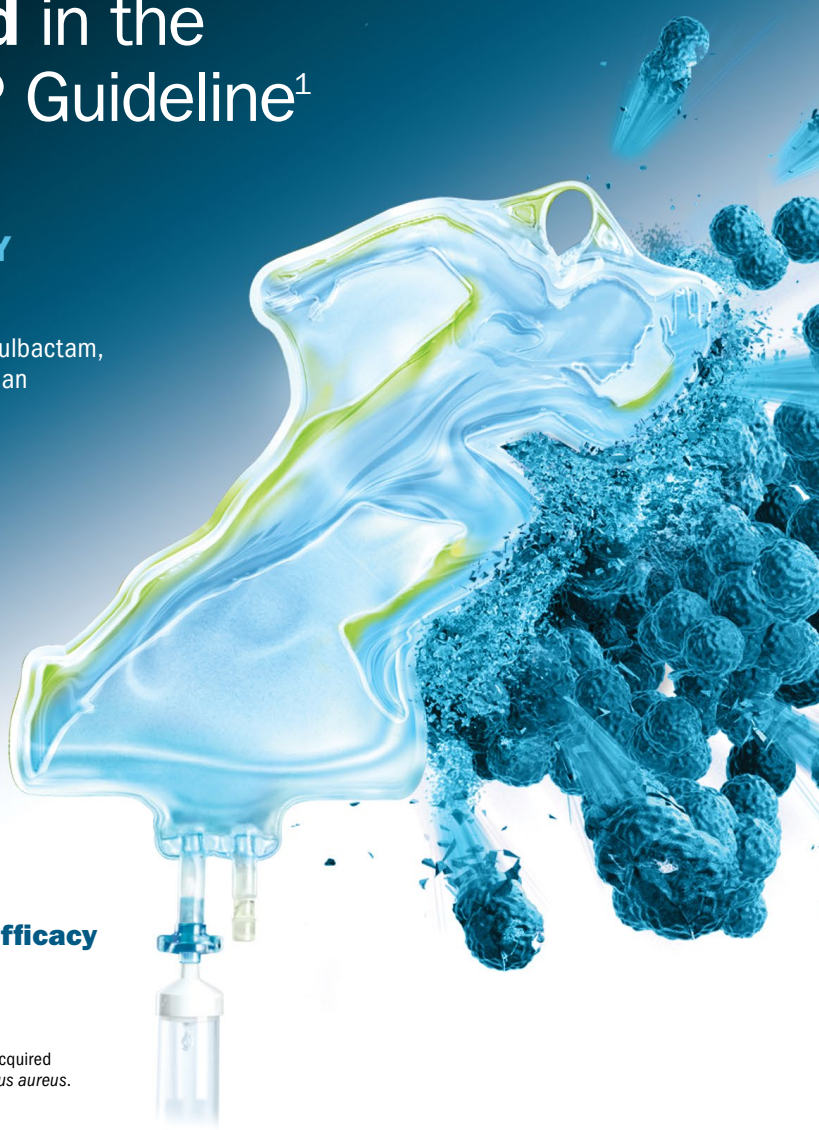
TEFLARO® Now Included in the 2019 ATS and IDSA CAP Guideline[1]



STRONG RECOMMENDATION, HIGH QUALITY OF EVIDENCE

- Empiric treatment with a β-lactam—**ceftaroline**, ampicillin plus sulbactam, cefotaxime, or ceftriaxone—plus a macrolide is recommended as an effective option for inpatient adults with nonsevere CAP without risk factors for MRSA or *Pseudomonas aeruginosa*
- In a systematic review of 20 experimental and observational studies in adults hospitalized with radiographically confirmed CAP, β-lactam plus macrolide combination therapy was generally associated with lower mortality than β-lactam monotherapy

Explore the ATS/IDSA CAP Guideline

Discover more about TEFLARO, including proven efficacy against *S. pneumoniae* in CABP, at TEFLARO.com.

ATS, American Thoracic Society; CABP, community-acquired bacterial pneumonia; CAP, community-acquired pneumonia; IDSA, Infectious Diseases Society of America; MRSA, methicillin-resistant *Staphylococcus aureus*.

INDICATION AND USAGE

- TEFLARO® (ceftaroline fosamil) is indicated in adult and pediatric patients 2 months of age and older for the treatment of **community-acquired bacterial pneumonia (CABP)** caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Streptococcus pneumoniae* (including cases with concurrent bacteremia), *Staphylococcus aureus* (methicillin-susceptible isolates only), *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, and *Escherichia coli*.
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of TEFLARO and other antibacterial drugs, TEFLARO should be used to treat only CABP that is proven or strongly suspected to be caused by susceptible bacteria. Appropriate specimens for microbiological examination should be obtained in order to isolate and identify the causative pathogens and to determine their susceptibility to ceftaroline. 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.

