

CEFOTETAN AND DEXTROSE- cefotetan and dextrose injection, solution
B. Braun Medical Inc.

CEFOTETAN FOR INJECTION USP
AND DEXTROSE INJECTION USP

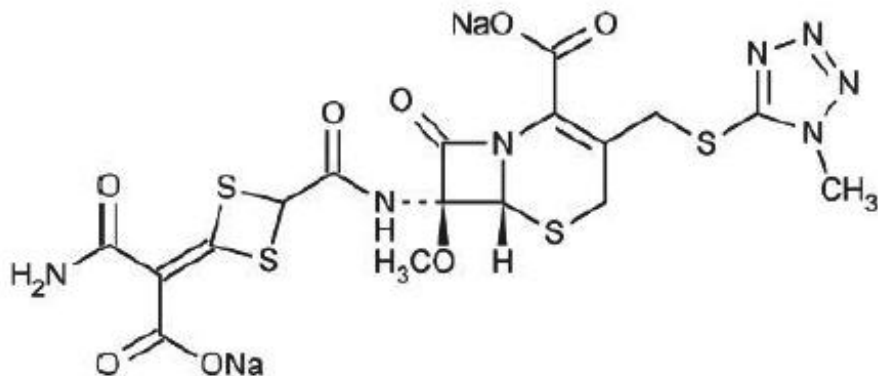
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefotetan for Injection USP and Dextrose Injection USP and other antibacterial drugs, Cefotetan for Injection USP and Dextrose Injection USP should be used only to treat or prevent infections that are proven or strongly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

DESCRIPTION

Cefotetan for Injection USP and Dextrose Injection USP in the DUPLEX® container is supplied as a sterile, nonpyrogenic, single use packaged combination of cefotetan disodium and dextrose injection (diluent) in the DUPLEX® sterile container. The DUPLEX® container is a flexible dual chamber container.

The drug chamber is filled with cefotetan disodium, a sterile, semisynthetic, broad-spectrum, beta-lactamase resistant, cephalosporin (cephamycin) antibiotic for intravenous administration. Cefotetan disodium is the disodium salt of [6*R*-(6α,7α)]-7-[[[4-(2-amino-1-carboxy-2-oxoethylidene)-1,3-dithietan-2-yl]carbonyl]amino]-7-methoxy-3-[[[(1-methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid.

Cefotetan disodium has the following structural formula:



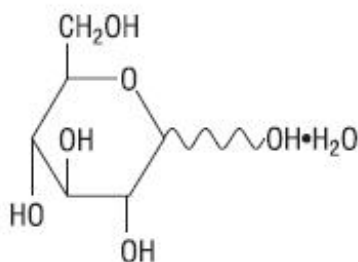
The molecular formula of cefotetan disodium is $C_{17}H_{15}N_7Na_2O_8S_4$ with a molecular weight of 619.59.

Cefotetan disodium is supplied as a dry powder form equivalent to either 1 g or 2 g of cefotetan. Cefotetan disodium is a white to pale yellow powder which is readily soluble in dextrose injection diluent provided in the DUPLEX® container. The pH of freshly reconstituted solution is between 4 to 6.5. The color of reconstituted solutions ranges from colorless to yellow depending on the length of storage and concentration. Cefotetan for Injection USP and Dextrose Injection USP contains approximately 80 mg (3.5 mEq) of sodium per gram of cefotetan activity.

The diluent chamber contains dextrose injection. The concentration of Hydrus Dextrose in Water for Injection USP has been adjusted to render the reconstituted drug product iso-osmotic. Dextrose USP has been added to adjust the osmolality to approximately 290 mOsmol/kg (approximately 1.79 g [3.58% w/v] and 1.04 g [2.08% w/v] to the 1 g and 2 g dosages, respectively). 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.

After removing the peelable foil strip, activating the seals, and thoroughly mixing, the reconstituted drug product is intended for single intravenous use. When reconstituted according to instructions in the product labeling, the approximate osmolality of the reconstituted solution of Cefotetan for Injection USP and Dextrose Injection USP is about 290 mOsmol/kg.

The DUPLEX® Container is Latex-free, PVC-free, and Di(2-ethylhexyl)phthalate (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

High plasma levels of cefotetan are attained after intravenous administration of single doses to normal volunteers.

PLASMA CONCENTRATIONS AFTER 1 GRAM IV* DOSE

Mean Plasma Concentration (mcg/mL)							
Time After Injection							
Route	15 min	30 min	1h	2h	4h	8h	12h
IV	92	158	103	72	42	18	9

* 30-minute infusion

PLASMA CONCENTRATIONS AFTER 2 GRAM IV* DOSE

Mean Plasma Concentration (mcg/mL)							
Time After Injection							
Route	5 min	10 min	1h	3h	5h	9h	12h
IV	237	223	135	74	48	22	12 [†]

* Injected over 3 minutes

[†] Concentrations estimated from regression line

The plasma elimination half-life of cefotetan is 3 to 4.6 hours after intravenous administration.

Repeated administration of Cefotetan for Injection USP and Dextrose Injection USP does not result in accumulation of the drug in normal subjects.

Cefotetan is 88% plasma protein bound.

No active metabolites of cefotetan have been detected; however, small amounts (less than 7%) of cefotetan in plasma and urine may be converted to its tautomer, which has antimicrobial activity similar to the parent drug.

In normal patients, from 51% to 81% of an administered dose of cefotetan is excreted unchanged by the kidneys over a 24 hour period, which results in high and prolonged urinary concentrations. Following intravenous doses of 1 gram and 2 grams, urinary concentrations are highest during the first hour and reach concentrations of approximately 1700 and 3500 mcg/mL, respectively.

