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

You are cordially invited to attend a professional lecture featuring

Avycaz®
ceftazidime and avibactam
for injection (2.5 g)

Community-Acquired and Hospital-Acquired/Ventilator-Associated Bacterial Pneumonia (CABP and HABP/VABP)

PRESENTED BY:

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University of South Florida Morsani College of Medicine

Thursday, February 03, 2022 at 6:15 PM

Ruth's Chris Steak House

1201 Riverplace Boulevard, Jacksonville, FL 32207

Please RSVP for this program by using the following link: http://www.medforcereg.net/SALG135789

MedForce can accept RSVPs from HCPs via phone at 888-335-8430. Please reference Meeting ID 135789.
For questions, contact your AbbVie Representative Lisa Reinstine 904-982-7981

TEFLARO ceftaroline fosamil for injection

INDICATIONS AND USAGE

- TEFLARO® (ceftaroline fosamil) is indicated in adult and pediatric patients (at least 34 weeks gestational age and 12 days postnatal age and older) 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.

AVYCAZ ceftazidime and avibactam for injection

INDICATIONS AND USAGE

Complicated Intra-Abdominal Infections (cIAI)
AVYCAZ (ceftazidime and avibactam), in combination with metronidazole, is indicated for the treatment of complicated intra-abdominal infections (cIAI) in adults and pediatric patients 3 months or older caused by the following susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae, Klebsiella oxytoca, Citrobacter freundii complex*, and *Pseudomonas aeruginosa*.

Complicated Urinary Tract Infections (cUTI), including Pyelonephritis
AVYCAZ is indicated for the treatment of complicated urinary tract infections (cUTI) including pyelonephritis in adults and pediatric patients 3 months or older caused by the following susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Citrobacter freundii* complex, *Proteus mirabilis,* and *Pseudomonas aeruginosa*.

Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)
AVYCAZ is indicated for the treatment of hospital-acquired bacterial pneumonia and ventilator associated bacterial pneumonia (HABP/VABP) caused by the following susceptible Gram-negative microorganisms: *Klebsiella pneumoniae, Enterobacter cloacae, Escherichia coli, Serratia marcescens, Proteus mirabilis, Pseudomonas aeruginosa*, and *Haemophilus influenzae* in patients 18 years or older.

Usage
To reduce the development of drug-resistant bacteria and maintain the effectiveness of AVYCAZ and other antibacterial drugs, AVYCAZ should be used to treat only indicated infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
AVYCAZ is contraindicated in patients with known serious hypersensitivity to the components of AVYCAZ (ceftazidime and avibactam), avibactam-containing products, or other members of the cephalosporin class.

Please see additional Important Safety Information on next page and accompanying full Prescribing Information.

IMPORTANT SAFETY INFORMATION FOR TEFLARO (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.

***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.

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.
- In children, seroconversion from a negative to a positive direct Coombs' test result occurred in 42/234 (17.9%) of patients receiving TEFLARO and 3/93 (3.2%) of patients receiving comparator drugs in the three pooled pediatric 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%).

Adverse Reactions in Pediatrics

- In the three pooled pediatric clinical trials, serious adverse reactions occurred in 10/257 (4%) of patients receiving TEFLARO and 3/102 (3%) of patients receiving comparator drugs. Treatment discontinuation due to adverse reactions occurred in 10/257 (3.9%) of patients receiving TEFLARO and 2/102 (2%) of patients receiving comparator drugs with the most common adverse reaction leading to discontinuation being rash in 2/257 (0.8%) of patients treated with TEFLARO.
- The most common adverse reactions occurring in ≥ 3% of patients receiving TEFLARO in the pooled pediatric clinical trials were diarrhea (8%), rash (7%), vomiting (5%), pyrexia (3%), and nausea (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 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.
- 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 Indications and Usage and additional Important Safety Information for TEFLARO on the previous page and accompanying full Prescribing Information.

IMPORTANT SAFETY INFORMATION AVYCAZ (Continued)

WARNINGS AND PRECAUTIONS

- In a Phase 3 cIAI trial in adult patients, clinical cure rates were lower in a subgroup of patients with baseline creatinine clearance (CrCl) of 30 to less than or equal to 50 mL/min compared to those with CrCl greater than 50 mL/min. The reduction in clinical cure rates was more marked in patients treated with AVYCAZ plus metronidazole compared to meropenem-treated patients. Within this subgroup, patients treated with AVYCAZ received a 33% lower daily dose than is currently recommended for patients with CrCl of 30 to less than or equal to 50 mL/min. Clinical cure rate in patients with normal renal function/mild renal impairment (CrCl greater than 50 mL/min) was 85% (322/379) with AVYCAZ plus metronidazole vs 86% (321/373) with meropenem, and clinical cure rate in patients with moderate renal impairment (CrCl 30 to less than or equal to 50 mL/min) was 45% (14/31) with AVYCAZ plus metronidazole vs 74% (26/35) with meropenem. The decreased clinical response was not observed for patients with moderate renal impairment at baseline (CrCl 30 to less than or equal to 50 mL/min) in the Phase 3 cUTI trials or the Phase 3 HABP/VABP trial. Monitor CrCl at least daily in patients with changing renal function and adjust the dosage of AVYCAZ accordingly.
- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Before therapy with AVYCAZ is instituted, careful inquiry about previous hypersensitivity reactions to other cephalosporins, penicillins, or carbapenems should be made. Exercise caution if this product is to be given to a penicillin or other beta-lactam-allergic patient because cross sensitivity among beta-lactam antibacterial drugs has been established. Discontinue the drug if an allergic reaction to AVYCAZ occurs.
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial drugs, including AVYCAZ, 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 drugs. If CDAD is suspected or confirmed, antibacterials not directed against *C. difficile* should be discontinued, if possible.
- Seizures, nonconvulsive status epilepticus (NCSE), encephalopathy, coma, asterixis, neuromuscular excitability, and myoclonia have been reported in patients treated with ceftazidime, particularly in the setting of renal impairment. Adjust dosing based on CrCl.
- Prescribing AVYCAZ 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.

ADVERSE REACTIONS

Adult cIAI, cUTI and HABP/VABP Patients:
The most common adverse reactions in adult patients with cIAI (≥ 5% when used with metronidazole) were diarrhea (8%), nausea (7%), and vomiting (5%). The most common adverse reactions in adult patients with cUTI (3%) were diarrhea and nausea. The most common adverse reactions in adult patients with HABP/VABP (≥ 5%) were diarrhea (15%) and vomiting (6%).

Pediatric cIAI and cUTI Patients:
The most common adverse reactions in pediatric patients with cIAI and cUTI (>3%) were vomiting, diarrhea, rash, and infusion site phlebitis.

Please see Indications and Usage and additional Important Safety Information on the previous page and accompanying full Prescribing Information.

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