

COMPOSITION

Each vial contains sterile mixture of Ceftaroline Fosamil with L-arginine equivalent to Ceftaroline Fosamil INN 600 mg and each of two ampoules contains 10 ml Water for Injections BP (Sterile).

PHARMACOLOGY

Ceftaroline is a 5th generation cephalosporin antibacterial with in vitro activity against Gram-positive and Gram-negative bacteria. The bactericidal action of Ceftaroline is mediated through binding to essential Penicillin Binding Proteins (PBPs). Biochemical studies have shown that Ceftaroline has high affinity for PBP2a of *Methicillin-Resistant Staphylococcus Aureus* (MRSA) and PBP2x of *Penicillin Non-Susceptible Streptococcus Pneumoniae* (PNSP).

Ceftaroline Fosamil (prodrug) is converted into the active Ceftaroline in plasma by phosphatase enzymes and concentrations of the prodrug are measurable in plasma primarily during intravenous infusion. The plasma protein binding of Ceftaroline is low (approximately 20%) and Ceftaroline is not distributed into erythrocytes. No appreciable accumulation of Ceftaroline is observed following multiple intravenous infusions of 600 mg every 8 or 12 hours in healthy adults with CrCL > 50 mL/min.

Ceftaroline is primarily eliminated by the kidneys. Renal clearance of Ceftaroline is approximately equal, or slightly lower than the glomerular filtration rate in the kidney, and in vitro transporter studies indicate that active secretion does not contribute to the renal elimination of Ceftaroline. The mean terminal elimination half-life of Ceftaroline in healthy adults is approximately 2.5 hours.

INDICATION

Cefamil-5™ is a cephalosporin antibacterial indicated in adult and pediatric patients for the treatment of the following infections caused by designated susceptible bacteria:

- Acute bacterial skin and skin structure infections (ABSSSI) in adult and pediatric patients (at least 34 weeks of gestational age and 12 days of postnatal age)
- Community-acquired bacterial pneumonia (CABP) in adult and pediatric patients (2 months of age and older)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of **Cefamil-5™** and other antibacterial drugs, **Cefamil-5™** should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Preparation of Cefamil-5™ for Administration

Constitution of Cefamil-5™ Powder for Infusion

Aseptic technique must be followed in preparing the infusion solution. The contents of **Cefamil-5™** vial should be constituted with 20 mL sterile Water for Injection (WFI); or 0.9% of Sodium Chloride Injection; or 5% of Dextrose Injection; or Lactated Ringer's Injection. Constitution time is less than 2 minutes. Mix gently to constitute and check to see that the contents have dissolved completely.

Preparation of **Cefamil-5™** for Intravenous Use (inside vial)

Dosage strength (mg)	Volume of Diluent to be added (mL)	Approximate Ceftaroline Fosamil concentration (mg/mL)	Amount to be withdrawn
600	20	30	Adults: Total Volume Pediatric*: Volume based on age and weight

Diluents for further dilution of the constituted solution of Cefamil-5™

The constituted solution must be further diluted in a range between 50 mL to 250 mL before intravenous infusion into patients. Use the same diluent used for constitution of the powder for this further dilution, unless sterile water for injection was used earlier. If sterile water for injection was used earlier, then appropriate infusion solutions include: 0.9% Sodium Chloride Injection, USP; 5% Dextrose Injection, USP; 2.5% Dextrose Injection, USP, and 0.45% Sodium Chloride Injection, USP; or Lactated Ringer's Injection, USP.

Dilution of the constituted solution of Cefamil-5™ in the 50 mL infusion bags (covers all required doses)

Preparation of 600 mg of **Cefamil-5™** dose in 50 ml infusion bag (for adult patients): Withdraw 20 mL of diluent from the infusion bag and discard. Proceed to inject entire content of the **Cefamil-5™** vial into the bag to provide a total volume of 50 mL. The resultant concentration is approximately 12 mg/ml.

The color of **Cefamil-5™** infusion solutions ranges from clear light to dark yellow depending on the concentration and storage conditions. When stored as recommended, the product potency is not affected. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

CONTRAINDICATION

Ceftaroline is contraindicated in patients with known serious hypersensitivity to Ceftaroline or other members of cephalosporin class. Anaphylaxis and anaphylactoid reactions have been reported with Ceftaroline.