In volunteers with reduced renal function, the plasma half-life of cefotetan is prolonged. The mean terminal half-life increases with declining renal function, from approximately 4 hours in volunteers with normal renal function to about 10 hours in those with moderate renal impairment. There is a linear correlation between the systemic clearance of cefotetan and creatinine clearance. When renal function is impaired, a reduced dosing schedule based on creatinine clearance must be used (see **DOSAGE AND ADMINISTRATION**).

In pharmacokinetics studies of eight elderly patients (greater than 65 years) with normal renal function and six healthy volunteers (aged 25 to 28 years), mean (\pm 1 sd) Total Body Clearance (1.8 (0.1) L/h vs. 1.8 (0.3) L/h) and mean Volume of Distribution (10.4 (1.2) L vs. 10.3 (1.6) L) were similar following administration of a one gram intravenous bolus dose.

Therapeutic levels of cefotetan are achieved in many body tissues and fluids including:

skin	ureter
muscle	bladder
fat	maxillary sinus mucosa
myometrium	tonsil
endometrium	bile
cervix	peritoneal fluid
ovary	umbilical cord serum
kidney	amniotic fluid

Microbiology

The bactericidal action of cefotetan results from inhibition of cell wall synthesis. Cefotetan has *in vitro* activity against a wide range of aerobic and anaerobic gram-positive and gram-negative organisms. The methoxy group in the 7-alpha position provides cefotetan with a high degree of stability in the presence of beta-lactamases including both penicillinases and cephalosporinases of gram-negative bacteria.

Cefotetan has been shown to be active against most strains of the following organisms **both *in vitro* and in clinical infections** (see **INDICATIONS AND USAGE**).

Gram-Negative Aerobes

Escherichia coli

Haemophilus influenzae (including ampicillin-resistant strains)

Klebsiella species (including *K. pneumoniae*)

Morganella morganii

Neisseria gonorrhoeae (nonpenicillinase-producing strains)

Proteus mirabilis

Proteus vulgaris

Providencia rettgeri

Serratia marcescens

NOTE: Approximately one-half of the usually clinically significant strains of *Enterobacter* species (e.g., *E. aerogenes* and *E. cloacae*) are resistant to cefotetan. Most strains of *Pseudomonas aeruginosa* and *Acinetobacter* species are resistant to cefotetan.

Gram-Positive Aerobes

Staphylococcus aureus (including penicillinase- and nonpenicillinase-producing strains)

Staphylococcus epidermidis

Streptococcus agalactiae (group B beta-hemolytic streptococcus)

Streptococcus pneumoniae

Streptococcus pyogenes

NOTE: Methicillin-resistant staphylococci are resistant to cephalosporins. Some strains of *Staphylococcus epidermidis* and most strains of enterococci, e.g., *Enterococcus faecalis* (formerly *Streptococcus faecalis*) are resistant to cefotetan.

Anaerobes

Prevotella bivia (formerly *Bacteroides bivius*)

Prevotella disiens (formerly *Bacteroides disiens*)

Bacteroides fragilis

Prevotella melaninogenica (formerly *Bacteroides melaninogenicus*)

Bacteroides vulgatus

Fusobacterium species

Gram-positive bacilli (including *Clostridium* species; see **WARNINGS**)

NOTE: Most strains of *C. difficile* are resistant (see **WARNINGS**).

Peptococcus niger

Peptostreptococcus species

NOTE: Many strains of *B. distasonis*, *B. ovatus* and *B. thetaiotaomicron* are resistant to cefotetan *in vitro*. However, the therapeutic utility of cefotetan against these organisms cannot be accurately predicted on the basis of *in vitro* susceptibility tests alone.

The following *in vitro* data are available but their clinical significance is unknown. Cefotetan has been shown to be active *in vitro* against most strains of the following organisms:

Gram-Negative Aerobes

Citrobacter species (including *C. diversus* and *C. freundii*)

Klebsiella oxytoca

Moraxella (Branhamella) catarrhalis

Neisseria gonorrhoeae (penicillinase-producing strains)

Salmonella species

Serratia species

Shigella species

Yersinia enterocolitica

Anaerobes

Porphyromonas asaccharolytica (formerly *Bacteroides asaccharolyticus*)

Prevotella oralis (formerly *Bacteroides oralis*)

Bacteroides splanchnicus

Clostridium difficile (see **WARNINGS**)

Propionibacterium species

Veillonella species

Susceptibility Tests

Dilution Techniques

Quantitative methods are used to determine antimicrobial minimal 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 method¹ (broth or agar) or equivalent with standardized inoculum concentrations and standardized

concentrations of cefotetan powder. The MIC values should be interpreted according to the following criteria:

MIC (mcg/mL)	Interpretation
≤16	Susceptible (S)
32	Intermediate (I)
≥64	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 cefotetan powder should provide the following MIC values:

Microorganism	MIC (mcg/mL)
<i>E. coli</i> ATCC® 25922	0.06–0.25
<i>S. aureus</i> ATCC® 29213	4–16

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 procedure² requires the use of the standardized inoculum concentrations. This procedure uses paper disks impregnated with 30 mcg cefotetan to test the susceptibility of microorganisms to cefotetan.

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

Zone Diameter (mm)	Interpretation
≥16	Susceptible (S)
13–15	Intermediate (I)
≤12	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 cefotetan.

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 mcg cefotetan disk should provide the following zone diameters in these laboratory test quality control strains.

