In ABSSSI and CABP:

See an EARLY CLINICAL RESPONSE* with TEFLARO®

*Defined as clinical response at 48-72 hours after starting therapy in ABSSSI, and clinical response at 72-96 hours after starting therapy in CABP.

INDICATIONS AND USAGE

- TEFLARO® (ceftaroline fosamil) is indicated in adult and pediatric patients (at least 34 weeks gestational age and 12 days postnatal age) for the treatment of **acute bacterial skin and skin structure infections (ABSSSI)** caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Klebsiella oxytoca*.
- TEFLARO is also 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 ABSSSI or CABP that are 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.

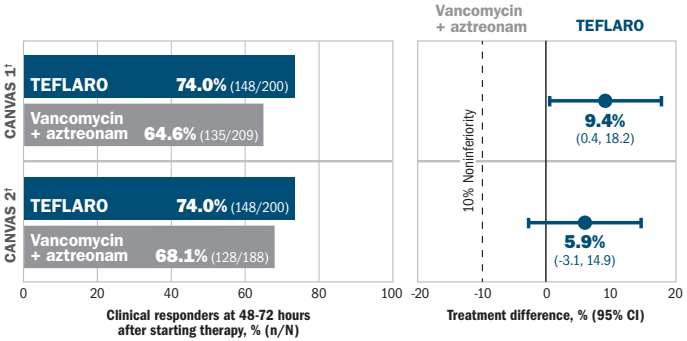
Please see Indications and Usage and additional Important Safety Information throughout.
Please also see accompanying full Prescribing Information.

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

For adult ABSSSI patients requiring hospitalization...

TEFLARO® delivers an early clinical response*[1,2]

CLINICAL RESPONSE AT DAY 3



***Defined as clinical response at 48-72 hours after starting therapy in ABSSSI.**

These data demonstrate the noninferiority of TEFLARO vs vancomycin plus aztreonam.

†CANVAS, ceftaroline vs vancomycin in skin and skin structure infection.

CANVAS 1, ABSSSI Trial 1; CANVAS 2, ABSSSI Trial 2.

CI, confidence interval.

- Clinical response identified as cessation of lesion spread with absence of fever[1]

When ABSSSI involves bacteremia[1]...

- **65%** (13/20) of TEFLARO adult patients with baseline *S. aureus* bacteremia demonstrated a clinical response at Day 3, and 90% (18/20) experienced clinical success at TOC

Please see ABSSSI study design on pages 14 and 15.

IMPORTANT SAFETY INFORMATION (continued)

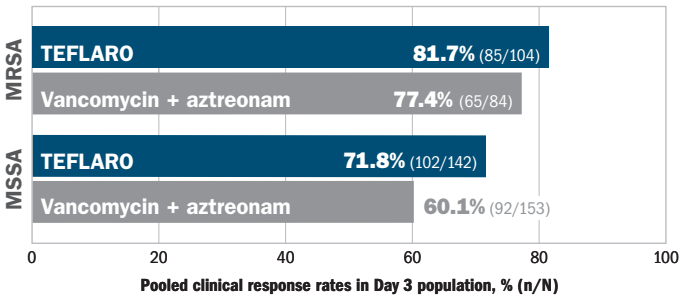
Warnings and Precautions

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.

Early clinical response against *S. aureus*[2]

CLINICAL RESPONSE AT DAY 3 FOR ABSSSI CAUSED BY *S. AUREUS*



No statistically significant differences between treatment groups can be inferred from the above pathogen response rates.

MRSA, methicillin-resistant *S. aureus*; MSSA, methicillin-susceptible *S. aureus*.

EFFICACY DEMONSTRATED AT TOC (CE)[1]

- In CANVAS 1, clinical cure rates were 91.1% (288/316) for TEFLARO and 93.3% (280/300) for vancomycin + aztreonam
- In CANVAS 2, clinical cure rates were 92.2% (271/294) for TEFLARO and 92.1% (269/292) for vancomycin + aztreonam

Comparisons at TOC cannot be used to establish noninferiority.‡

- **TOC occurred 8-15 days after the end of therapy**

‡ There are insufficient historical data to establish the magnitude of drug effect for antibacterial drugs compared with placebo at a TOC time point.[1]

CE, clinically evaluable; TOC, test of cure.

