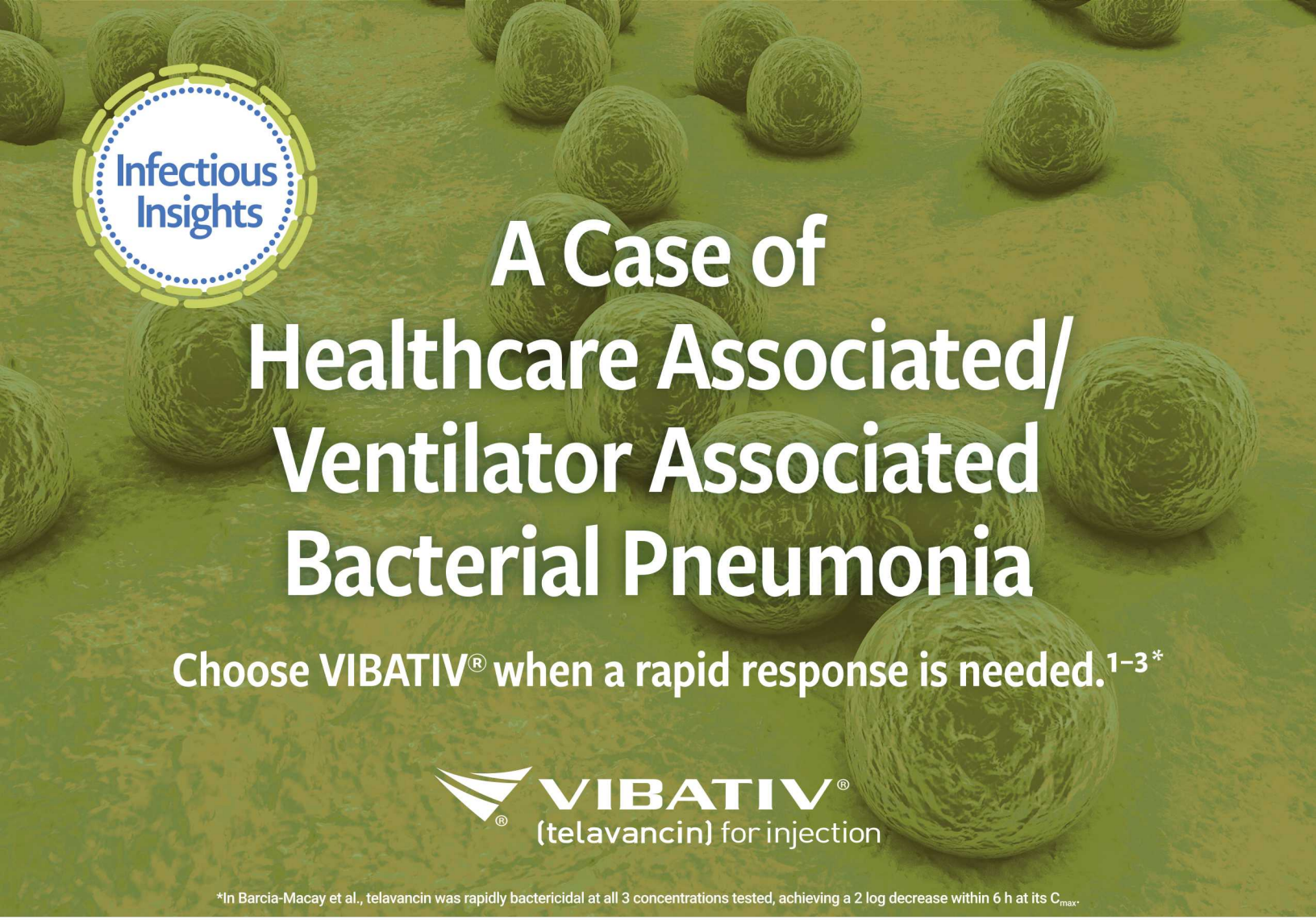


Vibativ® (telavancin) Injection

INDICATION: Vibativ is indicated in adults for the treatment of:

- complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), or *Enterococcus faecalis* (vancomycin-susceptible isolates only).
- hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of *Staphylococcus aureus* (both methicillin-susceptible and -resistant isolates). Vibativ should be reserved for use when alternative treatments are not suitable.

