CEFEPIME- cefepime injection, solution
Baxter Healthcare Company

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use CEFEPIME Injection safely and effectively. See full prescribing information for CEFEPIME Injection.

CEFEPIME injection, for intravenous use
Initial U.S. Approval: 1996

RECENT MAJOR CHANGES

Warnings and Precautions, Hypersensitivity Reactions (5.1) 12/2025

INDICATIONS AND USAGE

Cefepime Injection is a cephalosporin antibacterial indicated in the treatment of the following infections caused by susceptible isolates of the designated microorganisms: pneumonia (1.1); empiric therapy for febrile neutropenic patients (1.2); uncomplicated and complicated urinary tract infections (1.3); uncomplicated skin and skin structure infections (1.4); and complicated intra-abdominal infections (used in combination with metronidazole) (1.5).
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefepime Injection and other antibacterial drugs, Cefepime Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. (1.6)

DOSAGE AND ADMINISTRATION

Recommended Dosage in Adults With Creatinine Clearance (CrCL) Greater Than 60 mL/min (2.1)

Site and Type of Infection (Adults)	Dose (IV)	Frequency	Duration (Days)
Moderate to Severe Pneumonia*	1-2 g	Every 8-12 hours	10
Empiric therapy for febrile neutropenic patients	2 g	Every 8 hours	7†
Mild to Moderate Uncomplicated or Complicated Urinary Tract Infections	0.5-1 g	Every 12 hours	7-10
Severe Uncomplicated or Complicated Urinary Tract Infections	2 g	Every 12 hours	10
Moderate to Severe Uncomplicated Skin and Skin Structure Infections	2 g	Every 12 hours	10
Complicated Intra-abdominal Infections (used in combination with metronidazole) *	2 g	Every 8-12 hours	7-10

* For *Pseudomonas aeruginosa*, use 2 g IV every 8 hours (2.1)
† Or until resolution of neutropenia (2.1)

- Pediatric Patients (2 months to 16 years) – Recommended dosage in pediatric with CrCL greater than 60 mL/min. (2.2)
- The usual recommended dosage in pediatric patients is 50 mg per kg per dose administered every 12 hours (every 8 hours for febrile neutropenia). (2.2)
- Cefepime Injection in Galaxy Container should be used only in pediatric patients who require the entire 1 gram or 2 gram dose and not any fraction thereof. (2.2)
- Patients with Renal Impairment: Adjust dose in patients with CrCL less than or equal to 60 mL/min. (2.3)
- Administer intravenously over approximately 30 minutes. (2.1)
- Do not force thaw frozen container by immersion in water baths or by microwave irradiation. (2.4)

DOSAGE FORMS AND STRENGTHS

- Cefepime Injection: 1 g in 50 mL and 2 g in 100 mL single-dose Galaxy Container. (3)

CONTRAINDICATIONS

- Prior immediate hypersensitivity reactions to cefepime or the cephalosporin class of antibacterial drugs, penicillins, and other beta-lactam antibacterial drugs. (4)

WARNINGS AND PRECAUTIONS

- Cross-hypersensitivity among beta-lactam antibacterial drugs may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to Cefepime Injection occurs, discontinue the drug. (5.1)
- Neurotoxicity: May occur especially in patients with renal impairment administered unadjusted doses. If neurotoxicity associated with Cefepime Injection therapy occurs, discontinue the drug. (5.2)
- *Clostridioides difficile* Associated Diarrhea (CDAD): Evaluate if diarrhea occurs. (5.3)

ADVERSE REACTIONS

- The most common adverse reactions (incidence ≥ 1 %) were local reactions positive Coombs' test, decreased phosphorous, increased ALT and AST, increased PT and PTT and rash. (6.1)
- At the highest dose (2 g every 8 hours), incidence of adverse reactions was ≥1% for rash, diarrhea, nausea, vomiting, pruritis, fever, and headache. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Baxter at 1-866-888-2472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Aminoglycosides -- increased potential of nephrotoxicity and ototoxicity. (7.2)
- Diuretics -- nephrotoxicity has been reported following concomitant administration of other cephalosporins with potent diuretics such as furosemide. (7.3)

USE IN SPECIFIC POPULATIONS

- Geriatric Use – Serious adverse reactions have occurred in geriatric patients with renal impairment given unadjusted doses of cefepime. (8.5)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 12/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Pneumonia

Cefepime Injection is indicated for pneumonia (moderate to severe) caused by *Streptococcus pneumoniae,* including cases associated with concurrent bacteremia, *Pseudomonas aeruginosa, Klebsiella pneumoniae,* or *Enterobacter* species.

1.2 Empiric Therapy for Febrile Neutropenic Patients

Cefepime Injection as monotherapy is indicated for empiric treatment of febrile

neutropenic patients. In patients at high risk for severe infection (including patients with a history of recent bone marrow transplantation, with hypotension at presentation, with an underlying hematologic malignancy, or with severe or prolonged neutropenia), antimicrobial monotherapy may not be appropriate. Insufficient data exist to support the efficacy of cefepime monotherapy in such patients [*see Clinical Studies (14)*].

1.3 Uncomplicated and Complicated Urinary Tract Infections (including pyelonephritis)

Cefepime Injection is indicated for uncomplicated and complicated urinary tract infections (including pyelonephritis) caused by *Escherichia coli* or *Klebsiella pneumoniae,* when the infection is severe, or caused by *Escherichia coli, Klebsiella pneumoniae,* or *Proteus mirabilis,* when the infection is mild to moderate, including cases associated with concurrent bacteremia with these microorganisms.

1.4 Uncomplicated Skin and Skin Structure Infections

Cefepime Injection is indicated for uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes*.

1.5 Complicated Intra-abdominal Infections

Cefepime Injection is indicated for complicated intra-abdominal infections (used in combination with metronidazole) caused by *Escherichia coli,* viridans group streptococci, *Pseudomonas aeruginosa, Klebsiella pneumoniae, Enterobacter* species, or *Bacteroides fragilis [see Clinical Studies (14)].*

1.6 Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefepime Injection and other antibacterial drugs, Cefepime Injection 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.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage for Adults

The recommended adult dosages and routes of administration are outlined in Table 1 below for patients with creatinine clearance greater than 60 mL/min. Administer Cefepime Injection intravenously over approximately 30 minutes.