IMPORTANT SAFETY INFORMATION

Contraindications

- TEFLARO is contraindicated in patients with known serious hypersensitivity to ceftaroline or other members of the cephalosporin class. Anaphylaxis has been reported with ceftaroline.

Please see additional Important Safety Information on back.
Please also see enclosed full Prescribing Information.

Teflaro®
(ceftaroline fosamil) for injection
600 mg • 400 mg

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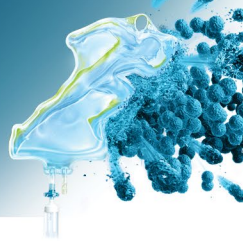

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

Hypersensitivity Reactions

- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported with beta-lactam antibacterial drugs. Before therapy with TEFLARO is instituted, careful inquiry about previous hypersensitivity reactions to other cephalosporins, penicillins, or carbapenems should be made. Maintain clinical supervision if this product is to be given to a penicillin- or other beta-lactam-allergic patient, because cross sensitivity among beta-lactam antibacterial agents has been clearly established.
- If an allergic reaction to TEFLARO occurs, discontinue TEFLARO and institute appropriate treatment and supportive measures.

Clostridium difficile-Associated Diarrhea

- *Clostridium difficile*-Associated Diarrhea (CDAD) has been reported for nearly all systemic antibacterial agents, including TEFLARO, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterials not directed against *C. difficile* should be discontinued, if possible.

Direct Coombs' Test Seroconversion

- In adults, seroconversion from a negative to a positive direct Coombs' test result occurred in 120/1114 (10.8%) of patients receiving TEFLARO and 49/1116 (4.4%) of patients receiving comparator drugs in the four pooled adult Phase 3 trials.
- No adverse reactions representing hemolytic anemia were reported in any treatment group. If anemia develops during or after treatment with TEFLARO, drug-induced hemolytic anemia should be considered. If drug-induced hemolytic anemia is suspected, discontinuation of TEFLARO should be considered and supportive care should be administered to the patient if clinically indicated.

Development of Drug-Resistant Bacteria

- Prescribing TEFLARO 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.

Adverse Reactions in Adults

- In the four pooled adult Phase 3 clinical trials, serious adverse reactions occurred in 98/1300 (7.5%) of patients receiving TEFLARO and 100/1297 (7.7%) of patients receiving comparator drugs. Treatment discontinuation due to adverse reactions occurred in 35/1300 (2.7%) of patients receiving TEFLARO and 48/1297 (3.7%) of patients receiving comparator drugs with the most common adverse reactions leading to discontinuation being hypersensitivity for both treatment groups at a rate of 0.3% in the TEFLARO group and 0.5% in the comparator group.
- The most common adverse reactions occurring in >2% of patients receiving TEFLARO in the adult pooled Phase 3 clinical trials were diarrhea (5%) nausea (4%), and rash (3%).

Drug Interactions

- No clinical drug-drug interaction studies have been conducted with TEFLARO. There is minimal potential for drug-drug interactions between TEFLARO and CYP450 substrates, inhibitors, or inducers; drugs known to undergo active renal secretion; and drugs that may alter renal blood flow.

Use in Specific Populations

- There have been no adequate and well-controlled studies with TEFLARO in pregnant or nursing women. TEFLARO should only be used if the potential benefit justifies the potential risk in these populations.
- Safety and effectiveness in pediatric patients below the age of 2 months have not been established for the treatment of CABP as no data are available.
- Because elderly patients, those ≥65 years of age, are more likely to have decreased renal function and ceftaroline is excreted primarily by the kidney, care should be taken in dose selection in this age group and it may be useful to monitor renal function. Dosage adjustment for elderly patients should therefore be based on renal function.
- Dosage adjustment is required in adult patients with moderate (CrCl >30 to ≤50 mL/min) or severe (CrCl ≥15 to ≤30mL/min) renal impairment and in patients with end-stage renal disease (CrCl <15 mL/min). There is insufficient information to recommend a dosage regimen for pediatric patients with CrCl <50 mL/min/1.73m^2.
- The pharmacokinetics of ceftaroline in patients with hepatic impairment have not been established.

Please see Indication and Usage and additional Important Safety Information on front.
Please also see enclosed full Prescribing Information.

Reference: 1. Metlay JP, Waterer GW, Long AC, et al. Diagnosis and treatment of adults with community-acquired pneumonia: an official clinical practice guideline of the American Thoracic Society and Infectious Diseases Society of America. *Am J Respir Care Med.* 2019;200(7):e45-e67.

abbvie

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