IMPORTANT SAFETY INFORMATION (continued)

***Clostridioides difficile*-Associated Diarrhea**

- *Clostridioides 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.

Neurological Adverse Reactions

- Neurological adverse reactions have been reported during postmarketing surveillance in patients treated with cephalosporins, including TEFLARO. These reactions include encephalopathy and seizures. Most cases occurred in patients with renal impairment who did not receive appropriate dosage adjustment. The neurological adverse reactions were reversible and resolved after discontinuation of TEFLARO or after hemodialysis. If neurological adverse reactions associated with TEFLARO therapy occur, consider discontinuing TEFLARO or making appropriate dosage adjustments in patients with renal impairment.

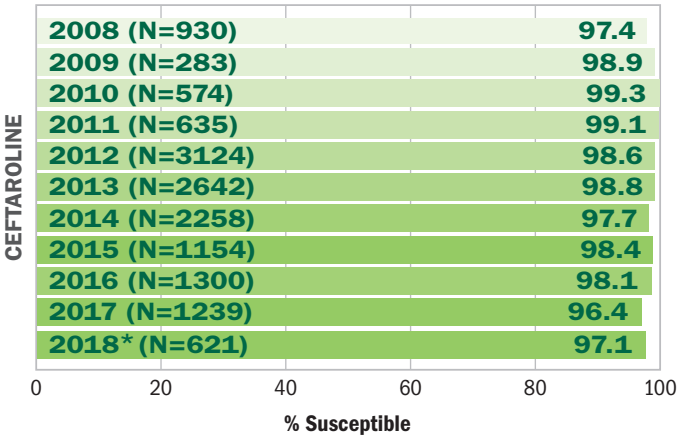
Please see additional Important Safety Information throughout. Please also see accompanying full Prescribing Information.

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

Ceftaroline has demonstrated consistent susceptibility against MRSA and MSSA since 2008[3]

NATIONAL SUSCEPTIBILITY RATES, 2008-2018

MRSA skin isolates



Study outline

AWARE (**A**ssessing **W**orldwide **A**ntimicrobial **R**esistance **E**valuation): This 2017 US study surveyed the *in vitro* susceptibility activity of ceftaroline and other agents against MRSA and other Gram-positive and Gram-negative pathogens, including *Streptococcus* spp, *Haemophilus* spp, and Enterobacteriaceae. A total of 23,255 bacterial isolates were collected from 70 medical centers distributed across all 9 US census regions.

*The AWARE study ended in 2017. These results are from a separate 2018 study that surveyed the *in vitro* susceptibility activity of ceftaroline and other agents against MRSA and other Gram-positive pathogens. A total of 5977 bacterial isolates were collected from 31 medical centers distributed across all 9 US census divisions.

***In vitro* activity does not necessarily correlate with clinical results.**

IMPORTANT SAFETY INFORMATION (continued)

Direct Coombs' Test Seroconversion

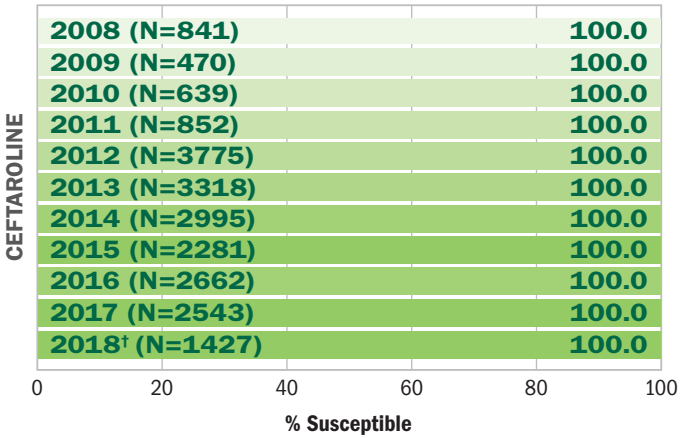
- In adults, seroconversion from a negative to a positive direct Coombs' test result occurred in 120/1114 (10.8%) of patients receiving TEFLARO and 49/1116 (4.4%) of patients receiving comparator drugs in the four pooled adult Phase 3 trials.
- No adverse reactions representing hemolytic anemia were 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.