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

WARNING: INCREASED MORTALITY IN HABP/VABP PATIENTS WITH PRE-EXISTING MODERATE OR SEVERE RENAL IMPAIRMENT, NEPHROTOXICITY, and EMBRYO-FETAL TOXICITY

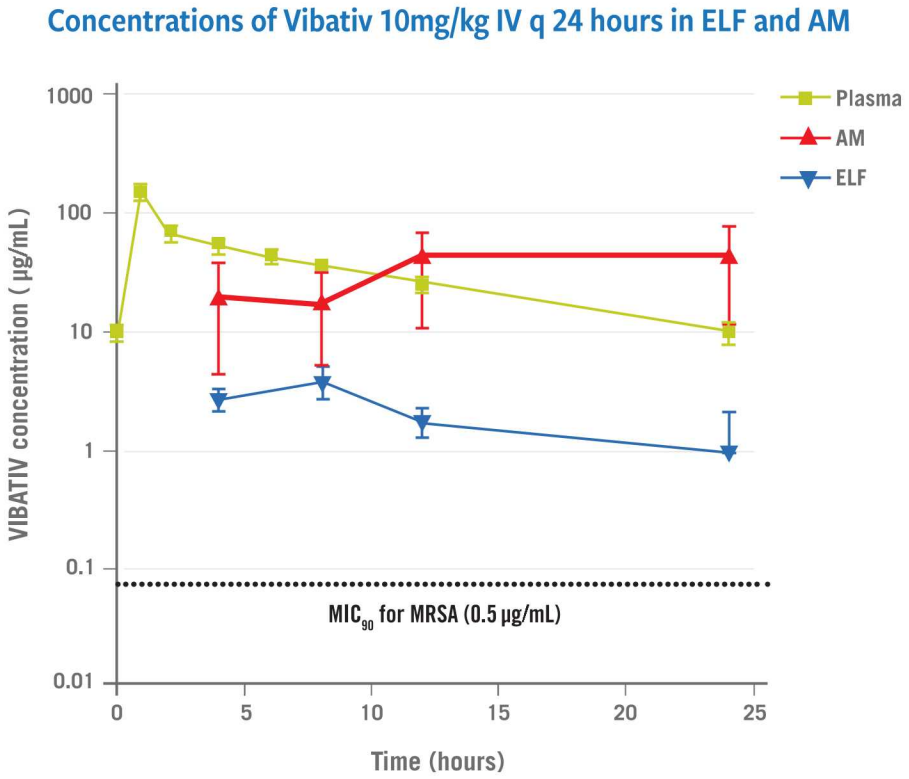
Patients with pre-existing moderate/severe renal impairment (CrCl ≤50 mL/min) who were treated with VIBATIV for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia had increased mortality observed versus vancomycin. Use of VIBATIV in patients with pre-existing moderate/severe renal impairment (CrCl ≤50 mL/min) should be considered only when the anticipated benefit to the patient outweighs the potential risk.

- Nephrotoxicity: New onset or worsening renal impairment has occurred. Monitor renal function in all patients.
- Embryo-Fetal Toxicity: VIBATIV may cause fetal harm. In animal reproduction studies, adverse developmental outcomes were observed in 3 animal species at clinically relevant doses. Verify pregnancy status prior to initiating treatment and advise females of reproductive potential to use effective contraception.

