextrose Injection USP 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.

Cefazolin is effective in the eradication of streptococci from the nasopharynx; however, data establishing the efficacy of cefazolin 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 cefazolin 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 cefazolin 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 cefazolin 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 cefazolin 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 Cefazolin for Injection USP and Dextrose Injection USP and other antibacterial drugs, Cefazolin for Injection USP and Dextrose Injection USP 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

CEFAZOLIN FOR INJECTION USP AND DEXTROSE INJECTION USP IS CONTRAINDICATED IN PATIENTS WITH KNOWN ALLERGY TO THE CEPHALOSPORIN GROUP OF ANTIBIOTICS.

Solutions containing dextrose may be contraindicated in patients with hypersensitivity to corn products.

WARNINGS

BEFORE THERAPY WITH CEFAZOLIN FOR INJECTION USP AND DEXTROSE INJECTION USP 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 CEFAZOLIN FOR INJECTION USP AND DEXTROSE INJECTION USP 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 Cefazolin for Injection USP and Dextrose Injection USP may result in the overgrowth of nonsusceptible organisms. Careful clinical observation of the patient is essential.

When Cefazolin for Injection USP and Dextrose Injection USP 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 beta-lactam antibiotics, seizures may occur if inappropriately high doses are administered to patients with impaired renal function (see **DOSAGE AND ADMINISTRATION**).

Cefazolin for Injection USP and Dextrose Injection USP, 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.

As with other dextrose-containing solutions, Cefazolin for Injection USP and Dextrose Injection USP should be prescribed with caution in patients with overt or known subclinical diabetes mellitus or carbohydrate intolerance for any reason.

Prescribing Cefazolin for Injection USP and Dextrose Injection USP 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.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

Use only if solution is clear and container and seals are intact.

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 Cefazolin for Injection USP and Dextrose Injection USP should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When Cefazolin for Injection USP and Dextrose Injection USP 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 Cefazolin for Injection USP and Dextrose Injection USP or other antibacterial drugs in the future.

Carcinogenesis/Mutagenesis

Mutagenicity studies and long-term studies in animals to determine the carcinogenic potential of Cefazolin for Injection USP and Dextrose Injection USP 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 cefazolin. 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

Cefazolin is present in very low concentrations in the milk of nursing mothers. Caution should be exercised when Cefazolin for Injection USP and Dextrose Injection USP 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.

Cefazolin for Injection USP and Dextrose Injection USP is designed to deliver a 500 mg or 1 g dose of cefazolin. To prevent unintentional overdose, Cefazolin for Injection USP and Dextrose Injection USP should not be used in pediatric patients who require less than the full adult dose of cefazolin.

Geriatric Use

Of the 920 subjects who received cefazolin 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. 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 hours
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 cefazolin 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 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 during surgery (administration modified depending on the duration of the operative procedure).

c. 500 mg to 1 gram IV 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) cefazolin 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 cefazolin may be continued for 3 to 5 days following the completion of surgery.

Dosage Adjustment for Patients with Reduced Renal Function

Cefazolin 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.

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 cefazolin in these patients is not recommended.

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.

Duplex® Drug Delivery System Directions for Use

Removal from Multi-Pack Tray

• Tear tape strips from one or both sides of the tray. Remove top tray.

• To avoid inadvertent activation, Duplex Container should remain in the folded position until activation is intended.

Patient Labeling and Drug Powder/Diluent Inspection

• Apply patient-specific label on foil side of container. USE CARE to avoid activation. Do not cover any portion of foil strip with patient label.

• Unlatch side tab and unfold Duplex Container. (See Diagram 1.)

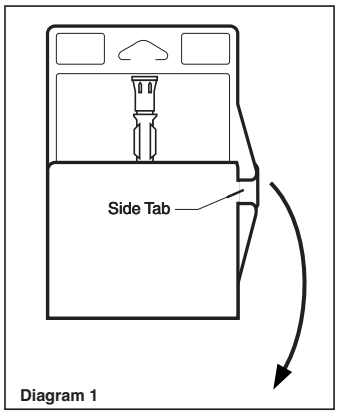


Diagram 1

• Visually inspect diluent chamber for particulate matter.

• Use only if container and seals are intact.

• To inspect the drug powder for foreign matter or discoloration, peel foil strip from drug chamber. (See Diagram 2.)

