CEFAZOLIN FOR INJECTION USP
and Dextrose Injection USP

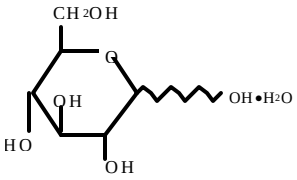
DESCRIPTION

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.

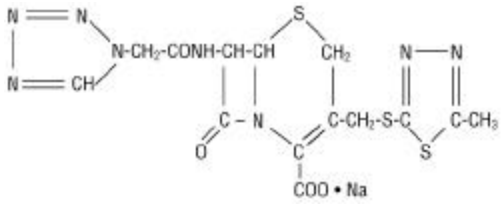
The diluent chamber contains Dextrose Injection USP, an iso-osmotic diluent using Hydrous Dextrose USP in Water for Injection USP. Dextrose Injection USP is sterile, nonpyrogenic, and contains no bacteriostatic or antimicrobial agents.

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



The molecular weight of Hydrous Dextrose USP is 198.17

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.

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 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

Human 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 concentration at the third hour of approximately 28 mcg/mL.

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

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

In synovial fluid, the cefazolin concentration 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 concentrations 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, AST (SGOT), ALT (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 has been shown to be active against most strains of the following microorganisms both *in vitro* and in clinical infections as described in the **INDICATIONS AND USAGE** section:

Aerobic Gram-positive microorganisms:
Staphylococcus aureus (including penicillinase-producing strains)
Staphylococcus epidermidis
Streptococcus pneumoniae
Streptococcus pyogenes and other strains of Streptococci

NOTE: Methicillin-resistant staphylococci are uniformly resistant to cefazolin. Many *Enterococcus* strains are resistant to cefazolin.

Aerobic Gram-negative microorganisms:
Escherichia coli
Haemophilus influenzae
Klebsiella species
Proteus mirabilis

NOTE: 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.

Susceptibility Testing:
Dilution Techniques:

Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MICs). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized procedure. Standardized procedures are based on a dilution method[1] (broth) or equivalent with standardized inoculum concentrations and standardized concentrations of cefazolin powder. The MIC values should be interpreted according to the following criteria:

For Enterobacteriaceae and *Staphylococcus* spp.

MIC (µg/mL)	Interpretation
< 8.0	Susceptible (S)
16.0	Intermediate (I)
> 32.0	Resistant (R)

A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of "Intermediate" indicates that the result should be considered equivocal, and, if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone which prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

Standardized susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures. Standard cefazolin powder should provide the following MIC values:

Microorganism	MIC (µg/mL)
S. aureus ATCC 29213	0.25 to 1.0
E. coli ATCC 25922	1.0 to 4.0

Diffusion Techniques:
Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. One such standardized procedure[2] requires the use of standardized inoculum concentrations. This procedure uses paper disks impregnated with 30-µg cefazolin to test the susceptibility of microorganisms to cefazolin.

Reports from the laboratory providing results of the standard single-disk susceptibility test with a 30-µg cefazolin disk should be interpreted according to the following criteria:

For Enterobacteriaceae using the 30-µg cefazolin disk

Zone diameter (mm)	Interpretation
> 18	Susceptible (S)
15 to 17	Intermediate (I)
< 14	Resistant (R)

For *Staphylococcus* spp. using the 30-µg cefazolin or the 30-µg cephalothin disks

Zone diameter (mm)	Interpretation
> 18	Susceptible (S)

15 to 17	Intermediate (I)
< 14	Resistant (R)

Interpretation should be as stated above for results using dilution techniques. Interpretation involves correlation of the diameter obtained in the disk test with the MIC for cefazolin.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 30-µg cefazolin disk should provide the following zone diameters in this laboratory test quality control strain:

Microorganism	**Zone diameter (mm)**
S. aureus ATCC 25923	29 to 35
E. coli ATCC 25922	23 to 29

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 *Streptococcus pneumoniae, Klebsiella* species, *Haemophilus influenzae, Staphylococcus 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 *Escherichia coli, Proteus mirabilis, Klebsiella* species and some strains of enterobacter and enterococci.

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

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

BONE AND JOINT INFECTIONS due to *Staphylococcus aureus*.

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

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

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

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to cefazolin.

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 over 70 years of age, 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.)

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

SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (anaphylactic) REACTIONS HAVE BEEN REPORTED IN PATIENTS ON PENICILLIN THERAPY. THESE REACTIONS ARE MORE LIKELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY AND/OR A HISTORY OF SENSITIVITY TO MULTIPLE ALLERGENS. THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE REACTIONS WHEN TREATED WITH CEPHALOSPORINS. BEFORE INITIATING THERAPY WITH CEFAZOLIN FOR INJECTION USP AND DEXTROSE INJECTION USP, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO PENICILLINS, CEPHALOSPORINS OR OTHER ALLERGENS. IF AN ALLERGIC REACTION OCCURS, CEFAZOLIN FOR INJECTION USP AND DEXTROSE INJECTION USP SHOULD BE DISCONTINUED AND APPROPRIATE THERAPY SHOULD BE INSTITUTED**. SERIOUS ANAPHYLACTIC REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE. OXYGEN, INTRAVENOUS STEROIDS AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE ADMINISTERED AS 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 one 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 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.