Table 1: Recommended Dosage Schedule for Cefepime Injection in Adult Patients with Creatinine Clearance (CrCL) Greater Than 60 mL/min

Site and Type of Infection	Dose	Frequency	Duration (days)

Adults			
Moderate to Severe Pneumonia due to *S. pneumoniae*, *P. aeruginosa*[*], *K. pneumoniae,* or *Enterobacter* species	1-2 g IV	Every 8-12 hours	10
Empiric therapy for febrile neutropenic patients *[see Indications and Usage (1) and Clinical Studies (14)]*	2 g IV	Every 8 hours	7[†]
Mild to Moderate Uncomplicated or Complicated Urinary Tract Infections, including pyelonephritis, due to *E. coli, K. pneumoniae,* or *P. mirabilis*	0.5-1 g IV	Every 12 hours	7-10
Severe Uncomplicated or Complicated Urinary Tract Infections, including pyelonephritis, due to *E. coli* or *K. pneumoniae*	2 g IV	Every 12 hours	10
Moderate to Severe Uncomplicated Skin and Skin Structure Infections due to *S. aureus* or *S. pyogenes*	2 g IV	Every 12 hours	10
Complicated Intra-abdominal Infections (used in combination with metronidazole) caused by *E. coli,* viridans group streptococci, *P. aeruginosa*[*], *K. pneumoniae, Enterobacter* species, or *B. fragilis*. *[see Clinical Studies (14)]*	2 g IV	Every 8-12 hours	7-10

* For *Pseudomonas aeruginosa*, use 2 g IV every 8 hours

† or until resolution of neutropenia. In patients whose fever resolves but who remain neutropenic for more than 7 days, the need for continued antimicrobial therapy should be re-evaluated frequently.

2.2 Pediatric Patients (2 months up to 16 years)

The maximum dose for pediatric patients should not exceed the recommended adult dose. The usual recommended dosage in pediatric patients up to 40 kg in weight for durations as given above for adults is:

- 50 mg per kg per dose, administered every 12 hours for uncomplicated and complicated urinary tract infections (including pyelonephritis), uncomplicated skin and skin structure infections, and pneumonia (see below).
- For moderate to severe pneumonia due to P. aeruginosa give 50 mg per kg per dose, every 8 hours.
- 50 mg per kg per dose, every 8 hours for febrile neutropenic patients.

Cefepime Injection in Galaxy Container should be used only in pediatric patients who

require the entire 1 or 2 g dose and not any fraction thereof.

2.3 Dosage Adjustments in Patients with Renal Impairment

Adult Patients

Adjust the dose of Cefepime Injection in patients with creatinine clearance less than or equal to 60 mL/min to compensate for the slower rate of renal elimination. In these patients, the recommended initial dose of Cefepime Injection should be the same as in patients with CrCL greater than 60 mL/min except in patients undergoing hemodialysis. The recommended doses of Cefepime Injection in patients with renal impairment are presented in **Table 2**.

When only serum creatinine is available, the following formula (Cockcroft and Gault equation)[1] may be used to estimate creatinine clearance. The serum creatinine should represent a steady state of renal function:

$$\text{Males: Creatinine Clearance (mL/min)} = \frac{\text{Weight (kg)} \times (140 - \text{age})}{72 \times \text{serum creatinine (mg/dL)}}$$

Females: 0.85 x above value

Table 2: Recommended Dosing Schedule for Cefepime Injection in Adult Patients With Creatinine Clearance Less Than or Equal to 60 mL/min

Creatinine Clearance (mL/min)	Recommended Maintenance Schedule			
Greater than 60	500 mg every 12 hours	1 g every 12 hours	2 g every 12 hours	2 g every 8 hours
30–60	500 mg every 24 hours	1 g every 24 hours	2 g every 24 hours	2 g every 12 hours
11–29	500 mg every 24 hours	500 mg every 24 hours	1 g every 24 hours	2 g every 24 hours
Less than 11	250 mg every 24 hours	250 mg every 24 hours	500 mg every 24 hours	1 g every 24 hours
Continuous Ambulatory Peritoneal Dialysis CAPD	500 mg every 48 hours	1 g every 48 hours	2 g every 48 hours	2 g every 48 hours
Hemodialysis*	1 g on day 1, then 500 mg every 24 hours thereafter			1 g every 24 hours

* On hemodialysis days, Cefepime Injection should be administered following hemodialysis. Whenever possible, Cefepime Injection should be administered at the same time each day.

In patients undergoing Continuous Ambulatory Peritoneal Dialysis (CAPD), Cefepime Injection may be administered at the recommended doses at a dosage interval of every 48 hours (see Table 2).

In patients undergoing hemodialysis, approximately 68% of the total amount of cefepime present in the body at the start of dialysis will be removed during a 3-hour dialysis

period. The dosage of Cefepime Injection for hemodialysis patients is 1 g on Day 1 followed by 500 mg every 24 hours for the treatment of all infections except febrile neutropenia, which is 1 g every 24 hours.

Cefepime Injection should be administered at the same time each day and following the completion of hemodialysis on hemodialysis days (see Table 2).

Pediatric Patients

Data in pediatric patients with impaired renal function are not available; however, since cefepime pharmacokinetics are similar in adults and pediatric patients *[see Clinical Pharmacology (12.3)]*, changes in the dosing regimen proportional to those in adults (see Table 1 and Table 2) are recommended for pediatric patients.

2.4 Directions for Use of Cefepime Injection in Galaxy Container

Cefepime Injection in Galaxy Container is for intravenous administration using sterile equipment after thawing to room temperature.

Thawing of Plastic Container

Thaw frozen container at room temperature 25°C (77°F) or under refrigeration 5°C (41°F). Do not force thaw by immersion in water baths or by microwave irradiation.*[See How Supplied/Storage and Handling (16).]*

Check for minute leaks by squeezing container firmly. If leaks are detected, discard solution as sterility may be impaired.

Do not add supplementary medication.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Components of the solution may precipitate in the frozen state and will dissolve upon reaching room temperature with little or no agitation. Potency is not affected. Agitate after solution has reached room temperature. If after visual inspection the solution remains cloudy or if an insoluble precipitate is noted or if any seals are not intact, the container should be discarded.

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.

Preparation for intravenous administration.

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

Cefepime Injection should be administered intravenously over approximately 30 minutes.

Intermittent intravenous infusion with a Y-type administration set can be accomplished with compatible solutions. However, during infusion of Cefepime Injection, it is desirable to discontinue the other solution.