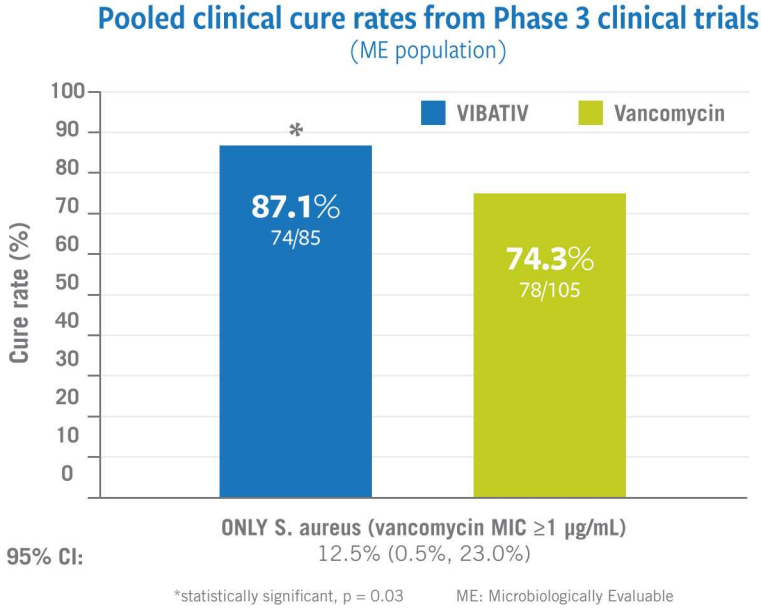
Please see Important Safety Information throughout, and the accompanying full Prescribing Information, including Boxed Warning.

VIBATIV (telavancin) for High Levels of Lung Penetration

VIBATIV demonstrated high levels of tissue penetration in epithelial lining fluid (ELF) and alveolar macrophages (AM) throughout 24 hours that exceeded the MIC_{90} for MRSA (0.5 µg/mL).[4]



VIBATIV demonstrated significantly higher cure rates in patients with HABP/VABP due to monomicrobial *S. aureus* infection with vancomycin MIC ≥ 1 µg/mL.[5]



IMPORTANT DOSAGE AND ADMINISTRATION INSTRUCTIONS

Because telavancin is eliminated primarily by the kidney, a dosage adjustment is required for patients whose creatinine clearance is ≤50 mL/min. There is insufficient information to make specific dosage adjustment recommendations for patients with end-stage renal disease (CrCl <10 mL/min), including patients undergoing hemodialysis.

ANNE W. | 70yo female, 5'8", 68 kg, Retired

(Not an actual patient. For illustration only.)

MEDICAL HISTORY

- AW is hospitalized for a recent fall.
- History of diabetes and hypertension
- Baseline BUN 11 mg/dL, SCr 0.8 mg/dL

CURRENT MEDICATIONS

- Sertraline 100mg daily
- Metformin 500mg BID
- Lisinopril 10mg daily

HISTORY OF PRESENT ILLNESS

- On hospital day 5, AW develops a fever. She is started on Vancomycin dosed per local protocol + Cefepime 2g IV q12h.
- 48 hours later, the patient showed no improvement, had difficulty breathing, and required oxygen support via a non-rebreather. AW is transferred to the Intensive Care Unit (ICU) and subsequently intubated for respiratory failure.

ICU ADMISSION

- Tmax 39.8°C, BP 182/136, HR 110
- WBC 18,000/mm^3, Procalcitonin 4.5 ng/mL
- Vancomycin trough = 15.1 mcg/mL
- Following intubation, a chest x-ray revealed left-lower lobe consolidation indicative of pneumonia.
- On ICU day 1, cultures obtained 2 days prior reported: blood cultures resulted no growth to date and sputum cultures revealed MRSA with MIC = 1 to vancomycin.

TREATMENT MODIFICATION

- On ICU day 2, AW was not improving clinically and the Pulmonary Critical Care intensivist discontinued the current antibiotic regimen and initiated VIBATIV® (telavancin) 10 mg/kg IV daily.
- CrCl 67 mL/min
- On ICU day 4, AW defervesced, WBC 9,500/mm^3, and her respiratory status improved. AW was successfully extubated.

CLINICAL COURSE

- On ICU day 5, AW was transferred to the medical step-down unit with minimal O2 requirements and treatment with VIBATIV® was continued for a total of 10 days.

Please see Important Safety Information throughout,
and the accompanying full Prescribing Information, including Boxed Warning.

Once-daily dosing with no therapeutic drug-level monitoring required.[3]

Dosing Adjustments for Patients with Renal Impairment

Creatinine Clearance CrCl (mL/min)	VIBATIV Dosage Regimen
>50	10 mg/kg every 24 hours
30-50	7.5 mg/kg every 24 hours
10-<30	10 mg/kg every 48 hours

Calculate CrCl using the Cockcroft-Gault formula and ideal body weight (IBW). Use actual body weight if it is less than IBW.
Insufficient data are available to make a dosing recommendation for patients with CrCl < 10 mL/min, including patients on hemodialysis.