Microorganism	Zone Diameter (mm)
<i>E. coli</i> ATCC® 25922	28–34
<i>S. aureus</i> ATCC® 25923	17–23

Anaerobic Techniques

For anaerobic bacteria, the susceptibility to cefotetan as MICs can be determined by standardized test methods³. The MIC values obtained should be interpreted according to the following criteria:

MIC (mcg/mL)	Interpretation
≤16	Susceptible (S)
32	Intermediate (I)
≥64	Resistant (R)

Interpretation is identical to that stated above for results using dilution techniques.

As with other susceptibility techniques, the use of laboratory control microorganisms is required to control the technical aspects of the laboratory standardized procedures. Standardized cefotetan powder should provide the following MIC values:

Microorganism	MIC (mcg/mL)
<i>Bacteroides fragilis</i> ATCC [®] 25285	4–16
<i>Bacteroides thetaiotaomicron</i> ATCC [®] 29741	32–128
<i>Eubacterium lentum</i> ATCC [®] 43055	32–128

INDICATIONS AND USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefotetan for Injection USP and Dextrose Injection USP and other antibacterial drugs, Cefotetan 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 antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Treatment

Cefotetan for Injection USP and Dextrose Injection USP is indicated for the therapeutic treatment of the following infections when caused by susceptible strains of the designated organisms:

Urinary Tract Infections caused by *E. coli*, *Klebsiella* spp (including *K. pneumoniae*), *Proteus mirabilis* and *Proteus* spp (which may include the organisms now called *Proteus vulgaris*, *Providencia rettgeri*, and *Morganella morganii*).

Lower Respiratory Tract Infections caused by *Streptococcus pneumoniae*, *Staphylococcus aureus* (penicillinase- and nonpenicillinase-producing strains), *Haemophilus influenzae* (including ampicillin-resistant strains), *Klebsiella* species (including *K. pneumoniae*), *E. coli*, *Proteus mirabilis*, and *Serratia marcescens*¹.

Skin and Skin Structure Infections due to *Staphylococcus aureus* (penicillinase- and nonpenicillinase-producing strains), *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Streptococcus* species (excluding enterococci), *Escherichia coli*, *Klebsiella pneumoniae*, *Peptococcus niger*¹, *Peptostreptococcus* species.

Gynecologic Infections caused by *Staphylococcus aureus* (including penicillinase- and nonpenicillinase-producing strains), *Staphylococcus epidermidis*, *Streptococcus* species (excluding enterococci), *Streptococcus agalactiae*, *E. coli*, *Proteus mirabilis*, *Neisseria gonorrhoeae*, *Bacteroides* species (excluding *B. distasonis*, *B. ovatus*, *B. thetaiotaomicron*), *Fusobacterium* species¹, and gram-positive anaerobic cocci (including *Peptococcus niger* and *Peptostreptococcus* species).

Cefotetan, like other cephalosporins, has no activity against *Chlamydia trachomatis*. Therefore, when

cephalosporins are used in the treatment of pelvic inflammatory disease, and *C. trachomatis* is one of the suspected pathogens, appropriate antichlamydial coverage should be added.

Intra-abdominal Infections caused by *E. coli*, *Klebsiella* species (including *K. pneumoniae*), *Streptococcus* species (excluding enterococci), *Bacteroides* species (excluding *B. distasonis*, *B. ovatus*, *B. thetaiotaomicron*) and *Clostridium* species¹.

Bone and Joint Infections caused by *Staphylococcus aureus*¹.

Specimens for bacteriological examination should be obtained in order to isolate and identify causative organisms and to determine their susceptibilities to cefotetan. Therapy may be instituted before results of susceptibility studies are known; however, once these results become available, the antibiotic treatment should be adjusted accordingly.

In cases of confirmed or suspected gram-positive or gram-negative sepsis or in patients with other serious infections in which the causative organism has not been identified, it is possible to use Cefotetan for Injection USP and Dextrose Injection USP concomitantly with an aminoglycoside. Cefotetan combinations with aminoglycosides have been shown to be synergistic *in vitro* against many Enterobacteriaceae and also some other gram-negative bacteria. The dosage recommended in the labeling of both antibiotics may be given and depends on the severity of the infection and the patient's condition.

NOTE: Increases in serum creatinine have occurred when cefotetan was given alone. If Cefotetan for Injection USP and Dextrose Injection USP and an aminoglycoside are used concomitantly, renal function should be carefully monitored, because nephrotoxicity may be potentiated.

¹ Efficacy for this organism in this organ system was studied in fewer than ten infections.

Prophylaxis

The preoperative administration of Cefotetan for Injection USP and Dextrose Injection USP may reduce the incidence of certain postoperative infections in patients undergoing surgical procedures that are classified as clean, contaminated or potentially contaminated (e.g., cesarean section, abdominal or vaginal hysterectomy, transurethral surgery, biliary tract surgery, and gastrointestinal surgery).

If there are signs and symptoms of infection, specimens for culture should be obtained for identification of the causative organism so that appropriate therapeutic measures may be initiated.

CONTRAINDICATIONS

Cefotetan for Injection USP and Dextrose Injection USP is contraindicated in patients with a known allergy to the cephalosporin group of antibiotics and in those individuals who have experienced a cephalosporin associated hemolytic anemia.

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

WARNINGS

BEFORE THERAPY WITH CEFOTETAN 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 CEFOTETAN DISODIUM, CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS TO BE 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 CEFOTETAN FOR INJECTION USP AND DEXTROSE INJECTION USP OCCURS, DISCONTINUE THE DRUG. SERIOUS

ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, INTRAVENOUS FLUIDS, INTRAVENOUS ANTIHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED.