Solutions of cefepime, like those of most beta-lactam antibacterial drugs, should not be added to solutions of ampicillin at a concentration greater than 40 mg per mL, and should not be added to metronidazole, vancomycin, gentamicin, tobramycin, netilmicin sulfate or aminophylline because of potential interaction. However, if concurrent therapy with cefepime is indicated, each of these antibacterials can be administered separately.

As with other cephalosporins, the color of Cefepime Injection tend to darken depending on storage conditions; however, when stored as recommended, the product potency is not adversely affected.

3 DOSAGE FORMS AND STRENGTHS

Cefepime Injection is available in the following strengths:

- 1 g in 50 mL (contains 1 g of cefepime as Cefepime Hydrochloride, USP) single-dose Galaxy Container
- 2 g in 100 mL (contains 2 g of cefepime as Cefepime Hydrochloride, USP) single-dose Galaxy Container

4 CONTRAINDICATIONS

Cefepime Injection is contraindicated in patients who have shown immediate hypersensitivity reactions to cefepime or the cephalosporin class of antibacterials, penicillins or other beta-lactam antibacterial drugs.

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Before therapy with Cefepime Injection is instituted, careful inquiry should be made to determine whether the patient has had previous immediate hypersensitivity reactions to cefepime, cephalosporins, penicillins, or other beta-lactams. Exercise caution if this product is to be given to penicillin-sensitive patients because cross-hypersensitivity among beta-lactam antibacterial drugs has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to Cefepime Injection occurs, discontinue the drug and institute appropriate supportive measures. Hypersensitivity reactions can progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction.

5.2 Neurotoxicity

Serious adverse reactions have been reported including life-threatening or fatal occurrences of the following: encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), aphasia, myoclonus, seizures, and nonconvulsive status epilepticus *[see Adverse Reactions (6.2)].* Most cases occurred in patients with renal impairment who did not receive appropriate dosage adjustment. However, some cases of neurotoxicity occurred in patients receiving a dosage

adjustment appropriate for their degree of renal impairment.

In the majority of cases, symptoms of neurotoxicity were reversible and resolved after discontinuation of cefepime and/or after hemodialysis. If neurotoxicity associated with cefepime therapy occurs, discontinue cefepime and institute appropriate supportive measures.

5.3 *Clostridioides difficile* Associated Diarrhea

Clostridioides difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Cefepime Injection, 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 antibacterial drug 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 antibacterial drug use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

5.4 Development of Drug-Resistant Bacteria

Prescribing cefepime in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

As with other antimicrobials, prolonged use of cefepime may result in overgrowth of nonsusceptible microorganisms. Repeated evaluation of the patient’s condition is essential. Should superinfection occur during therapy, appropriate measures should be taken.

5.5 Drug/Laboratory Test Interactions

Urinary Glucose

The administration of cefepime may result in a false-positive reaction for glucose in the urine when using some methods (e.g. Clinitest tablets) *[see Drug Interactions (7.1)].*

Coombs' Tests

Positive direct Coombs’ tests have been reported during treatment with cefepime. In patients who develop hemolytic anemia, discontinue the drug and institute appropriate therapy. Positive Coombs’ test may be observed in newborns whose mothers have received cephalosporin antibacterials before parturition.

Prothrombin Time

Many cephalosporins, including cefepime, have been 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 antibacterial

therapy. Prothrombin time should be monitored in patients at risk, and exogenous vitamin K administered as indicated.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in other sections of the labeling:

- Hypersensitivity reactions *[see Warnings and Precautions (5.1)]*
- Neurotoxicity *[see Warnings and Precautions (5.2)]*
- *Clostridioides difficile*-associated diarrhea *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials using multiple doses of cefepime, 4137 patients were treated with the recommended dosages of cefepime (500 mg to 2 g intravenously every 12 hours). There were no deaths or permanent disabilities thought related to drug toxicity. Sixty-four (1.5%) patients discontinued medication due to adverse reactions. Thirty-three (51%) of these 64 patients who discontinued therapy did so because of rash. The percentage of cefepime-treated patients who discontinued study drug because of drug-related adverse reactions was similar at daily doses of 500 mg, 1 g, and 2 g every 12 hours (0.8%, 1.1%, and 2%, respectively). However, the incidence of discontinuation due to rash increased with the higher recommended doses.

The following adverse reactions (Table 3) were identified in clinical trials conducted in North America (n=3125 cefepime-treated patients).

Table 3: Adverse Reactions in Cefepime Multiple-Dose Dosing Regimens Clinical Trials in North America

INCIDENCE EQUAL TO OR GREATER THAN 1%	Local adverse reactions (3%), including phlebitis (1.3%), pain and/or inflammation (0.6%)*; rash (1.1%)
INCIDENCE LESS THAN 1% BUT GREATER THAN 0.1%	Colitis (including pseudomembranous colitis), diarrhea, erythema, fever, headache, nausea, oral moniliasis, pruritus, urticaria, vaginitis, vomiting, anemia

* Local reactions, irrespective of relationship to cefepime in those patients who received intravenous infusion (n=3048).

At the higher dose of 2 g every 8 hours, the incidence of adverse reactions was higher among the 795 patients who received this dose of cefepime. They consisted of rash (4%), diarrhea (3%), nausea (2%), vomiting (1%), pruritus (1%), fever (1%), and headache (1%).

The following (Table 4) adverse laboratory changes with cefepime, were seen during clinical trials conducted in North America.

Table 4: Adverse Laboratory Changes in Cefepime Multiple-Dose Dosing Regimens Clinical Trials in North America

INCIDENCE EQUAL TO OR GREATER THAN 1%	Positive Coombs' test (without hemolysis) (16.2%); decreased phosphorus (2.8%); increased Alanine Transaminase (ALT) (2.8%), Aspartate Transaminase (AST) (2.4%), eosinophils (1.7%); abnormal PTT (1.6%), Prothrombin Time (PT) (1.4%)
INCIDENCE LESS THAN 1% BUT GREATER THAN 0.1%	Increased alkaline phosphatase, Blood Urea Nitrogen (BUN), calcium, creatinine, phosphorus, potassium, total bilirubin; decreased calcium*, hematocrit, neutrophils, platelets, White Blood Cells (WBC)

* Hypocalcemia was more common among elderly patients. Clinical consequences from changes in either calcium or phosphorus were not reported.

A similar safety profile was seen in clinical trials of pediatric patients.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Cefepime Injection. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

In addition to the adverse reactions reported during North American clinical trials with cefepime, the following adverse reactions have been reported during worldwide postmarketing experience.

Encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), aphasia, myoclonus, seizures, and nonconvulsive status epilepticus have been reported *[see Warnings and Precautions (5.2)].*

Anaphylaxis including anaphylactic shock, transient leukopenia, neutropenia, agranulocytosis, and thrombocytopenia, have been reported.

6.3 Cephalosporin-Class Adverse Reactions

In addition to the adverse reactions listed above that have been observed in patients treated with cefepime, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibacterial drugs:

Kounis syndrome, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, renal dysfunction, toxic nephropathy, aplastic anemia, hemolytic anemia, hemorrhage, fall in prothrombin activity, hepatic dysfunction including cholestasis, and pancytopenia.

7 DRUG INTERACTIONS

7.1 Drug/Laboratory Test Interactions

The administration of cefepime may result in a false-positive reaction for glucose in the

urine with certain methods. It is recommended that glucose tests based on enzymatic glucose oxidase reactions be used *[see Warning and Precautions (5.5)].*

7.2 Aminoglycosides

Renal function should be monitored carefully if high doses of aminoglycosides are to be administered with Cefepime Injection because of the increased potential of nephrotoxicity and ototoxicity of aminoglycoside antibacterial drugs.

7.3 Diuretics

Nephrotoxicity has been reported following concomitant administration of other cephalosporins with potent diuretics such as furosemide.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk summary

There are no cases of cefepime exposure during pregnancy reported from postmarketing experience or from clinical trials. Available data from published observational studies and case reports over several decades with cephalosporin use in pregnant women have not established drug-associated risks of major birth defects, miscarriage or adverse maternal or fetal outcomes (see *Data*).

Cefepime was not associated with adverse developmental outcomes in rats, mice, or rabbits when administered parenterally during the period of organogenesis. The doses used in these studies were 1.6 times (rats), approximately equal to (mice) and 0.3 times (rabbits) the maximum recommended clinical dose (*see Data)*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Human Data

While available studies cannot definitively establish the absence of risk, published data from case-control studies and case reports over several decades have not identified an association with cephalosporin use during pregnancy and major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Available studies have methodologic limitations, including small sample size, retrospective data collection, and inconsistent comparator groups.

Animal data

Cefepime was not embryocidal and did not cause fetal malformations when administered parenterally during the period of organogenesis to rats at doses up to 1000 mg/kg/day, to mice at doses up to 1200 mg/kg/day, or to rabbits at doses up to 100 mg/kg/day. These doses are 1.6 times (rats), approximately equal to (mice), and 0.3 times (rabbits)

the maximum recommended clinical dose based on body surface area.

8.2 Lactation

Risk Summary

Cefepime is present in human milk at low concentration (0.5 mcg/mL). A nursing infant consuming approximately 1000 mL of human milk per day would receive approximately 0.5 mg of cefepime per day. There is no information regarding effects of cefepime on milk production or on the breastfed infant. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for cefepime and any potential adverse effects on the breastfed child from cefepime or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of cefepime in the treatment of uncomplicated and complicated urinary tract infections (including pyelonephritis), uncomplicated skin and skin structure infections, pneumonia, and as empiric therapy for febrile neutropenic patients have been established in the age groups 2 months up to 16 years. Use of Cefepime Injection in these age groups is supported by evidence from adequate and well-controlled studies of cefepime in adults with additional pharmacokinetic and safety data from pediatric trials *[see Clinical Pharmacology (12)].*

Safety and effectiveness in pediatric patients below the age of 2 months have not been established. There are insufficient clinical data to support the use of Cefepime Injection in pediatric patients under 2 months of age or for the treatment of serious infections in the pediatric population where the suspected or proven pathogen is *Haemophilus influenzae* type b. In those patients in whom meningeal seeding from a distant infection site or in whom meningitis is suspected or documented, an alternate agent with demonstrated clinical efficacy in this setting should be used.

Cefepime Injection in Galaxy Container should be used only in pediatric patients who require the entire 1 or 2 g dose and not any fraction thereof.

8.5 Geriatric Use

Of the more than 6400 adults treated with cefepime in clinical studies, 35% were 65 years or older while 16% were 75 years or older. When geriatric patients received the usual recommended adult dose, clinical efficacy and safety were comparable to clinical efficacy and safety in nongeriatric adult patients.

Serious adverse events have occurred in geriatric patients with renal impairment given unadjusted doses of cefepime, including life-threatening or fatal occurrences of the following: encephalopathy, myoclonus, and seizures *[see Warnings and Precautions (5) and Adverse Reactions (6)].*

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 renal function should be monitored *[see Clinical Pharmacology (12), Warnings and Precautions (5), and Dosage and Administration (2)].*

8.6 Renal Impairment

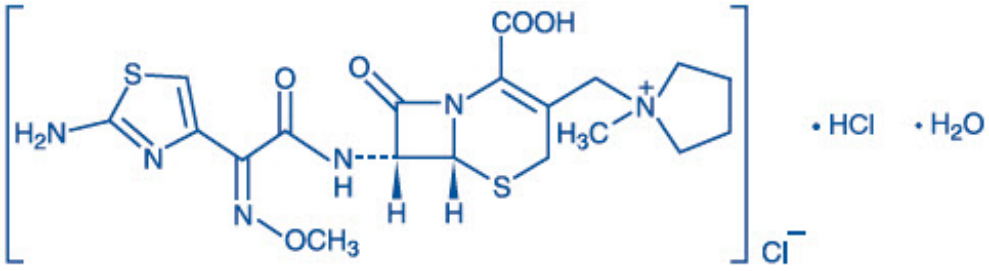
Adjust the dose of Cefepime Injection in patients with creatinine clearance less than or equal to 60 mL/min to compensate for the slower rate of renal elimination *[see Dosage and Administration (2.3)].*

10 OVERDOSAGE

Patients who receive an overdose should be carefully observed and given supportive treatment. In the presence of renal impairment, hemodialysis, not peritoneal dialysis, is recommended to aid in the removal of cefepime from the body. Accidental overdosing has occurred when large doses were given to patients with impaired renal function. Symptoms of overdose include encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), myoclonus, seizures, and neuromuscular excitability *[see Warnings and Precautions (5), Adverse Reactions (6), and Dosage and Administration (2)].*

11 DESCRIPTION

Cefepime Injection in Galaxy Container is a sterile, injectable product consisting of Cefepime Hydrochloride, USP, a semi-synthetic, broad spectrum, cephalosporin antibacterial for parenteral administration. The chemical name is 1-[[(6R,7R)-7-[2-(2-Amino-4-thiazolyl) glyoxylamido]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0] oct-2-en-3-yl]methyl]-1-methylpyrrolidinium chloride, 7^2-(Z)-(O-methyloxime), monohydrochloride, monohydrate, which corresponds to the following structural formula:



Cefepime hydrochloride (monohydrate) has a molecular mass of 571.50 and a molecular formula of $C_{19}H_{25}ClN_6O_5S_2 \bullet HCl \bullet H_2O$.