NATIONAL SUSCEPTIBILITY RATES, 2008-2018

MSSA respiratory and skin isolates



†The AWARE study ended in 2017. These results are from a separate 2018 study that surveyed the *in vitro* susceptibility activity of ceftaroline and other agents against MRSA and other Gram-positive pathogens. A total of 5977 bacterial isolates were collected from 31 medical centers distributed across all 9 US census divisions.

***In vitro* activity does not necessarily correlate with clinical results.**

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions in Adults

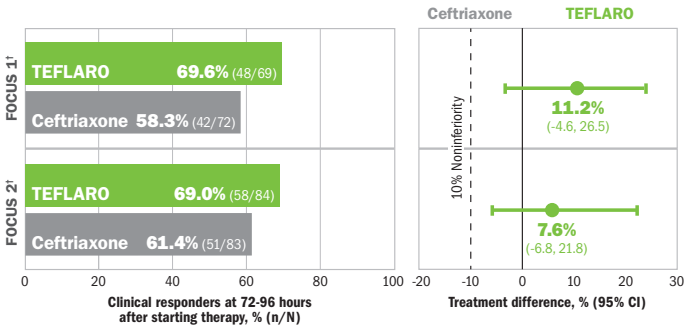
- In the four pooled adult Phase 3 clinical trials, serious adverse reactions occurred in 98/1300 (7.5%) of patients receiving TEFLARO and 100/1297 (7.7%) of patients receiving comparator drugs. Treatment discontinuation due to adverse reactions occurred in 35/1300 (2.7%) of patients receiving TEFLARO 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%).

Please see additional Important Safety Information throughout. Please also see accompanying full Prescribing Information.

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

TEFLARO® delivers an early clinical response* in adult patients with CABP[1,4]

CLINICAL RESPONSE AT DAY 4 (mITT)



***Defined as clinical response at 72-96 hours after starting therapy in CABP.**

These data demonstrate the noninferiority of TEFLARO vs ceftriaxone.

†FOCUS, ceftaroline community-acquired pneumonia trial vs ceftriaxone in hospital patients. FOCUS 1, CABP Trial 1; FOCUS 2, CABP Trial 2; mITT, microbiological intent-to-treat.

To meet responder criteria, patients had to[1]:

- Be in stable condition according to consensus treatment guidelines
- Show improvement from baseline on at least 1 symptom of cough, dyspnea, pleuritic chest pain, or sputum production, while not worsening on any of these 4 symptoms

TEFLARO is included in the 2019 ATS and IDSA CAP Guideline[5]

Strong recommendation

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 CAP without risk factors for MRSA or *P. aeruginosa*.

Please see CABP study design on pages 16 and 17.

ATS, American Thoracic Society; CAP, community-acquired pneumonia; IDSA, Infectious Diseases Society of America.

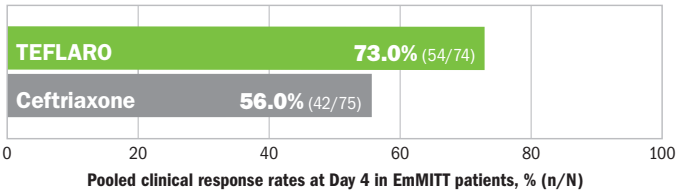
IMPORTANT SAFETY INFORMATION (continued)

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.

Early clinical response against *S. pneumoniae*[4]

CLINICAL RESPONSE AT DAY 4 FOR CABP CAUSED BY *S. PNEUMONIAE*



No statistically significant differences between treatment groups can be inferred from the above pathogen response rates.

EFFICACY DEMONSTRATED AT TOC (CE)[1]

- In FOCUS 1, clinical cure rates were 86.6% (194/224) for TEFLARO and 78.2% (183/234) for ceftriaxone
- In FOCUS 2, clinical cure rates were 82.3% (191/232) for TEFLARO and 77.1% (165/214) for ceftriaxone

Comparisons at TOC cannot be used to establish noninferiority.‡

- **TOC occurred 8-15 days after the end of therapy**

‡There are insufficient historical data to establish the magnitude of drug effect for antibacterial drugs compared with placebo at a TOC time point.[1]

CE, clinically evaluable; EmMITT, exploratory microbiological modified intent-to-treat; TOC, test of cure.

When CABP involves bacteremia[3]...