AN IMMUNE MEDIATED HEMOLYTIC ANEMIA HAS BEEN OBSERVED IN PATIENTS RECEIVING CEPHALOSPORIN CLASS ANTIBIOTICS. SEVERE CASES OF HEMOLYTIC ANEMIA, INCLUDING FATALITIES, HAVE BEEN REPORTED IN ASSOCIATION WITH THE ADMINISTRATION OF CEFOTETAN. SUCH REPORTS ARE UNCOMMON. THERE APPEARS TO BE AN INCREASED RISK OF DEVELOPING HEMOLYTIC ANEMIA ON CEFOTETAN RELATIVE TO OTHER CEPHALOSPORINS OF AT LEAST 3 FOLD. IF A PATIENT DEVELOPS ANEMIA ANYTIME WITHIN 2–3 WEEKS SUBSEQUENT TO THE ADMINISTRATION OF CEFOTETAN, THE DIAGNOSIS OF A CEPHALOSPORIN ASSOCIATED ANEMIA SHOULD BE CONSIDERED AND THE DRUG STOPPED UNTIL THE ETIOLOGY IS DETERMINED WITH CERTAINTY. BLOOD TRANSFUSIONS MAY BE CONSIDERED AS NEEDED (see **CONTRAINDICATIONS**).

PATIENTS WHO RECEIVE COURSES OF CEFOTETAN FOR THE TREATMENT OR PROPHYLAXIS OF INFECTIONS SHOULD HAVE PERIODIC MONITORING FOR SIGNS AND SYMPTOMS OF HEMOLYTIC ANEMIA INCLUDING A MEASUREMENT OF HEMATOLOGICAL PARAMETERS WHERE APPROPRIATE.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Cefotetan for Injection USP and Dextrose Injection USP, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

In common with many other broad-spectrum antibiotics, Cefotetan for Injection USP and Dextrose Injection USP may be associated with a fall in prothrombin activity and, possibly, subsequent bleeding. Those at increased risk include patients with renal or hepatobiliary impairment or poor nutritional state, the elderly, and patients with cancer. Prothrombin time should be monitored and exogenous vitamin K administered as indicated.

PRECAUTIONS

General

Prescribing Cefotetan 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.

As with other broad-spectrum antibiotics, prolonged use of Cefotetan for Injection USP and Dextrose Injection USP may result in overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection does occur during therapy, appropriate measures should be taken.

Cefotetan for Injection USP and Dextrose Injection USP should be used with caution in individuals with a history of gastrointestinal disease, particularly colitis.

As with other dextrose-containing solutions, Cefotetan 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.

Information for Patients

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Patients should be counseled that antibacterial drugs, including Cefotetan 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 Cefotetan 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 Cefotetan for Injection USP and Dextrose Injection USP or other antibacterial drugs in the future.

As with some other cephalosporins, a disulfiram-like reaction characterized by flushing, sweating, headache, and tachycardia may occur when alcohol (beer, wine, etc.) is ingested within 72 hours after Cefotetan for Injection USP and Dextrose Injection USP administration. Patients should be cautioned about the ingestion of alcoholic beverages following the administration of Cefotetan for Injection USP and Dextrose Injection USP.

Drug Interactions

Increases in serum creatinine have occurred when Cefotetan for Injection USP and Dextrose Injection USP was given alone. If Cefotetan for Injection USP and Dextrose Injection USP and an aminoglycoside are used concomitantly, renal function should be carefully monitored, because nephrotoxicity may be potentiated.

Drug/Laboratory Test Interactions

The administration of Cefotetan for Injection USP and Dextrose Injection USP may result in a false positive reaction for glucose in the urine using Clinitest®, Benedict's solution, or Fehling's solution. It is recommended that glucose tests based on enzymatic glucose oxidase be used.

As with other cephalosporins, high concentrations of cefotetan may interfere with measurement of serum and urine creatinine levels by Jaffé reaction and produce false increases in the levels of creatinine reported.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Although long-term studies in animals have not been performed to evaluate carcinogenic potential, no mutagenic potential of cefotetan was found in standard laboratory tests.

Cefotetan has adverse effects on the testes of prepubertal rats. Subcutaneous administration of 500 mg/kg/day (approximately 8–16 times the usual adult human dose) on days 6–35 of life (thought to be developmentally analogous to late childhood and prepuberty in humans) resulted in reduced testicular weight and seminiferous tubule degeneration in 10 of 10 animals. Affected cells included spermatogonia and spermatocytes; Sertoli and Leydig cells were unaffected. Incidence and severity of lesions were dose-dependent; at 120 mg/kg/day (approximately 2–4 times the usual human dose) only 1

of 10 treated animals was affected, and the degree of degeneration was mild.

Similar lesions have been observed in experiments of comparable design with other methylthiotetrazole-containing antibiotics and impaired fertility has been reported, particularly at high dose levels. No testicular effects were observed in 7-week-old rats treated with up to 1000 mg/kg/day SC for 5 weeks, or in infant dogs (3 weeks old) that received up to 300 mg/kg/day IV for 5 weeks. The relevance of these findings in humans is unknown.

Pregnancy

Teratogenic Effects

Pregnancy Category B

Reproduction studies have been performed in rats and monkeys at doses up to 20 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cefotetan. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Cefotetan is excreted in human milk in very low concentrations. Caution should be exercised when cefotetan is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Of the 925 subjects who received cefotetan in clinical studies, 492 (53%) were 60 years and older, while 76 (8%) were 80 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and the other reported clinical experience has not identified differences in responses between 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 **DOSAGE AND ADMINISTRATION – Impaired Renal Function.**)

ADVERSE REACTIONS

In clinical studies, the following adverse effects were considered related to Cefotetan for Injection USP and Dextrose Injection USP therapy. Those appearing in italics have been reported during postmarketing experience.