Cefepime Injection in Galaxy Container is a frozen, iso-osmotic, sterile, non-pyrogenic premixed solution supplied for intravenous administration in strengths equivalent to 1 g and 2 g of cefepime *[see Dosage and Administration (2)].* It contains the equivalent of not less than 90 percent and not more than 115 percent of the labeled amount of cefepime ($C_{19}H_{24}N_6O_5S_2$).

The solution is intended for intravenous use after thawing to room temperature. The components and dosage formulations are given in the table below:

Table 5: Cefepime Injection in Galaxy Containers Premixed Frozen Solution

Component*	Function	Dosage Formulations	
		1 g in 50 mL	2 g in 100 mL

Cefepime	active ingredient	1 g	2 g
Dextrose Hydrous, USP	osmolality adjuster	1.03 g	2.06 g
L-Arginine, USP†	pH adjuster	725 mg	1.45 g
Hydrochloric Acid†	pH adjuster	As needed	As needed
Water for Injection, USP	vehicle	q.s.‡ 50 mL	q.s.‡ 100 mL

* Cefepime is present in the formulation as Cefepime Hydrochloride, USP. The amounts of Dextrose Hydrous, USP and L-Arginine, USP are approximate.
† The pH may have been adjusted with hydrochloric acid and/or additional L-Arginine, USP. The pH is 4.0 – 6.0.
‡ This is an abbreviation for sufficient quantity.

Cefepime Injection will range in color from colorless to amber.

The plastic container is fabricated from a specially designed multilayer plastic. Solutions are in contact with the polyethylene layer of this container and can leach out certain chemical components of the plastic in very small amounts within the expiration period. The suitability of the plastic has been confirmed in tests in animals according to the USP biological tests for plastic containers, as well as by tissue culture toxicity studies.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Cefepime is an antibacterial drug. *[See Microbiology (12.4)]*

12.2 Pharmacodynamics

Similar to other beta-lactam antibacterial drugs, the time that the unbound plasma concentration of cefepime exceeds the MIC of the infecting organism has been shown to best correlate with efficacy in animal models of infection. However, the pharmacokinetic/pharmacodynamic relationship for cefepime has not been evaluated in patients.

12.3 Pharmacokinetics

Pharmacokinetic parameters for cefepime in healthy adult male volunteers (n=9) following single 30-minute intravenous infusions of cefepime 500 mg, 1 g, and 2 g are summarized in Table 6. Elimination of cefepime is principally via renal excretion with an average (±SD) half-life of 2 (±0.3) hours and total body clearance of 120 (±8) mL/min in healthy volunteers. Cefepime pharmacokinetics are linear over the range 250 mg to 2 g. There is no evidence of accumulation in healthy adult male volunteers (n=7) receiving clinically relevant doses for a period of 9 days.

Table 6: Mean Pharmacokinetic Parameters for Cefepime (±SD), Intravenous Administration

	CEFEPIME		
Parameter	**500 mg IV**	**1 g IV**	**2 g IV**
C_{max}, mcg/mL	39.1 (3.5)	81.7 (5.1)	163.9 (25.3)
AUC, h•mcg/mL	70.8 (6.7)	148.5 (15.1)	284.8 (30.6)
Number of subjects	9	9	9

(male)

Distribution

The average steady-state volume of distribution of cefepime is 18.0 (±2.0) L. The serum protein binding of cefepime is approximately 20% and is independent of its concentration in serum.

Concentrations of cefepime achieved in specific tissues and body fluids are listed in Table 7.

Table 7: Mean Concentrations of Cefepime in Specific Body Fluids (mcg/mL) or Tissues (mcg/g)

Tissue or Fluid	Dose/Route	# of Patients	Mean Time of Sample Post-Dose (h)	Mean Concentration
Blister Fluid	2 g IV	6	1.5	81.4 mcg/mL
Bronchial Mucosa	2 g IV	20	4.8	24.1 mcg/g
Sputum	2 g IV	5	4	7.4 mcg/mL
Urine	500 mg IV	8	0-4	292 mcg/mL
	1 g IV	12	0-4	926 mcg/mL
	2 g IV	12	0-4	3120 mcg/mL
Bile	2 g IV	26	9.4	17.8 mcg/mL
Peritoneal Fluid	2 g IV	19	4.4	18.3 mcg/mL
Appendix	2 g IV	31	5.7	5.2 mcg/g
Gall Bladder	2 g IV	38	8.9	11.9 mcg/g
Prostate	2 g IV	5	1	31.5 mcg/g

Data suggest that cefepime does cross the inflamed blood-brain barrier. The clinical relevance of these data is uncertain **at** this time.

Metabolism and Excretion

Cefepime is metabolized to N-methylpyrrolidine (NMP), which is rapidly converted to the N-oxide (NMP-N-oxide). Urinary recovery of unchanged cefepime accounts for approximately 85% of the administered dose. Less than 1% of the administered dose is recovered from urine as NMP, 6.8% as NMP-N-oxide, and 2.5% as an epimer of cefepime. Because renal excretion is a significant pathway of elimination, patients with renal dysfunction and patients undergoing hemodialysis require dosage adjustment *[see Dosage and Administration (2)].*

Specific Populations

Patients with Renal Impairment

Cefepime pharmacokinetics have been investigated in patients with various degrees of renal impairment (n=30). The average half-life in patients requiring hemodialysis was 13.5 (±2.7) hours and in patients requiring continuous peritoneal dialysis was 19 (±2.0) hours. Cefepime total body clearance decreased proportionally with creatinine clearance

in patients with abnormal renal function, which serves as the basis for dosage adjustment recommendations in this group of patients *[see Dosage and Administration (2)].*

Patients with Hepatic Impairment

The pharmacokinetics of cefepime were unaltered in patients with hepatic impairment who received a single 1 g dose (n=11).