- **83.3%** (20/24) of TEFLARO adult patients with baseline *S. pneumoniae* bacteremia demonstrated clinical cure at TOC, compared with 62.5% (10/16) of ceftriaxone patients

IMPORTANT SAFETY INFORMATION (continued)

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 of TEFLARO for the treatment of ABSSSI in pediatric patients less than 34 weeks gestational age and less than 12 days postnatal age have not been established. Safety and effectiveness for the treatment of CABP in pediatric patients below the age of 2 months have not been established as no data are available.

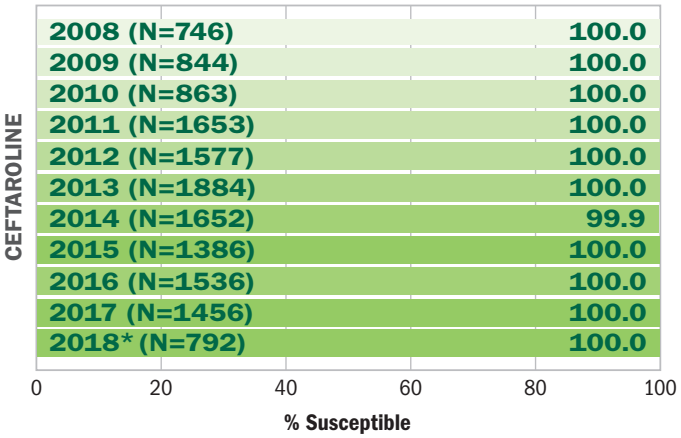
Please see additional Important Safety Information throughout. Please also see accompanying full Prescribing Information.

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

Susceptibility ≥99.9% against *S. pneumoniae* for more than a decade[3]

NATIONAL SUSCEPTIBILITY RATES, 2008-2018

S. pneumoniae respiratory isolates



Study outline

AWARE (**A**ssessing **W**orldwide **A**ntimicrobial **R**esistance **E**valuation): This 2017 US study surveyed the *in vitro* susceptibility activity of ceftaroline and other agents against MRSA and other Gram-positive and Gram-negative pathogens, including *Streptococcus* spp, *Haemophilus* spp, and Enterobacteriaceae. A total of 23,255 bacterial isolates were collected from 70 medical centers distributed across all 9 US census regions.

*The AWARE study ended in 2017. These results are from a separate 2018 study that surveyed the *in vitro* susceptibility activity of ceftaroline and other agents against MRSA and other Gram-positive pathogens. A total of 5977 bacterial isolates were collected from 31 medical centers distributed across all 9 US census divisions.

***In vitro* activity does not necessarily correlate with clinical results.**

IMPORTANT SAFETY INFORMATION (continued)

Use in Specific Populations (continued)

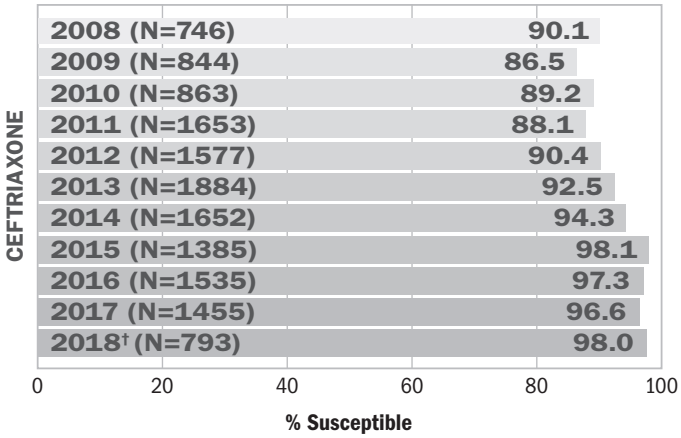
- Because elderly patients, those ≥65 years of age, are more likely to have decreased renal function and ceftaroline is excreted primarily by the kidney, care should be taken in dose selection in this age group and it may be useful to monitor renal function. Dosage adjustment for elderly patients should 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 ≤30 mL/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/1.73 m^2.
- The pharmacokinetics of ceftaroline in patients with hepatic impairment have not been established.

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.

NATIONAL SUSCEPTIBILITY RATES, 2008-2018

S. pneumoniae respiratory isolates



†The AWARE study ended in 2017. These results are from a separate 2018 study that surveyed the *in vitro* susceptibility activity of ceftaroline and other agents against MRSA and other Gram-positive pathogens. A total of 5977 bacterial isolates were collected from 31 medical centers distributed across all 9 US census divisions.