Gas trointes tinal: symptoms occurred in 1.5% of patients, the most frequent were diarrhea (1 in 80) and nausea (1 in 700); *pseudomembranous colitis*. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment or surgical prophylaxis. (See **WARNINGS.**)

Hematologic: laboratory abnormalities occurred in 1.4% of patients and included eosinophilia (1 in 200), positive direct Coombs' test (1 in 250), and thrombocytosis (1 in 300); *agranulocytosis, hemolytic anemia, leukopenia, thrombocytopenia, and prolonged prothrombin time with or without bleeding.*

Hepatic: enzyme elevations occurred in 1.2% of patients and included a rise in ALT (SGPT) (1 in 150), AST (SGOT) (1 in 300), alkaline phosphatase (1 in 700), and LDH (1 in 700).

Hypersensitivity: reactions were reported in 1.2% of patients and included rash (1 in 150) and itching (1 in 700); *anaphylactic reactions* and *urticaria*.

Local: effects were reported in less than 1% of patients and included phlebitis at the site of injection (1 in 300), and discomfort (1 in 500).

Renal: *Elevations in BUN and serum creatinine* have been reported.

Urogenital: *Nephrotoxicity* has rarely been reported.

Miscellaneous: *Fever*

In addition to the adverse reactions listed above which have been observed in patients treated with cefotetan, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics: pruritus, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, vomiting, abdominal pain, colitis, superinfection, vaginitis including vaginal candidiasis, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemorrhage, elevated bilirubin, pancytopenia, and neutropenia.

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

OVERDOSAGE

Information on overdosage with Cefotetan for Injection USP and Dextrose Injection USP in humans is not available. If overdosage should occur, it should be treated symptomatically and hemodialysis considered, particularly if renal function is compromised.

DOSAGE AND ADMINISTRATION

Cefotetan for Injection USP and Dextrose Injection USP in the DUPLEX® Container is intended for intravenous use only.

Treatment

The usual adult dosage is 1 or 2 grams of Cefotetan for Injection USP and Dextrose Injection USP administered intravenously every 12 hours for 5 to 10 days. Proper dosage should be determined by the condition of the patient, severity of the infection, and susceptibility of the causative organism.

General Guidelines for Dosage of Cefotetan for Injection USP and Dextrose Injection USP

Type of Infection	Daily Dose	Frequency and Route
Urinary Tract	1–4 grams	500 mg every 12 hours IV 1 or 2 g every 24 hours IV 1 or 2 g every 12 hours IV
Skin & Skin Structure		
Mild – Moderate*	2 grams	2 g every 24 hours IV 1 g every 12 hours IV
Severe	4 grams	2 g every 12 hours IV
Other Sites	2–4 grams	1 or 2 g every 12 hours IV
Severe	4 grams	2 g every 12 hours IV
Life-Threatening	6 grams [†]	3 g every 12 hours IV

* *Klebsiella pneumoniae* skin and skin structure infections should be treated with 1 or 2 grams every 12 hours IV.

[†] Maximum daily dosage should not exceed 6 grams.

If *Chlamydia trachomatis* is a suspected pathogen in gynecologic infections, appropriate antichlamydial coverage should be added, since cefotetan has no activity against this organism.

Prophylaxis

To prevent postoperative infection in clean, contaminated, or potentially contaminated surgery in adults, the recommended dosage is 1 or 2 g of Cefotetan for Injection USP and Dextrose Injection USP administered once, intravenously, 30 to 60 minutes prior to surgery. In patients undergoing cesarean section, the dose should be administered as soon as the umbilical cord is clamped.

Impaired Renal Function

When renal function is impaired, a reduced dosage schedule must be employed. The following dosage guidelines may be used.

DOSAGE GUIDELINES FOR PATIENTS WITH IMPAIRED RENAL FUNCTION

Creatinine Clearance mL/min	Dose	Frequency
> 30	Usual Recommended Dosage*	Every 12 hours
10 – 30	Usual Recommended Dosage*	Every 24 hours
< 10	Usual Recommended Dosage*	Every 48 hours

* Dose determined by the type and severity of infection, and susceptibility of the causative organism.

Alternatively, the dosing interval may remain constant at 12 hour intervals, but the dose reduced to one-half the usual recommended dose for patients with a creatinine clearance of 10–30 mL/min, and one-quarter the usual recommended dose for patients with a creatinine clearance of less than 10 mL/min.

When only serum creatinine levels are available, creatinine clearance may be calculated from the following formula. The serum creatinine level should represent a steady state of renal function.

Males:	$\frac{\text{Weight (kg)} \times (140 - \text{age})}{72 \times \text{serum creatinine (mg/100 mL)}}$
Females:	$0.9 \times \text{value for males}$

Cefotetan is dialyzable and it is recommended that for patients undergoing intermittent hemodialysis, one-quarter of the usual recommended dose be given every 24 hours on days between dialysis and one-half the usual recommended dose on the day of dialysis.

Intravenous Administration

The intravenous route is preferable for patients with bacteremia, bacterial septicemia, or other severe or life-threatening infections, or for patients who may be poor risks because of lowered resistance resulting from such debilitating conditions as malnutrition, trauma, surgery, diabetes, heart failure, or malignancy, particularly if shock is present or impending.