IMPORTANT SAFETY INFORMATION CONTINUED

CONTRAINDICATIONS

Vibativ should not be used with intravenous unfractionated heparin sodium because the activated partial thromboplastin time (aPTT) test results are expected to be artificially prolonged for 0 to 18 hours after Vibativ administration. Do not be use in patients with known hypersensitivity to Vibativ (telavancin).

WARNINGS AND PRECAUTIONS

- Decreased efficacy among patients treated for cSSSI with moderate/severe pre-existing renal impairment. Consider when selecting antibacterial therapy for patients with baseline CrCl ≤50 mL/min.
- Laboratory tests: interferes with some laboratory coagulation tests, including prothrombin time, international normalized ratio, and activated partial thromboplastin time.
- Serious and potentially fatal hypersensitivity reactions, including anaphylactic reactions, may occur after first or subsequent doses. Use with caution in patients with known hypersensitivity to vancomycin.
- Administer Vibativ over at least 60 minutes to minimize infusion-related reactions.
- Clostridium difficile-Associated Diarrhea; may range from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.
- Avoid use in patients at risk for QTc prolongation and who are taking drugs known to prolong the QT interval.

ADVERSE REACTIONS

The most common adverse reaction (≥10% of patients treated with Vibativ) in the HABP/VABP trials is diarrhea; in the cSSSI trials, the most common adverse reactions (≥10% of patients treated with Vibativ) include: taste disturbance, nausea, vomiting, and foamy urine.

USE IN SPECIAL POPULATIONS

Pediatric Use: Safety and efficacy have not been established. There is a concern for poor clinical outcomes in pediatric patients less than one year of age due to immature renal function.

References:

1. Ruggero MA, et al. Telavancin for refractory methicillin-resistant Staphylococcus aureus bacteremia and infective endocarditis. *Infectious Dis.* 2015; 1 – 6.
2. Barcia-Macay M, et al. Evaluation of the extracellular and intracellular activities (human THP-1 macrophages) of telavancin versus vancomycin against methicillin-susceptible, methicillin-resistant, vancomycin-intermediate and vancomycin-resistant *Staphylococcus aureus. J Antimicrob Chemother*. 2006; 58: 1177-1184.
3. Vibativ® [Package Insert]. Nashville, TN: Cumberland Pharmaceuticals Inc.; November 2023.
4. Gotfried MH, et al. Intrapulmonary distribution of intravenous telavancin in healthy subjects and effect of pulmonary surfactant on in vitro activities of telavancin and other antibiotics. *Antimicrob Agents Chemother.* 2008; 52: 92-97.
5. Rubinstein E, et al. Telavancin versus vancomycin for hospital-acquired pneumonia due to Gram-positive pathogens. *Clin Infect Dis.* 2011; 52(1): 31-40.

**Please see Important Safety Information throughout,
and the accompanying full Prescribing Information, including Boxed Warning.**

CUMBERLAND® PHARMACEUTICALS

POT2300124

Infectious Insights

A Case of Healthcare Associated/ Ventilator Associated Bacterial Pneumonia

A short three-part video series with case study and commentary by Micah A. Jacobs, MD, FACP

2

Infectious Insights is a case series designed to discuss challenges and offer solutions for difficult-to-treat gram-positive bacterial infections. These cases offer real-world examples of the use of telavancin as a treatment for complicated post-surgical infections, infections that involve biofilm-forming bacteria, and hospital-acquired infections.

VIBATIV® (telavancin) is a product of Cumberland Pharmaceuticals. Please see full Important Safety Information including Boxed Warning and full Prescribing Information at the links below.

VIBATIV® (telavancin)
vibativ.com

Important Safety Information
vibativ.com/#importantsafetyinformation

Clinical References
vibativ.com/references

Reference Request
vibativ.com/contact-us

Urgent Response Needed for HABP/VABP

Compounded Problems with HABP/VABP

Cost Benefit of Telavancin

Visit youtube.com/@Infectious_Insights/playlists or scan QR code with your mobile device.

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