***In vitro* activity does not necessarily correlate with clinical results.**

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.

Please see additional Important Safety Information throughout. Please also see accompanying full Prescribing Information.

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

Dosing TEFLARO® for ABSSSI and CABP in adult patients[1]

600 mg | **IV every 12 hours for CABP for 5-7 days and for ABSSSI for 5-14 days***

*For patients with CrCl >50 mL/min.

- Duration of therapy should be guided by the severity and site of infection and the patient's clinical and bacteriological progress

Patients with renal impairment should receive TEFLARO 5- to 60-minute IV infusion every 12 hours at the following dosages:

- >50 CrCl† (mL/min): 600 mg
- >30 to ≤50 CrCl† (mL/min): 400 mg
- ≥15 to ≤30 CrCl† (mL/min): 300 mg
- End-stage renal disease, including hemodialysis‡: 200 mg§

Vials shown not actual size.

†CrCl estimated using the Cockcroft-Gault formula.

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

§TEFLARO is hemodialyzable; thus, TEFLARO should be administered after hemodialysis on hemodialysis days.

CrCl, creatinine clearance; IV, intravenous.

IMPORTANT SAFETY INFORMATION (continued)

***Clostridioides difficile*-Associated Diarrhea**

- *Clostridioides 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.

Neurological Adverse Reactions

- Neurological adverse reactions have been reported during postmarketing surveillance in patients treated with cephalosporins, including TEFLARO. These reactions include encephalopathy and seizures. Most cases occurred in patients with renal impairment who did not receive appropriate dosage adjustment. The neurological adverse reactions were reversible and resolved after discontinuation of TEFLARO or after hemodialysis. If neurological adverse reactions associated with TEFLARO therapy occur, consider discontinuing TEFLARO or making appropriate dosage adjustments in patients with renal impairment.

Short infusion time adds flexibility[1]

5- TO 60-MINUTE INFUSION FOR TEFLARO IN ABSSSI AND CABP ALLOWS INCREASED FLEXIBILITY OF INFUSION TIME

- Low infusion volume (50 mL)

STRAIGHTFORWARD ADMINISTRATION

- No specific weight-related dosing adjustments required in adults‖
- No drug-level monitoring required
- No need to monitor CPK levels
- No refrigeration required for TEFLARO vials
- No known drug-drug interactions, including SSRIs and statins
- Can be used with the Baxter® Mini-Bag Plus™ System

Unreconstituted TEFLARO vials should be stored at room temperature, 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Please see individual product label for storage instructions and product expiration date.

‖Weight-based dosing is required for pediatric patients.

CPK, creatine phosphokinase; SSRI, selective serotonin reuptake inhibitor.

Baxter® is a registered trademark and Mini-Bag Plus™ is a trademark of Baxter International Inc.

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout. Please also see accompanying full Prescribing Information.

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

TEFLARO® has a demonstrated safety and tolerability profile in ABSSSI and CABP[1]

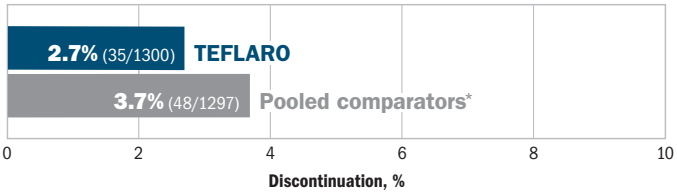
IN ADULT CLINICAL TRIALS, NO ADVERSE REACTIONS OCCURRED IN >5% OF PATIENTS RECEIVING TEFLARO

ADVERSE REACTIONS		TEFLARO (N=1300)	POOLED COMPARATORS* (N=1297)
GASTROINTESTINAL DISORDERS	Diarrhea Nausea Constipation Vomiting	5% 4% 2% 2%	3% 4% 2% 2%
INVESTIGATIONS	Increased transaminases	2%	3%
METABOLISM AND NUTRITION DISORDERS	Hypokalemia	2%	3%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rash	3%	2%
VASCULAR DISORDERS	Phlebitis	2%	1%

*Comparators included vancomycin 1 g IV every 12 hours plus aztreonam 1 g IV every 12 hours in the Phase 3 adult ABSSSI trials, and ceftriaxone 1 g IV every 24 hours in the Phase 3 adult CABP trials.

