

Resistance Threatens

The efficacy of antimicrobial drugs
in the daily practice of medicine¹

Dear Doctor,
You may prescribe with confidence

Ceftalin™



Abscess with cellulitis Infected wound Deep and extensive cellulitis

Acute Bacterial Skin and Skin Structure Infections (ABSSSI)



Community-Acquired Bacterial Pneumonia (CABP)

Recommended for special populations ^{3,4}



Hepatic Impairment

Does not undergo significant hepatic metabolism
Excellent safety-applicable for all ages



Renal Impairment

Can be given with dose adjustment



Neonates

Extensive safety profile with easy dose adjustment



Pregnancy

Category B



Geriatric Patients

Dose is as similar as adult dose

PRESCRIBING INFORMATION

DESCRIPTION: Ceftalin is a preparation of Ceftaroline Fosamil. Ceftaroline is a cephalosporin with in vitro activity against Gram-positive and negative bacteria. The bactericidal action of Ceftaroline is mediated through binding to essential penicillin-binding proteins (PBPs). Ceftaroline is bactericidal against *S. aureus* due to affinity for PBP2a and against *Streptococcus pneumoniae* due to its affinity for PBP2x. **INDICATIONS:** • Acute Bacterial Skin and Skin Structure Infections • Community-Acquired Bacterial Pneumonia. **DOSAGE & ADMINISTRATION:** The recommended dosage of Ceftalin is 600 mg administered every 12 hours by intravenous (IV) infusion over 5 to 60 minutes in patients ≥ 18 years of age. The duration of therapy should be guided by the severity and site of infection and the patient's clinical and bacteriological progress. For Acute Bacterial Skin and Skin Structure Infections (ABSSSI) Recommended Duration of Treatment is 5-14 days & in case of Community Acquired Bacterial Pneumonia (CABP) Recommended Duration of Treatment is 5-7 days. The recommended dosage of Ceftalin in pediatric patients is based on the age and weight of the child. The duration of therapy should be guided by the severity, site of infection and the patient's clinical and bacteriological progress. Pediatric Patients 2 months of Age and Older. For pediatric patients 2 months of age and older, Ceftalin is administered every 8 hours by intravenous infusion over 5 to 60 minutes. Ceftalin dosing regimen is dependent on the type of infection (ABSSSI, CABP). **CONTRAINDICATIONS:** 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 EFFECTS:** • Hypersensitivity reactions • Clostridium difficile-associated diarrhea • Direct Coombs' test seroconversion. **PRECAUTION & 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 clinically indicated. **USE IN PREGNANCY & LACTATION:** Pregnancy category B. There are no adequate and well-controlled trials in pregnant women. Ceftaroline should be used during pregnancy if the potential benefit justifies the potential risk to the fetus. 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. **PHARMACEUTICAL PRECAUTION:** Keep away from light and wet place. Keep out of reach of children. Do not store above 25 °C temperature. Reconstituted solution in the infusion bag is stable for 6 hours at controlled room temperature (20°C to 25°C) and for 24 hours in a refrigerator (2°C to 8°C temperature). **PACKAGING: Ceftalin™ Injection:** Box containing one vial of sterile mixture of Ceftaroline Fosamil Monoacetate Monohydrate with L-Arginine equivalent to Ceftaroline Fosamil INN 600 mg and two ampoules of 10 ml sterile water for Injection USP.

Reference:

01. Cleveland Clinic Journal of Medicine, Volume 82, Number 5, July 2017
02. Ceftaroline: A New Cephalosporin with Activity against Methicillin-Resistant Staphylococcus aureus (MRSA), Clinical Medicine Reviews in Therapeutics, February 2011
03. www.teflaro.com
04. Craig WA. Interrelationship between pharmacokinetics and pharmacodynamics in determining dosage regimens for broad-spectrum cephalosporins. Diagn Microbiol Infect Dis. 1995;22:89-96. 1

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ESKAYEF PHARMACEUTICALS LTD.