Geriatric Patients

Cefepime pharmacokinetics have been investigated in elderly (65 years of age and older) men (n=12) and women (n=12) whose mean (SD) creatinine clearance was 74.0 (±15.0) mL/min. There appeared to be a decrease in cefepime total body clearance as a function of creatinine clearance. Therefore, dosage administration of cefepime in the elderly should be adjusted as appropriate if the patient's creatinine clearance is 60 mL/min or less *[see Dosage and Administration (2)].*

Pediatric Patients

Cefepime pharmacokinetics have been evaluated in pediatric patients from 2 months to 11 years of age following single and multiple doses on every 8 hours (n=29) and every 12 hours (n=13) schedules. Following a single intravenous dose, total body clearance and the steady-state volume of distribution averaged 3.3 (±1.0) mL/min/kg and 0.3 (±0.1) L/kg, respectively. The urinary recovery of unchanged cefepime was 60.4 (±30.4)% of the administered dose, and the average renal clearance was 2.0 (±1.1) mL/min/kg. There were no significant effects of age or gender (25 male vs. 17 female) on total body clearance or volume of distribution, corrected for body weight. No accumulation was seen when cefepime was given at 50 mg per kg every 12 hours (n=13), while C_{max}, AUC, and $t_{1/2}$ were increased about 15% at steady state after 50 mg per kg every 8 hours. The exposure to cefepime following a 50 mg per kg intravenous dose in a pediatric patient is comparable to that in an adult treated with a 2 g intravenous dose.

12.4 Microbiology

Mechanism of Action

Cefepime is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Cefepime has a broad spectrum of *in vitro* activity that encompasses a wide range of Gram-positive and Gram-negative bacteria. Cefepime has a low affinity for chromosomally-encoded beta-lactamases. Cefepime is highly resistant to hydrolysis by most beta-lactamases and exhibits rapid penetration into Gram-negative bacterial cells. Within bacterial cells, the molecular targets of cefepime are the penicillin binding proteins (PBP).

Antimicrobial Activity

Cefepime has been shown to be active against most isolates of the following bacteria, both *in vitro* and in clinical infections *[see Indications and Usage (1)]:*

Gram-negative bacteria

Enterobacter spp.
Escherichia coli

Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

Gram-positive bacteria

Staphylococcus aureus (methicillin-susceptible isolates only)
Streptococcus pneumoniae
Streptococcus pyogenes (Lancefield's Group A streptococci)
Viridans group streptococci

The following *in vitro* data are available, but their clinical significance is unknown. At least 90 percent of the following bacteria exhibit an *in vitro* minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for cefepime against isolates of similar genus or organism group. However, the efficacy of cefepime in treating clinical infections due to these bacteria has not been established in adequate and well-controlled clinical trials.

Gram-positive bacteria

Staphylococcus epidermidis (methicillin-susceptible isolates only)
Staphylococcus saprophyticus
Streptococcus agalactiae (Lancefield's Group B streptococci)

NOTE: Most isolates of enterococci, eg, *Enterococcus faecalis*, and methicillin-resistant staphylococci are resistant to cefepime.

Gram-negative bacteria

Acinetobacter calcoaceticus subsp. *lwoffii*
Citrobacter diversus
Citrobacter freundii
Enterobacter agglomerans
Haemophilus influenzae
Hafnia alvei
Klebsiella oxytoca
Moraxella catarrhalis
Morganella morganii
Proteus vulgaris
Providencia rettgeri
Providencia stuartii
Serratia marcescens

NOTE: Cefepime is inactive against many isolates of *Stenotrophomonas* (formerly *Xanthomonas maltophilia* and *Pseudomonas maltophilia*).

Susceptibility Test Methods

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: http://www.fda.gov/STIC.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No animal carcinogenicity studies have been conducted with cefepime. In chromosomal aberration studies, cefepime was positive for clastogenicity in primary human lymphocytes, but negative in Chinese hamster ovary cells. In other *in vitro* assays (bacterial and mammalian cell mutation, DNA repair in primary rat hepatocytes, and sister chromatid exchange in human lymphocytes), cefepime was negative for genotoxic effects. Moreover, *in vivo* assessments of cefepime in mice (2 chromosomal aberration and 2 micronucleus studies) were negative for clastogenicity. No untoward effects on fertility were observed in rats when cefepime was administered subcutaneously at doses up to 1000 mg/kg/day (1.6 times the recommended maximum human dose based on body surface area).

14 CLINICAL STUDIES

14.1 Febrile Neutropenic Patients

The safety and efficacy of empiric cefepime monotherapy of febrile neutropenic patients have been assessed in two multicenter, randomized trials, comparing cefepime monotherapy (at a dose of 2 g intravenously every 8 hours) to ceftazidime monotherapy (at a dose of 2 g intravenously every 8 hours). These studies comprised 317 evaluable patients. Table 8 describes the characteristics of the evaluable patient population.

Table 8: Demographics of Evaluable Patients (First Episodes Only)

	Cefepime	**Ceftazidime**
Total	**164**	**153**
Median age (yr)	56 (range, 18-82)	55 (range, 16-84)
Male	86 (52%)	85 (56%)
Female	78 (48%)	68 (44%)
Leukemia	65 (40%)	52 (34%)
Other hematologic malignancies	43 (26%)	36 (24%)
Solid tumor	54 (33%)	56 (37%)
Median ANC nadir (cells per microliter)	20 (range, 0-500)	20 (range, 0-500)
Median duration of neutropenia (days)	6 (range, 0-39)	6 (range, 0-32)
Indwelling venous catheter	97 (59%)	86 (56%)
Prophylactic antibiotics	62 (38%)	64 (42%)
Bone marrow graft	9 (5%)	7 (5%)
SBP less than 90 mm Hg at entry	7 (4%)	2 (1%)

ANC = absolute neutrophil count; SBP = systolic blood pressure

Table 9 describes the clinical response rates observed. For all outcome measures, cefepime was therapeutically equivalent to ceftazidime.