- In the 4 pooled Phase 3 adult 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

LOW INCIDENCE OF DISCONTINUATION IN ADULTS DUE TO ADVERSE REACTIONS[1]



*Comparators included vancomycin 1 g IV every 12 hours plus aztreonam 1 g IV every 12 hours in the Phase 3 adult ABSSSI trials, and ceftriaxone 1 g IV every 24 hours in the Phase 3 adult CABP trials.

- The most common adverse reactions leading to discontinuation were hypersensitivity for both treatment groups at a rate of 0.3% in the TEFLARO group and 0.5% in the comparator group[1]

References: 1. TEFLARO® (ceftaroline fosamil) [prescribing information]. Madison, NJ: Allergan USA, Inc. **2.** Friedland HD, O'Neal T, Biek D, et al. CANVAS 1 and 2: analysis of clinical response at day 3 in two phase 3 trials of ceftaroline fosamil versus vancomycin plus aztreonam in treatment of acute bacterial skin and skin structure infections. *Antimicrob Agents Chemother.* 2012;56(5):2231-2236. **3.** Data on file. Allergan, Inc. **4.** Eckburg PB, Friedland HD, Llorens L, et al. Day 4 clinical response of ceftaroline fosamil versus ceftriaxone for community-acquired bacterial pneumonia. *Infect Dis Clin Pract.* 2012;20(4):254-260. **5.** Metlay JP, Waterer GW, Long AC, et al; on behalf of the American Thoracic Society and Infectious Diseases Society of America. 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 Crit Care Med.* 2019;200(7):e45-e67. **6.** Corey GR, Wilcox M, Talbot GH, et al. Integrated analysis of CANVAS 1 and 2: phase 3, multicenter, randomized, double-blind studies to evaluate the safety and efficacy of ceftaroline versus vancomycin plus aztreonam in complicated skin and skin-structure infection. *Clin Infect Dis.* 2010;51(6):641-650. **7.** File TM Jr, Low DE, Eckburg PB, et al. Integrated analysis of FOCUS 1 and FOCUS 2: randomized, double-blinded, multicenter phase 3 trials of the efficacy and safety of ceftaroline fosamil versus ceftriaxone in patients with community-acquired pneumonia. *Clin Infect Dis.* 2010;51(12):1395-1405.

IMPORTANT SAFETY INFORMATION (continued)

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.

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout. Please also see accompanying full Prescribing Information.

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

TEFLARO® ABSSSI study design[1,3]

TYPE OF TRIAL	Two identical, randomized, multicenter, multinational, double-blind, noninferiority trials.
STUDY POPULATION	1396 adults with clinically documented cSSSI.
COMPARATIVE AGENTS	TEFLARO—600 mg administered IV over 1 hour every 12 hours for 5-14 days; vancomycin plus aztreonam—1 g vancomycin administered IV over 1 hour followed by 1 g aztreonam administered IV over 1 hour every 12 hours for 5-14 days.
TREATMENT DURATION	Treatment duration was 5-14 days. A switch to oral therapy was not allowed.

TEFLARO STUDY POPULATIONS

DAY 3 POPULATION* (CLINICAL RESPONSE DEMONSTRATED 48-72 HOURS AFTER STARTING THERAPY)	The analysis evaluated patients with lesion size ≥75 cm^2 and having 1 of the following infection types: – Major abscess with ≥5 cm of surrounding erythema – Wound infection – Deep/extensive cellulitis
TEST OF CURE (TOC) POPULATIONS†	
MODIFIED INTENT-TO-TREAT (MITT)	All randomized subjects who received any amount of study drug.
CLINICALLY EVALUABLE (CE)	Patients in the MITT population who demonstrated sufficient adherence to the protocol. Sufficient adherence is defined as patients who met the minimal clinical disease criteria for cSSSI and all evaluability criteria, including subjects who received at least the prespecified minimal amount of the intended dose and duration of study drug therapy, for whom sufficient information regarding the cSSSI site is available to determine the subject's outcome, and for whom there were no confounding factors that interfered with the assessment of that outcome.
MICROBIOLOGICALLY EVALUABLE (ME)	This population consists of a subset of subjects from the CE population who had at least 1 bacterial pathogen identified from a blood culture or culture of an adequate microbiological sample obtained from the cSSSI site at baseline and who had susceptibility testing performed on at least 1 of the isolated baseline pathogens.