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.

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 concentrations.

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® and Tes-Tape®.

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

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 in rats at doses of 3-4 times the human dose based on body surface area, in mice at doses of 3-4 times the human dose based on body surface area, and in rabbits at doses approximately equal to the human dose based on body surface area, 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 concentrations in cord blood have been approximately one quarter to one third of maternal drug concentrations. 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
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.

The potential for the toxic effect in children from chemicals that may leach from the single-dose IV preparation in plastic has not been determined.

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 and Renal: Transient rise in AST (SGOT), ALT (SGPT), BUN and alkaline phosphatase concentrations has been observed without clinical evidence of renal or hepatic impairment. Interstitial nephritis and other renal disorders have been reported rarely. Most patients experiencing these reactions have been seriously ill and were receiving multiple drug therapies. The role of cefazolin in the development of nephropathies has not been determined. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

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).

Cephalosporin-class Adverse Reactions: In addition to the adverse reactions listed above that have been observed in patients treated with cefazolin, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics:

Adverse Reactions: Allergic reactions, urticaria, serum sickness-like reaction, erythema multiforme, toxic epidermal necrolysis, colitis, renal dysfunction, toxic nephropathy, abdominal pain, reversible hyperactivity, hypertonia, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage, and superinfection.

Altered Laboratory Tests: Prolonged prothrombin time, positive direct Coombs' test, false-positive test for urinary glucose, elevated bilirubin, elevated LDH, increased creatinine, pancytopenia, and agranulocytosis.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced (see **DOSAGE AND ADMINISTRATION**). If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

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 + cocci	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., endo-carditis, 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 concentrations 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 concentrations 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.

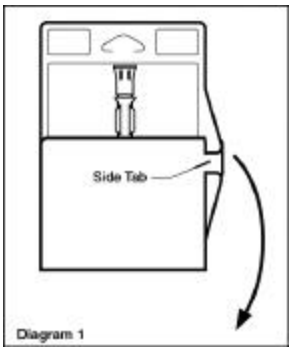
Dosage Adjustment for Patients with Reduced Renal Function
Cefazolin may be used in patients with reduced renal function with the following dosage adjustments: Patients with a creatinine clearance of 55 mL/min. or greater or a serum creatinine of 1.5 mg % or less can be given full doses. Patients with 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.

Duplex™ Drug Delivery System Directions for Use
Removal from Multi-Pack Tray

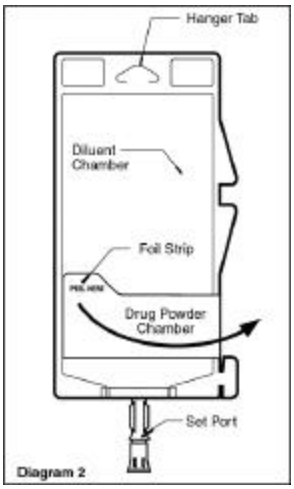
- Tear shrink wrap by grasping red tear strip and remove Duplex Container(s) from multi-pack tray.
- To avoid inadvertent activation, Duplex Container should remain in the folded position until activation is intended.

Drug Powder/Diluent Inspection and Patient Labeling

- Unlatch side tab and unfold Duplex Container. (See 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.)



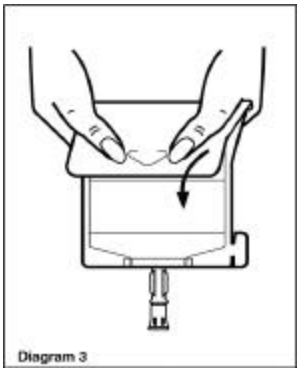
- Protect from light after removal of foil strip.

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

- Apply patient-specific label on foil side of container. USE CARE to avoid activation.
- The product should be re-folded and the side tab latched until ready to activate.

Reconstitution (Activation)

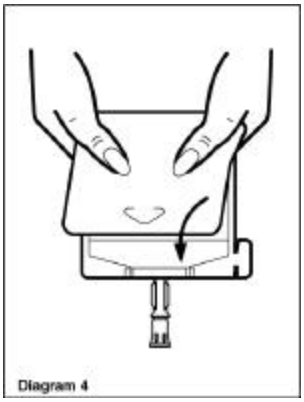
- Do not use directly after storage by refrigeration, allow the product to equilibrate to room temperature before patient use.
- Unfold the Duplex Container and point the set port in a downward direction. Starting at the hanger tab end, fold the Duplex Container just below the diluent meniscus trapping 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.)



- 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.)



- 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 25°C (77°F). Excursions permitted to 15-30°C (59-86°F).

Rx only

REFERENCES:

[1] National Committee for Clinical Laboratory Standards, Method for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically - Fifth Edition. Approved Standard NCCLS Document M7-A4, Vol. 20, No. 2, NCCLS, Wayne, PA, January 2000.

[2] National Committee for Clinical Laboratory Standards, Performance Standards for Antimicrobial Disk Susceptibility Tests - Seventh Edition. Approved Standard NCCLS Document M2-A7, Vol. 20, No. 1, NCCLS, Wayne, PA, January 2000.

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