Using an infusion system, Cefotetan for Injection USP and Dextrose Injection USP may be given over a longer period of time through the tubing system by which the patient may be receiving other intravenous solutions. Butterfly or scalp vein-type needles are preferred for this type of infusion. However, during infusion of the solution containing Cefotetan for Injection USP and Dextrose Injection USP, it is advisable to discontinue temporarily the administration of other solutions at the same site.

NOTE: Solutions of Cefotetan for Injection USP and Dextrose Injection USP must not be admixed with solutions containing aminoglycosides. If Cefotetan for Injection USP and Dextrose Injection USP and

aminoglycosides are to be administered to the same patient, they must be administered separately and not as a mixed injection.

Caution: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is complete.

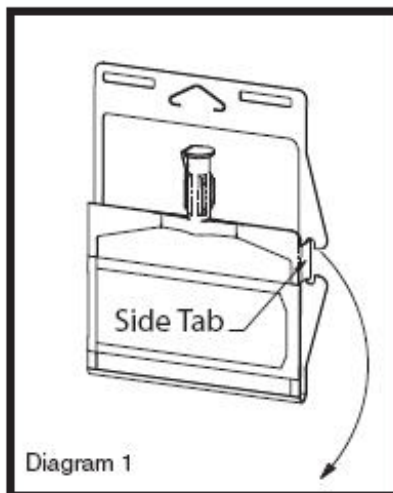
NOTE: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

DUPLEX® Drug Delivery System Directions for Use

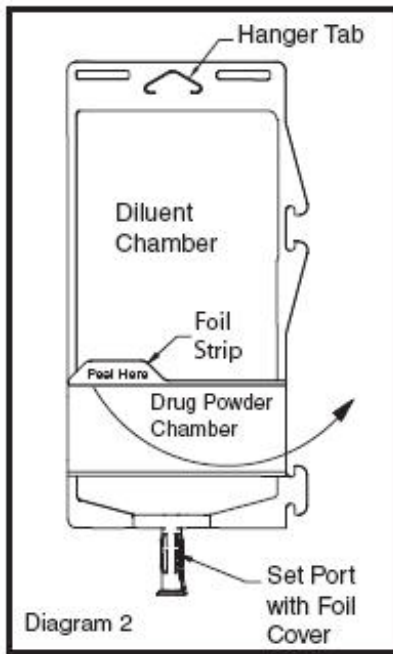
- To avoid inadvertent activation, DUPLEX® Container should remain in the folded position until activation is intended.

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.)



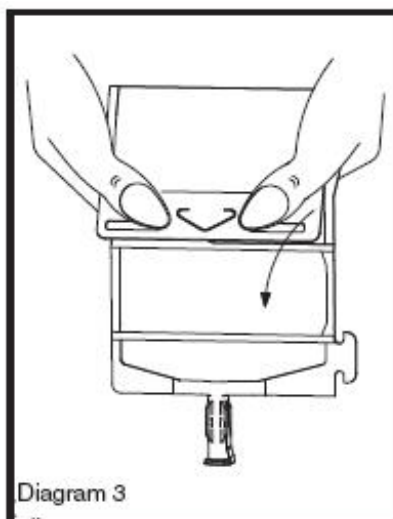
- Visually inspect diluent chamber for particulate matter.
- Use only if container and seals are intact.
- To inspect the drug powder for foreign matter or discoloration, peel foil strip from drug chamber. (See Diagram 2.)



- Protect from light after removal of foil strip.
Note: If foil strip is removed, product must be used within 7 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.)

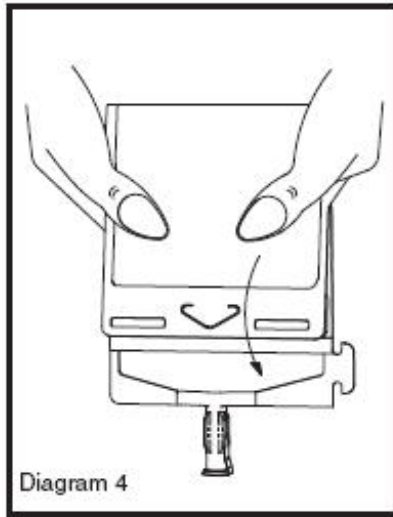


- Agitate the liquid-powder mixture until the drug powder is completely dissolved.
Note: Following reconstitution (activation), product must be used within 12 hours if stored at

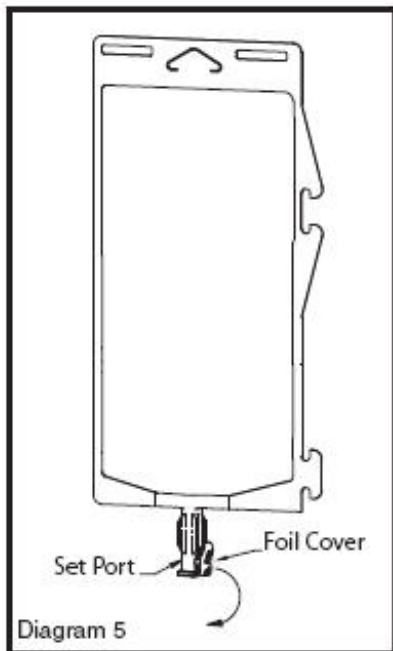
room temperature or within 5 days if stored under refrigeration.

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, peel foil cover from the set port and attach sterile administration set. (See Diagram 5.)



- Refer to Directions for Use accompanying the administration set.