SIDE EFFECT

- Hypersensitivity reactions
- *Clostridioides difficile*-associated diarrhea
- Direct Coombs' test seroconversion

DOSAGE & ADMINISTRATION

Indication-wise dosage in adult and pediatric patients

Indication	Age Range	Dosage	Infusion Time	Duration
Acute Bacterial Skin and Skin Structure Infections (ABSSSI)	18 years and older	600 mg every 12 hours	5 to 60 minutes	5 to 14 days
	≥ 2 years to < 18 years (> 33 kg)	400 mg every 8 hours OR 600 mg every 12 hours	5 to 60 minutes	5 to 14 days
	≥ 2 years to < 18 years (≤ 33kg)	12 mg/kg every 8 hours	5 to 60 minutes	5 to 14 days
	2 months to < 2 years	8 mg/kg every 8 hours	5 to 60 minutes	5 to 14 days
	0* to < 2 months	6 mg/kg every 8 hours	30 to 60 minutes	5 to 14 days
Community Acquired Bacterial Pneumonia (CABP)	18 years and older	600 mg every 12 hours	5 to 60 minutes	5 to 7 days
	≥ 2 years to < 18 years (> 33 kg)	400 mg every 8 hours OR 600 mg every 12 hours	5 to 60 minutes	5 to 14 days
	≥ 2 years to < 18 years (≤ 33kg)	12 mg/kg every 8 hours	5 to 60 minutes	5 to 14 days
	2 months to < 2 years	8 mg/kg every 8 hours	5 to 60 minutes	5 to 14 days

*Gestational age 34 weeks & older and postnatal age 12 days & older

Dosage adjustment in adult patients with renal impairment.

Estimated CrCl(mL/min)	Recommended Dosage Regimen for Cefamil-5™
>50	No dosage adjustment necessary
> 30 to ≤ 50	400 mg IV (over 5 to 60 minutes) every 12 hours
≥15 to ≤ 30	300 mg IV (over 5 to 60 minutes) every 12 hours
End-stage renal disease, including hemodialysis	200 mg IV (over 5 to 60 minutes) every 12 hours

a) Creatinine clearance (CrCl) estimated using the Cockcroft-Gault formula.

b) End-stage renal disease is defined as CrCl < 15 mL/min.

c) **Cefamil-5™** is hemodialyzable; thus **Cefamil-5™** should be administered after hemodialysis on hemodialysis days.

Pediatrics: No dosage adjustment is required in pediatric patients with CrCL > 50 mL/min/1.73 m², estimated using the Schwartz equation. There is insufficient information to recommend a dosage regimen for pediatric patients with CrCL <50 mL/min/1.73 m².

PRECAUTION AND WARNING

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterials. Before therapy with Ceftaroline is instituted, careful inquiry about previous hypersensitivity reactions to other cephalosporins, penicillins, or carbapenems should be made. If this product is to be given to penicillin- or other beta-lactam allergic patient, caution should be exercised because cross sensitivity among beta-lactam antibacterial agents has been clearly established. If an allergic reaction to Ceftaroline occurs, the drug should be discontinued. Serious acute hypersensitivity (anaphylactic) reactions require emergency treatment with epinephrine and other emergency measures, that may include airway management, oxygen, intravenous fluids, antihistamines, corticosteroids and vasopressors.

USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled trials in pregnant women. There are no or limited amount of data from the use of Ceftaroline Fosamil in pregnant women. Animal studies conducted in rat and rabbit do not indicate harmful effects with respect to reproductive toxicity at exposures similar to therapeutic concentrations. Following administration throughout pregnancy and lactation in the rat, there was no effect on pup birth weight or growth, although minor changes in foetal weight and delayed ossification of the interparietal bone were observed when Ceftaroline Fosamil was administered during organogenesis.

As a precautionary measure, it is preferable to avoid the use of Ceftaroline Fosamil during pregnancy unless the clinical condition of the woman requires treatment with an antibiotic with Ceftaroline Fosamil's antibacterial profile.

It is not known whether Ceftaroline is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ceftaroline is administered to a nursing woman.

STORAGE

Store below 25°C temperature. Protect from light and moisture. Reconstituted solution in the infusion bag is stable for 6 hours at controlled room temperature (20 - 25°C) and for 24 hours in a refrigerator (2 - 8°C temperature). Keep out of reach of children.

HOW SUPPLIED

Cefamil-5™ Powder for IV Infusion: Each box contains 1 vial of sterile mixture of Ceftaroline Fosamil with L-Arginine equivalent to Ceftaroline Fosamil INN 600 mg with two ampoules of 10 ml Water for Injections BP (Sterile).

Manufactured by-



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