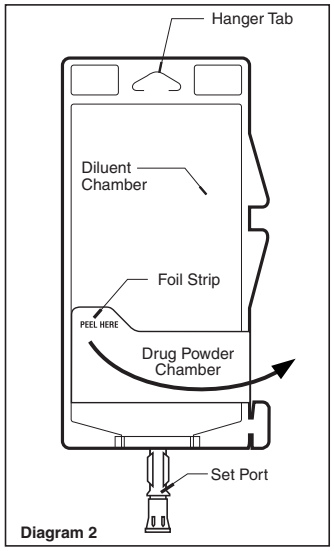


Diagram 2

• Protect from light after removal of foil strip.

Note: If foil strip is removed, product must be used within 30 days, but not beyond the labeled expiration date.

• The product should be re-folded and the side tab latched until ready to activate.

Reconstitution (Activation)

• Do not use directly after storage by refrigeration, allow the product to equilibrate to room temperature before patient use.

• Unfold the DUPLEX® Container and point the set port in a downward direction. Starting at the hanger tab end, fold the DUPLEX Container just below the diluent meniscus trapping all air above the fold. To activate, squeeze the folded diluent chamber until the seal between the diluent and powder opens, releasing diluent into the drug powder chamber. (See Diagram 3.)

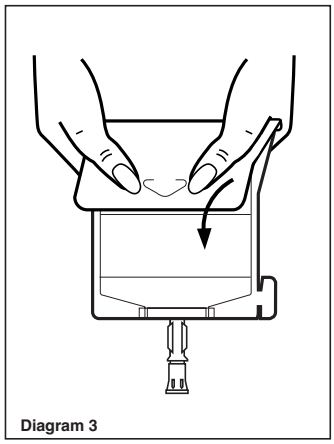


Diagram 3

• Agitate the liquid-powder mixture until the drug powder is completely dissolved.

Note: Following reconstitution (activation), product must be used within 24 hours if stored at room temperature or within 7 days if stored under refrigeration.

Administration

• Visually inspect the reconstituted solution for particulate matter.

• Point the set port in a downwards direction. Starting at the hanger tab end, fold the DUPLEX® Container just below the solution meniscus trapping all air above the fold. Squeeze the folded DUPLEX Container until the seal between reconstituted drug solution and set port opens, releasing liquid to set port. (See Diagram 4.)

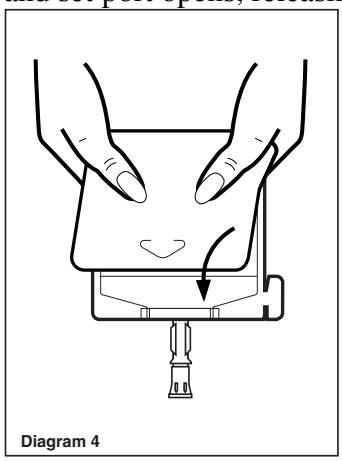


Diagram 4

• Prior to attaching the IV set, check for minute leaks by squeezing container firmly. If leaks are found, discard container and solution as sterility may be impaired.

• Using aseptic technique, remove the set port cover from the set port and attach sterile administration set.

• Refer to Directions for Use accompanying the administration set.

Precautions

• As with other cephalosporins, reconstituted Cefazolin for Injection USP and Dextrose Injection USP tends to darken depending on storage conditions, within the stated recommendations. However, product potency is not adversely affected.

• Use only if prepared solution is clear and free from particulate matter.

• Do not use in series connection.
• Do not introduce additives into the DUPLEX Container.
• Do not freeze.

HOW SUPPLIED

Cefazolin for Injection USP and Dextrose Injection USP in the DUPLEX® Drug Delivery System is a flexible dual chamber container supplied in two concentrations. After reconstitution, the concentrations are equivalent to 500 mg and 1 g cefazolin. The diluent chamber contains approximately 50 mL of Dextrose Injection USP. Dextrose Injection USP has been adjusted to 4.8% and 4.0% for the 500 mg and 1 g doses, respectively, such that the reconstituted solution is iso-osmotic.

Cefazolin for Injection USP and Dextrose Injection USP is supplied sterile and nonpyrogenic in the DUPLEX Drug Delivery System containers packaged 12 units per tray, 2 trays per case.

NDC	Cat. No.	Dose	Volume
Cefazolin for Injection USP and Dextrose Injection USP			
0264-3103-11	3103-11	1 g	50 mL
Cefazolin for Injection USP and Dextrose Injection USP			
0264-3102-11	3102-11	500 mg	50 mL

Store the unactivated unit at 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F).

REFERENCES:

[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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