Precautions

- As with other cephalosporins, reconstituted Cefotetan 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

Cefotetan 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 1 g and 2 g cefotetan. The diluent chamber contains approximately 50 mL of Dextrose Injection. Dextrose Injection has been adjusted to 3.58% w/v and 2.08% w/v for the 1 g and 2 g doses, respectively, such that the reconstituted solution is iso-osmotic.

Cefotetan for Injection USP and Dextrose Injection USP in the DUPLEX® Container is supplied sterile and nonpyrogenic in the DUPLEX® Drug Delivery System containers packaged 24 units per case.

NDC	REF	Dose	Volume
Cefotetan for Injection USP and Dextrose Injection USP in the DUPLEX® Container			
0264-3173-11	3173-11	1 g	50 mL
Cefotetan for Injection USP and Dextrose Injection USP in the DUPLEX® Container			
0264-3175-11	3175-11	2 g	50 mL

Store the unactivated unit at 20–25°C (68–77°F). Excursions permitted to 15–30°C (59–86°F). [See USP Controlled Room Temperature.]

Rx only

Revised: August 2012

REFERENCES

1. Clinical and Laboratory Standards Institute (CLSI). *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically*; Approved Standard - Ninth Edition. CLSI document M07-A9. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, 2012.
2. Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Disk Susceptibility Tests*; Approved Standard - Eleventh Edition. CLSI document M02-A11. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, 2012.
3. Clinical and Laboratory Standards Institute (CLSI). *Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria*; Approved Standard - Eighth Edition. CLSI document M11-A8. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, 2012.
4. Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Susceptibility Testing*; Twenty-second Informational Supplement. CLSI document M100-S22. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087, 2012.

DUPLEX is a registered trademark of B. Braun Medical Inc.

ATCC is a registered trademark of American Type Culture Collection.

Clintest is a registered trademark of Siemens Healthcare Diagnostics Inc.

U.S. Patent Nos. 5,944,709, 6,165,161, 6,203,535, 6,846,305, and 6,996,951.

B. Braun Medical Inc.

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1-800-227-2862

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Made in USA

Y36-002-815 LD-198-3

PRINCIPAL DISPLAY PANEL - 1 g Container Label

**Cefotetan for Injection USP
and Dextrose Injection USP
1g***

REF 3173-11

NDC 0264-3173-11

DUPLEX®

DRUG DELIVERY SYSTEM

50 mL

Use only after mixing contents of both chambers.

For IV Use Only Iso-osmotic Single Dose Sterile/Nonpyrogenic

*Contains Cefotetan disodium equivalent to 1 g cefotetan.

Reconstitution: Hold container with set port in a downward direction and fold the diluent chamber just below the solution meniscus. To activate seal, squeeze folded diluent chamber until seal between diluent and drug chamber opens, releasing diluent into drug chamber. Agitate the reconstituted solution until the drug powder is completely dissolved. Fold the container a second time and squeeze until seal between drug chamber and set port opens.

After reconstitution each 50 mL single dose unit contains: Cefotetan for Injection (equivalent to 1 g cefotetan) with approx. 1.79 g (3.58% w/v) Hydrous Dextrose in Water for Injection USP. Sodium content is 80 mg (3.5 mEq) per gram of cefotetan. Approximate osmolality: 290 mOsmol/kg.

Prior to Reconstitution: Store at 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature.] Use only if container and seals are intact. Do not peel foil strip until ready for use. After foil strip removal, product must be used within 7 days, but not beyond the labeled expiration date. Protect from light after removal of foil strip.

After Reconstitution: Use only if prepared solution is clear and free from particulate matter. Use within 12 hours if stored at room temperature or within 5 days if stored under refrigeration. Do not use in a series connection. Do not introduce additives into this container. Prior to administration check for minute leaks by squeezing container firmly. If leaks are found, discard container and solution as sterility may be impaired. Do not freeze.

**The DUPLEX Container is Latex-free, PVC-free, and DEHP-free
Rx only**

B. Braun Medical Inc.

Made in USA

Y37-002-400 LD-208-2

PEEL HERE

Drug Chamber

Discard unit if foil strip is damaged. Peel foil strip only when ready for use. Visually inspect drug prior to reconstitution.

See package insert for complete directions for reconstitution and administration.

LD-336-1 X27-001-485

Cefotetan for Injection USP and Dextrose Injection USP

1g*

REF 3173-11

DUPLEX®

NDC 0264-3173-11

DRUG DELIVERY SYSTEM

50 mL

Use only after mixing contents of both chambers.

For IV Use Only Iso-osmotic Single Dose Sterile/Nonpyrogenic

* Contains Cefotetan disodium equivalent to 1 g cefotetan.

Reconstitution: Hold container with set port in a downward direction and fold the diluent chamber just below the solution meniscus. To activate seal, squeeze folded diluent chamber until seal between diluent and drug chamber opens, releasing diluent into drug chamber. Agitate the reconstituted solution until the drug powder is completely dissolved. Fold the container a second time and squeeze until seal between drug chamber and set port opens.

After reconstitution each 50 mL single dose unit contains: Cefotetan for Injection (equivalent to 1 g cefotetan) with approx. 1.79 g (3.58% w/v) Hydrated Dextrose in Water for Injection USP. Sodium content is 80 mg (3.5 mEq) per gram of cefotetan. Approximate osmolality: 290 mOsmol/kg.

Prior to Reconstitution: Store at 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature.] Use only if container and seals are intact. Do not peel foil strip until ready for use. After foil strip removal, product must be used within 7 days, but not beyond the labeled expiration date. Protect from light after removal of foil strip.