Approved by: US FDA | UK MHRA | EU GMP | TGA Australia | VMD UK

A smart choice for patients when there's no time to wait in light of the increasing prevalence of multidrug-resistant organisms, newer antimicrobial agents with novel mechanisms of action are needed.

ESKAYEF offers,

5th
Generation
Cephalosporin

1st time in
Bangladesh



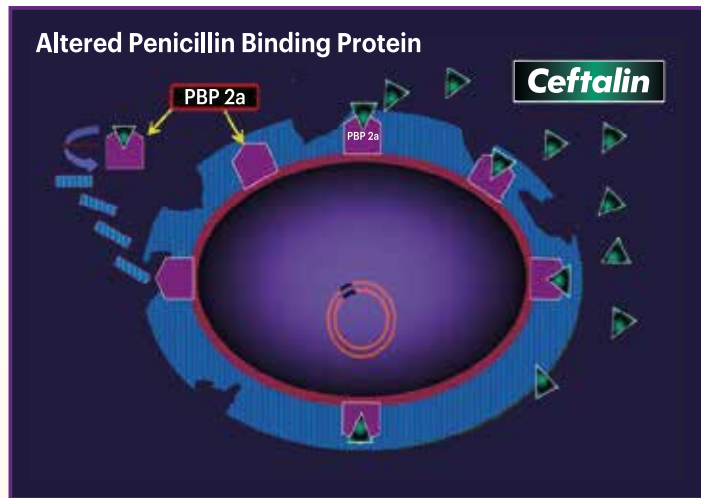
Ceftalin™

Ceftaroline Fosamil 600mg IV Injection

A Super Cephalosporin

▶ Ceftaroline Fosamil (Ceftalin) Initiates Lysis of Bacterial Cell Wall³

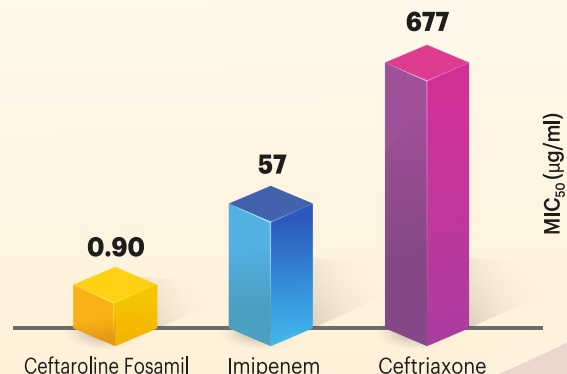
Ceftaroline binds to and inactivates penicillin binding protein (PBP) located on the inner membrane of the bacterial cell wall. Inactivation of PBPs interferes with the cross linkage of peptidoglycan chains necessary for bacterial cell wall strength and rigidity. This results in weakening of bacterial cell wall & causing cell lysis.



▶ Higher Affinity for Bacterial Cell Wall Death²

Ceftaroline demonstrates superior affinity for all PBPs including MRSA associated PBP2a as it requires least MIC₅₀

256x



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Ensures Complete Cure

5th
Generation
Cephalosporin

1st time in
Bangladesh



Ceftalin™

Ceftaroline Fosamil 600mg IV Injection

A Super Cephalosporin

▶ Demonstrates Excellent Clinical Cure rates³

✓ In Acute Bacterial Skin and Skin Structure Infections (ABSSI)

In two identical randomized, multi-center, multinational, double-blind trials with total of 797 adults with complicated skin and skin structure infection exhibited amazing outcome by administering Ceftaroline Fosamil (Ceftalin) in respective of comparator drugs



Bacterial Eradication Rate

✓ In Community Acquired Bacterial Pneumonia (CABP)

A study involving two randomized, multi-center, multinational, double-blind, non-inferiority trials on a total of 1231 adults with CABP showed excellent results



Bacterial Eradication Rate

✓ Less Chance of Discontinuation of Treatment

In the four pooled adult phase 3 clinical trials executed among 1297 patients, Ceftaroline Fosamil showed less adverse effects in respective of comparator drugs