- In the 2 ABSSSI adult studies, 20 of the 693 patients in the TEFLARO group had baseline *S. aureus* bacteremia (9 MRSA and 11 MSSA).[1]

*To evaluate the treatment effect of ceftaroline, an analysis was conducted in 797 patients with ABSSSI (such as deep/extensive cellulitis or a wound infection [surgical or traumatic]) for whom the treatment effect of antibacterials may be supported by historical evidence. This analysis evaluated responder rates based on achieving both cessation of lesion spread and absence of fever on Trial Day 3.[1]

†The protocol-specified analyses included clinical cure rates at the TOC (8-15 days after the end of therapy) in the co-primary CE and MITT populations and clinical cure rates at TOC by pathogen in the ME population.[1]

cSSSI, complicated skin and skin structure infection.

TEFLARO ABSSSI studies: selected patient demographics and baseline characteristics (integrated MITT)[6]

CHARACTERISTIC		TEFLARO (n=693)	VANCOMYCIN + AZTREONAM (n=685)
Age, median years (range)		48.0 (18-93)	48.0 (18-96)
Male sex, no. (%)		444 (64.1)	419 (61.2)
BMI	Median (range) >30, no. (%)	26.9 (14.1-74.1) 222 (32.0)	27.4 (16.6-66.5) 227 (33.1)
Duration of therapy, mean days ± SD		8.3 ± 3.2	8.4 ± 3.3
Comorbid conditions, no. (%)	Diabetes mellitus Peripheral vascular disease Injection drug use	122 (17.6) 93 (13.4) 46 (6.6)	120 (17.5) 93 (13.6) 59 (8.6)
Site of primary infection, no. (%)	Lower limb Head/neck Other	338 (48.8) 45 (6.5) 310 (44.7)	339 (49.5) 33 (4.8) 313 (45.7)
Prior antimicrobial therapy, no. (%)		276 (39.8)	260 (38.0)
Infection measurements	Length, median cm (range) Width, median cm (range)	15.00 (0.4-65.0) 10.00 (0.5-55.0)	15.00 (0.2-99.0) 10.00 (0.2-61.3)
Surgical procedures on primary infection site ≤48 hours after enrollment,‡ no. (%)	≥1 procedure Incision and drainage Debridement	97 (14.0) 46 (6.6) 31 (4.5)	108 (15.8) 51 (7.4) 29 (4.2)

NOTE: BMI, body mass index (calculated as the weight in kilograms divided by the square of height in meters).

‡Includes patients with surgical procedures performed <24 hours before first dose or randomization and <48 hours after first dose.

Adapted from Corey GR et al. *Clin Infect Dis*. 2010. Reproduced with permission of the IDSA.

SD, standard deviation.

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions in Adults (continued)

- 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%).

Please see additional Important Safety Information throughout. Please also see accompanying full Prescribing Information.

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

TEFLARO® CABP study design[1,3,4]

TYPE OF TRIAL	Two randomized, multicenter, multinational, double-blind, noninferiority trials.
STUDY POPULATION	1231 adults with a diagnosis of CABP.
COMPARATIVE AGENTS	TEFLARO—600 mg administered IV over 1 hour every 12 hours for 5-7 days; ceftriaxone—1 g ceftriaxone administered IV over 30 minutes every 24 hours for 5-7 days.
ADJUNCTIVE THERAPY	CABP Trial 1, 2 doses on Day 1 of oral clarithromycin 500 mg every 12 hours; CABP Trial 2, no adjunctive macrolide therapy.

TEFLARO STUDY POPULATIONS

DAY 4 POPULATION*

MICROBIOLOGICAL INTENT-TO-TREAT (MITT)	All subjects with a confirmed bacterial pathogen at baseline.
EXPLORATORY MICROBIOLOGICAL MODIFIED INTENT-TO-TREAT (EmMITT)	All randomized patients who received any study drug, had CAP that met radiographic criteria and had 1 or more symptoms at baseline, and had 1 or more acceptable baseline typical pathogens.