Table 9: Pooled Response Rates for Empiric Therapy of Febrile Neutropenic

Patients

Outcome Measures	% Response	
	Cefepime (n = 164)	Ceftazidime (n = 153)
Primary episode resolved with no treatment modification, no new febrile episodes or infection, and oral antibiotics allowed for completion of treatment	51	55
Primary episode resolved with no treatment modification, no new febrile episodes or infection, and no post-treatment oral antibiotics	34	39
Survival, any treatment modification allowed	93	97
Primary episode resolved with no treatment modification and oral antibiotics allowed for completion of treatment	62	67
Primary episode resolved with no treatment modification and no post-treatment oral antibiotics	46	51

Insufficient data exist to support the efficacy of cefepime monotherapy in patients at high risk for severe infection (including patients with a history of recent bone marrow transplantation, with hypotension at presentation, with an underlying hematologic malignancy, or with severe or prolonged neutropenia). No data are available in patients with septic shock.

14.2 Complicated Intra-abdominal Infections

Patients hospitalized with complicated intra-abdominal infections participated in a randomized, double-blind, multicenter trial comparing the combination of cefepime (2 g every 12 hours) plus intravenous metronidazole (500 mg every 6 hours) versus imipenem/cilastatin (500 mg every 6 hours) for a maximum duration of 14 days of therapy. The study was designed to demonstrate equivalence of the two therapies. The primary analyses were conducted on the protocol-valid population, which consisted of those with a surgically confirmed complicated infection, at least one pathogen isolated pretreatment, at least 5 days of treatment, and a 4 to 6 week follow-up assessment for cured patients. Subjects in the imipenem/cilastatin arm had higher APACHE II scores at baseline. The treatment groups were otherwise generally comparable with regard to their pretreatment characteristics. The overall clinical cure rate among the protocol-valid patients was 81% (51 cured/63 evaluable patients) in the cefepime plus metronidazole group and 66% (62/94) in the imipenem/cilastatin group. The observed differences in efficacy may have been due to a greater proportion of patients with high APACHE II scores in the imipenem/cilastatin group.

15 REFERENCES

1. Cockcroft DW, Gault MH. Prediction of creatinine clearance from serum creatinine. *Nephron.* 1976; 16:31-41.

16 HOW SUPPLIED/STORAGE AND HANDLING

Cefepime Injection is supplied as a frozen, iso-osmotic, sterile, nonpyrogenic solution in 50 mL and 100 mL single-dose Galaxy Containers as follows:

1 g* in 50 mL	Supplied 24/box	NDC 0338-1301-41
2 g* in 100 mL	Supplied 12/box	NDC 0338-1301-48

* Based on cefepime activity

Store at or below –20°C (-4°F).

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

Thaw frozen container at room temperature 25°C (77°F) or under refrigeration 5°C (41°F). Do not force thaw by immersion in water baths or by microwave irradiation.

The thawed solution remains stable for 7 days under refrigeration 5°C (41°F) or 24 hours at room temperature 25°C (77°F). Do not refreeze. *[See Dosage and Administration (2.4)].*

17 PATIENT COUNSELING INFORMATION

Antibacterial Resistance

Patients should be counseled that antibacterial drugs including Cefepime Injection should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When Cefepime Injection 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 Cefepime Injection or other antibacterial drugs in the future.

Diarrhea

Diarrhea is a common problem caused by antibacterial drugs, which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibacterial drugs, 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 antibacterial drug. If this occurs, patients should be instructed to contact their physician as soon as possible.

Neurotoxicity

Advise patients of neurological adverse events that could occur with Cefepime Injection use. Instruct patients or their caregivers to inform their healthcare provider at once of any neurological signs and symptoms, including encephalopathy (disturbance of consciousness including confusion, hallucinations, stupor, and coma), aphasia (disturbance of speaking and understanding spoken and written language), myoclonus, seizures and nonconvulsive status epilepticus, for immediate treatment, dosage adjustment, or discontinuation of Cefepime Injection.

Manufactured by:

Baxter Healthcare Corporation

Deerfield, IL 60015

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Clinitest is a registered trademark of Siemens Healthcare Diagnostics Inc.

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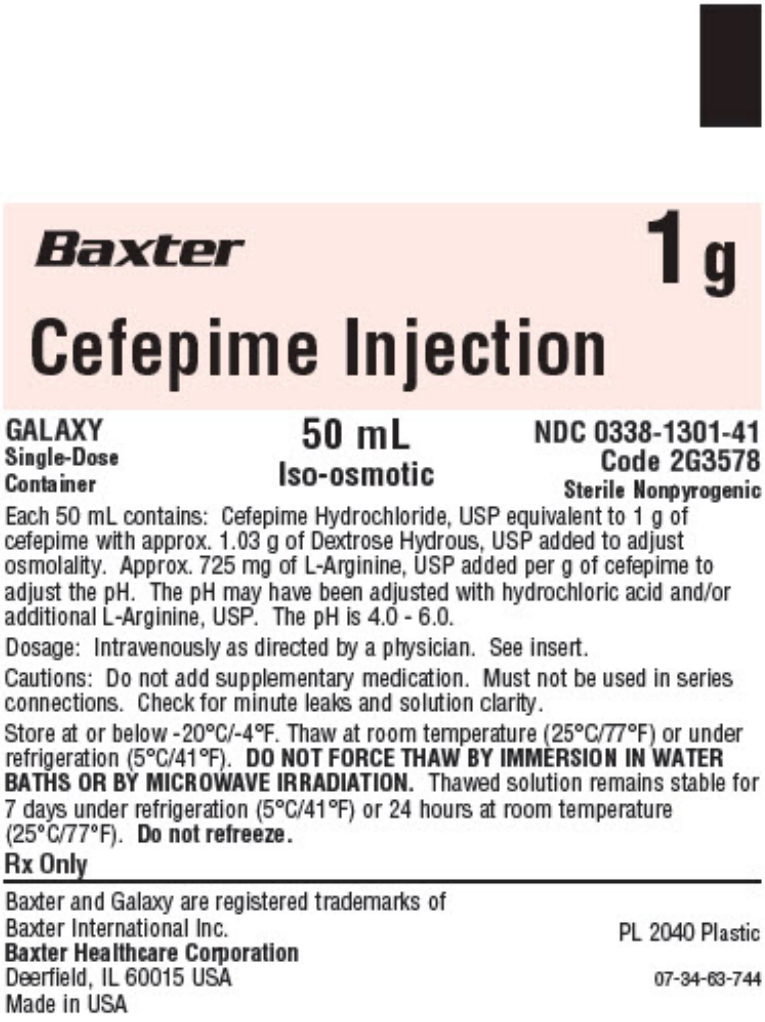
07-19-06-951

PACKAGE LABEL - PRINCIPLE DISPLAY PANEL



Container Label

Baxter 1 g

Cefepime Injection

GALAXY
Single-Dose

Container

50 mL
Iso-osmotic

NDC 0338-1301-41
Code 2G3578

Each 50 mL contains: Cefepime Hydrochloride, USP equivalent to 1 g of cefepime with approx. 1.03 g of Dextrose Hydrous, USP added to adjust osmolality. Approx. 725 mg of L-Arginine, USP added per g of cefepime to adjust the pH. The pH may have been adjusted with hydrochloric acid and/or additional L-Arginine, USP. The pH is 4.0 - 6.0.