After Reconstitution: Use only if prepared solution is clear and free from particulate matter. Use within 12 hours if stored at room temperature or within 5 days if stored under refrigeration. Do not use in a series connection. Do not introduce additives into this container. Prior to administration check for minute leaks by squeezing container firmly. If leaks are found, discard container and solution as sterility may be impaired. Do not freeze.

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

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Y37-002-400
LD-208-2



NDC No. (01)10302643173118

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PEEL HERE



Drug Chamber

Discard unit if foil strip is damaged. Peel foil strip only when ready for use. Visually inspect drug prior to reconstitution.

See package insert for complete directions for reconstitution and administration.

LD-336-1 X27-001-485

PRINCIPAL DISPLAY PANEL - 2 g Container Label

**Cefotetan for Injection USP
and Dextrose Injection USP**
2g*

REF 3175-11

NDC 0264-3175-11

DUPLEX®

DRUG DELIVERY SYSTEM

50 mL

Use only after mixing contents of both chambers.

For IV Use Only Iso-osmotic Single Dose Sterile/Nonpyrogenic

*Contains Cefotetan disodium equivalent to 2 g cefotetan.

Reconstitution: Hold container with set port in a downward direction and fold the diluent chamber just below the solution meniscus. To activate seal, squeeze folded diluent chamber until seal between diluent and drug chamber opens, releasing diluent into drug chamber. Agitate the reconstituted solution until the drug powder is completely dissolved. Fold the container a second time and squeeze until seal between drug chamber and set port opens.

After reconstitution each 50 mL single dose unit contains: Cefotetan for Injection (equivalent to 2 g cefotetan) with approx. 1.04 g (2.08% w/v) Hydrous Dextrose in Water for Injection USP. Sodium content is 80 mg (3.5 mEq) per gram of cefotetan. Approximate osmolality: 290 mOsmol/kg.

Prior to Reconstitution: Store at 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature.] Use only if container and seals are intact. Do not peel foil strip until ready for use. After foil strip removal, product must be used within 7 days, but not beyond the labeled expiration date. Protect from light after removal of foil strip.

After Reconstitution: Use only if prepared solution is clear and free from particulate matter. Use within 12 hours if stored at room temperature or within 5 days if stored under refrigeration. Do not use in a series connection. Do not introduce additives into this container. Prior to administration check for minute leaks by squeezing container firmly. If leaks are found, discard container and solution as sterility

may be impaired. Do not freeze.

**The DUPLEX Container is Latex-free, PVC-free, and DEHP-free
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Made in USA

Y37-002-401 LD-209-2

PEEL HERE

Drug Chamber

Discard unit if foil strip is damaged. Peel foil strip only when ready for use. Visually inspect drug prior to reconstitution.

See package insert for complete directions for reconstitution and administration.

LD-336-1 X27-001-485

Cefotetan for Injection USP and Dextrose Injection USP

2g*

REF 3175-11

DUPLEX®

NDC 0264-3175-11

DRUG DELIVERY SYSTEM

50 mL

Use only after mixing contents of both chambers.

For IV Use Only Iso-osmotic Single Dose Sterile/Nonpyrogenic

* Contains Cefotetan disodium equivalent to 2 g cefotetan.

Reconstitution: Hold container with set port in a downward direction and fold the diluent chamber just below the solution meniscus. To activate seal, squeeze folded diluent chamber until seal between diluent and drug chamber opens, releasing diluent into drug chamber. Agitate the reconstituted solution until the drug powder is completely dissolved. Fold the container a second time and squeeze until seal between drug chamber and set port opens.

After reconstitution each 50 mL single dose unit contains: Cefotetan for Injection (equivalent to 2 g cefotetan) with approx. 1.04 g (2.08% w/v) Hydrous Dextrose in Water for Injection USP. Sodium content is 80 mg (3.5 mEq) per gram of cefotetan. Approximate osmolality: 290 mOsmol/kg.

Prior to Reconstitution: Store at 20-25°C (68-77°F). Excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature.] Use only if container and seals are intact. Do not peel foil strip until ready for use. After foil strip removal, product must be used within 7 days, but not beyond the labeled expiration date. Protect from light after removal of foil strip.

After Reconstitution: Use only if prepared solution is clear and free from particulate matter. Use within 12 hours if stored at room temperature or within 5 days if stored under refrigeration. Do not use in a series connection. Do not introduce additives into this container. Prior to administration check for minute leaks by squeezing container firmly. If leaks are found, discard container and solution as sterility may be impaired. Do not freeze.

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

Rx only

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Y37-002-401
LD-209-2



NDC No. (01)10302643175112

Made in USA

PEEL HERE



Drug Chamber

Discard unit if foil strip is damaged. Peel foil strip only when ready for use. Visually inspect drug prior to reconstitution.

See package insert for complete directions for reconstitution and administration.

LD-336-1 X27-001-485

CEFOTETAN AND DEXTROSE

cefotetan and dextrose injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0264-3173
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CEFOTETAN DISODIUM (UNII: 0GXP746VXB) (CEFOTETAN - UNII:48SPP0PA9Q)	CEFOTETAN	1 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	1.79 g in 50 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-3173-11	24 in 1 CASE		
1		50 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA065430	08/20/2010	

CEFOTETAN AND DEXTROSE

cefotetan and dextrose injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0264-3175
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CEFOTETAN DISODIUM (UNII: 0GXP746VXB) (CEFOTETAN - UNII:48SPP0PA9Q)	CEFOTETAN	2 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	1.04 g in 50 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-3175-11	24 in 1 CASE		
1		50 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA065430	08/20/2010	

Labeler - B. Braun Medical Inc. (002397347)

Revised: 2/2013

B. Braun Medical Inc.