TEST OF CURE (TOC) POPULATION†

MODIFIED INTENT-TO-TREAT (MITT)	All randomized subjects who received any amount of study drug.
MODIFIED INTENT-TO-TREAT EFFICACY (MITTE)	All subjects in the MITT population who were in PORT risk class III or IV at baseline.
CLINICALLY EVALUABLE (CE)	Patients in the MITTE population who demonstrated sufficient adherence to the protocol. Sufficient adherence is defined as patients who met the minimal clinical disease criteria for CABP and for whom sufficient information regarding the CABP was available to determine the patient's outcome.
MICROBIOLOGICALLY EVALUABLE (ME)	All subjects in the CE population who had at least 1 typical bacterial pathogen identified at baseline from an appropriate microbiological specimen (eg, blood, sputum, or pleural fluid).

*To evaluate the treatment effect of ceftaroline, an analysis was conducted in CABP patients for whom the treatment effect of antibacterials may be supported by historical evidence. This analysis endpoint required subjects to meet sign and symptom criteria at Day 4 of therapy: a responder had to both (a) be in stable condition according to consensus treatment guidelines, and (b) show improvement from baseline on at least 1 symptom of cough, dyspnea, pleuritic chest pain, or sputum production, while not worsening on any of these 4 symptoms.[1]

†The protocol-specified analyses included clinical cure rates at the TOC (8-15 days after the end of therapy) in the co-primary MITTE and CE populations and clinical cure rates at TOC by pathogen in the ME population.[1]

PORT, Pneumonia Outcomes Research Team.

TEFLARO CABP studies: selected patient demographics and baseline characteristics (integrated MITTE)[7]

CHARACTERISTIC	TEFLARO GROUP (n=580) no. (%)	CEFTRIAXONE GROUP (n=573) no. (%)
Age		
Mean years (±SD)	60.8±16.4	61.6±15.6
>50 years	438 (75.5)	445 (77.7)
≥65 years	273 (47.1)	281 (49.0)
≥75 years	130 (22.4)	128 (22.3)
Sex: male	362 (62.4)	366 (63.9)
Most common comorbid conditions		
Structural lung disease‡	160 (27.6)	147 (25.7)
Any prior pneumonia	123 (21.2)	92 (16.1)
Asthma	49 (8.4)	38 (6.6)
PORT risk class of III or IV		
III	360 (62.1)	353 (61.6)
IV	220 (37.9)	220 (38.4)
Bacteremia	23 (4.0)	20 (3.5)
Renal impairment		
Mild (CrCl level, 51-80 mL/min)	199 (34.3)	190 (33.2)
Moderate (CrCl level, 31-50 mL/min)	88 (15.2)	85 (14.8)
WBC count		
<4500 cells/mm^3	26 (4.5)	28 (4.9)
4500-10,000 cells/mm^3	210 (36.2)	220 (38.4)
>10,000 cells/mm^3	229 (39.5)	216 (37.7)
Immature band count		
>10%	9 (1.6)	5 (0.9)
>15%	6 (1.0)	3 (0.5)

NOTE: Data are no. (%) of patients, unless otherwise indicated.

‡Defined as any chronic parenchymal or airway disease (eg, chronic obstructive pulmonary disease [emphysema, chronic bronchitis], bronchiectasis, or interstitial fibrosis).

Adapted from File TM et al. *Clin Infect Dis*. 2010. Reproduced with permission of the IDSA.

WBC, white blood cell.

IMPORTANT SAFETY INFORMATION (continued)

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.

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In ABSSSI and CABP:

See an EARLY CLINICAL RESPONSE with TEFLARO®

- In ABSSSI, clinical response was achieved 48-72 hours after starting TEFLARO monotherapy—including cases caused by MRSA—with efficacy demonstrated at TOC[1,2]
- In CABP, clinical response was achieved 72-96 hours after starting TEFLARO—including patients with baseline *S. pneumoniae* bacteremia—with efficacy demonstrated at TOC[1,3,4]
- TEFLARO has a demonstrated safety and tolerability profile in ABSSSI and CABP[1]
- 5- to 60-minute infusion in ABSSSI and CABP allows increased flexibility of infusion time[1]

INDICATIONS AND USAGE

- TEFLARO® (ceftaroline fosamil) is indicated in adult and pediatric patients (at least 34 weeks gestational age and 12 days postnatal age) for the treatment of **acute bacterial skin and skin structure infections (ABSSSI)** caused by susceptible isolates of the following Gram-positive and Gram-negative microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Klebsiella oxytoca*.
- TEFLARO is also 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 ABSSSI or CABP that are 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 Indications and Usage and additional Important Safety Information throughout.
Please also see accompanying full Prescribing Information.

abbvie

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