Dosage: Intravenously as directed by a physician. See insert.

Cautions: Do not add supplementary medication. Must not be used in series connections. Check for minute leaks and solution clarity.

Store at or below -20°C/-4°F. Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). **DO NOT FORCE THAW BY IMMERSION IN WATER BATHS OR BY MICROWAVE IRRADIATION.** Thawed solution remains stable for 7 days under refrigeration (5°C/41°F) or 24 hours at room temperature (25°C/77°F). **Do not refreeze.**

Rx Only

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Baxter Healthcare Corporation

Deerfield, IL 60015 USA
PL 2040 Plastic

Made in USA
07-34-63-744

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). **DO NOT FORCE THAW BY IMMERSION IN WATER BATHS OR BY MICROWAVE IRRADIATION.** Thawed solution remains stable for 7 days under refrigeration (5°C/41°F) or 24 hours at room temperature (25°C/77°F). **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

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Baxter Healthcare Corporation, Deerfield, IL 60015 USA
Made in USA

07-04-65-195
PL 2040 Plastic

Baxter
Cefepime Injection **1 g** **Rx Only**

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). **DO NOT FORCE THAW BY IMMERSION IN WATER BATHS OR BY MICROWAVE IRRADIATION.** Thawed solution remains stable for 7 days under refrigeration (5°C/41°F) or 24 hours at room temperature (25°C/77°F). **Do not refreeze.**

Handle frozen product containers with care. Product containers may be fragile in the frozen state.

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Made in USA

07-04-65-195
PL 2040 Plastic

Baxter
Cefepime Injection **1 g** **Rx Only**

Carton Label_panel 1 of 3

Thaw at room temperature (25°C/77°F) or under refrigeration (5°C/41°F). **DO NOT FORCE THAW BY IMMERSION IN WATER BATHS OR BY MICROWAVE IRRADIATION.** Thawed solution remains stable for 7 days under refrigeration (5°C/41°F) or 24 hours at room
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07-04-65-195

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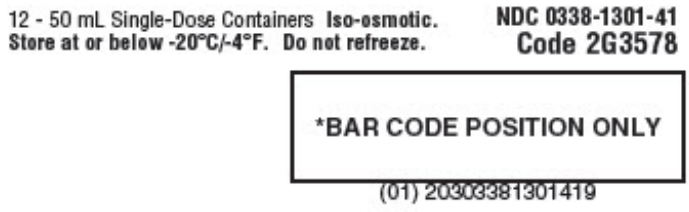
PL 2040 Plastic

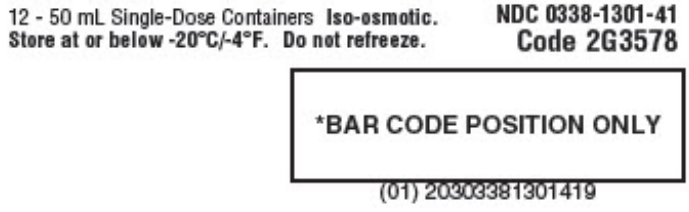
Baxter Logo

1 g

Cefepime Injection

Rx Only





Carton Label_panel 2 of 3

12 - 50 mL Single-Dose Containers. Iso-osmotic. NDC 0338-1301-41

Store at or below -20°C/-4°F. Do not refreeze. Code 2G3578

***BAR CODE POSITION ONLY**
(01) 20303381301419

GALAXY Container Sterile Nonpyrogenic
Each 50 mL contains: Cefepime Hydrochloride, USP equivalent to 1 g of cefepime with approx. 1.03 g of Dextrose Hydrous, USP added to adjust osmolality. Approx. 725 mg of L-Arginine, USP added per g of cefepime to adjust the pH. The pH may have been adjusted with hydrochloric acid and/or additional L-Arginine, USP. The pH is 4.0 - 6.0.
Dosage: Intravenously as directed by a physician. See insert.
Cautions: Do not add supplementary medication. Must not be used in series connections. Check for minute leaks and solution clarity. Check for minute leaks by squeezing thawed bag firmly. If leaks are found, discard bag, as sterility may be impaired. Do not use unless solution is clear.

GALAXY Container Sterile Nonpyrogenic
Each 50 mL contains: Cefepime Hydrochloride, USP equivalent to 1 g of cefepime with approx. 1.03 g of Dextrose Hydrous, USP added to adjust osmolality. Approx. 725 mg of L-Arginine, USP added per g of cefepime to adjust the pH. The pH may have been adjusted with hydrochloric acid and/or additional L-Arginine, USP. The pH is 4.0 - 6.0.
Dosage: Intravenously as directed by a physician. See insert.
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Carton Label_panel 3 of 3

GALAXY Container
Sterile Nonpyrogenic

Each 50 mL contains: Cefepime Hydrochloride, USP equivalent to 1 g of cefepime with approx. 1.03 g of Dextrose Hydrous, USP added to adjust osmolality. Approx. 725 mg of L-Arginine, USP added per g of cefepime to adjust the pH. The pH may have been adjusted with hydrochloric acid and/or additional L-Arginine, USP. The pH is 4.0 - 6.0.

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CEFEPIME

cefepime injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-1301
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CEFEPIME HYDROCHLORIDE (UNII: I8X1O0607P) (CEFEPIME - UNII:807PW4VQE3)	CEFEPIME	1 g in 50 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	1.03 g in 50 mL

ARGININE (UNII: 94ZLA3W45F)	725 mg in 50 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-1301-41	24 in 1 BOX	08/05/2008	
1		50 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0338-1301-48	12 in 1 BOX	08/05/2008	
2		100 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050817	08/05/2008	

Labeler - Baxter Healthcare Company (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	MANUFACTURE(0338-1301) , LABEL(0338-1301) , PACK(0338-1301) , STERILIZE(0338-1301) , ANALYSIS(0338-1301)

Revised: 12/2025 Baxter Healthcare Company