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

You are cordially invited to attend a professional lecture featuring

Dalvance®
(dalbavancin) for injection
500 mg

Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

PRESENTED BY:

Juan Diaz, DO
Infectious Disease, Infectious Disease Specialist
Maitland, FL

Sponsored by AbbVie

Please RSVP for this program by using the following link:
http://www.medforcereg.net/SALG127806

Wednesday, November 03, 2021 at 6:30 PM ET

Ruth's Chris Steak House

1201 Riverplace Boulevard
Jacksonville, FL 32207
Phone: (904) 396-6200

MedForce can accept RSVPs from HCPs via phone at 888-335-8430. Please reference Meeting ID 127806.
For questions, contact your AbbVie Representative Lisa Reinstine Phone 0 Email: lisa.reinstine@abbvie.com

Now that shelter in place restrictions have been modified in our area, it is possible for us to resume education in an out-of-office as we have historically done. Please review the below safety requirements that will be in place to determine your level of comfort with attending live. Please let your AbbVie Representative know if you have any questions or prefer to attend virtually:

- Attendees and the AbbVie Host must wear a mask and observe 3ft of social distancing if they are not vaccinated (except when consuming food or beverages), or as required by the venue or state/local requirements.
- Food may be consumed during the program, or individually boxed to be taken offsite to be consumed after the program has concluded, based on the preference of attendees.
- Alcohol will no longer be provided by AbbVie at programs.

AbbVie is committed to the health and safety of patients, health care workers, employees and all other stakeholders; therefore, the above are mandatory safety requirements.

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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*.
- 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 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.

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.

DALVANCE dalbavancin for injection

INDICATIONS AND USAGE

DALVANCE® (dalbavancin) for injection is indicated for the treatment of adult patients with **acute bacterial skin and skin structure infections (ABSSSI)** caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus* group (including *S. anginosus, S. intermedius, S. constellatus*) and *Enterococcus faecalis* (vancomycin-susceptible strains).

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DALVANCE is contraindicated in patients with known hypersensitivity to dalbavancin.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity (anaphylactic) and skin reactions have been reported with glycopeptide antibacterial agents, including DALVANCE. Exercise caution in patients with known hypersensitivity to glycopeptides due to the possibility of cross-sensitivity. If an allergic reaction occurs, treatment with DALVANCE should be discontinued.

Infusion-related Reactions

Rapid intravenous infusion of DALVANCE can cause reactions, including flushing of the upper body, urticaria, pruritus, rash, and/or back pain.

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

IMPORTANT SAFETY INFORMATION FOR TEFLARO (Continued)

WARNINGS AND PRECAUTIONS (continued)

Hypersensitivity Reactions (continued)

- 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.
- 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 FOR DALVANCE (Continued)

WARNINGS AND PRECAUTIONS (continued)

Hepatic Effects

ALT elevations with DALVANCE treatment were reported in clinical trials.

***Clostridium difficile*-associated Diarrhea**

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including DALVANCE, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

Development of Drug-resistant Bacteria

Prescribing DALVANCE 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

The most common adverse reactions in patients treated with DALVANCE were nausea (4.7%), headache (3.8%), and diarrhea (3.4%).

Use in Specific Populations

- There have been no adequate and well-controlled studies with DALVANCE in pregnant or nursing women. DALVANCE should only be used if the potential benefit justifies the potential risk in these populations.
- In patients with renal impairment whose known creatinine clearance is less than 30 mL/min and who are not receiving regularly scheduled hemodialysis, the recommended regimen of DALVANCE is 1125 mg, administered as a single dose, or 750 mg followed one week later by 375 mg. No dosage adjustment is recommended for patients receiving regularly scheduled hemodialysis, and DALVANCE can be administered without regard to the timing of hemodialysis.
- Caution should be exercised when prescribing DALVANCE to patients with moderate or severe hepatic impairment (Child-Pugh Class B or C) as no data are available to determine the appropriate dosing in these patients.

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

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