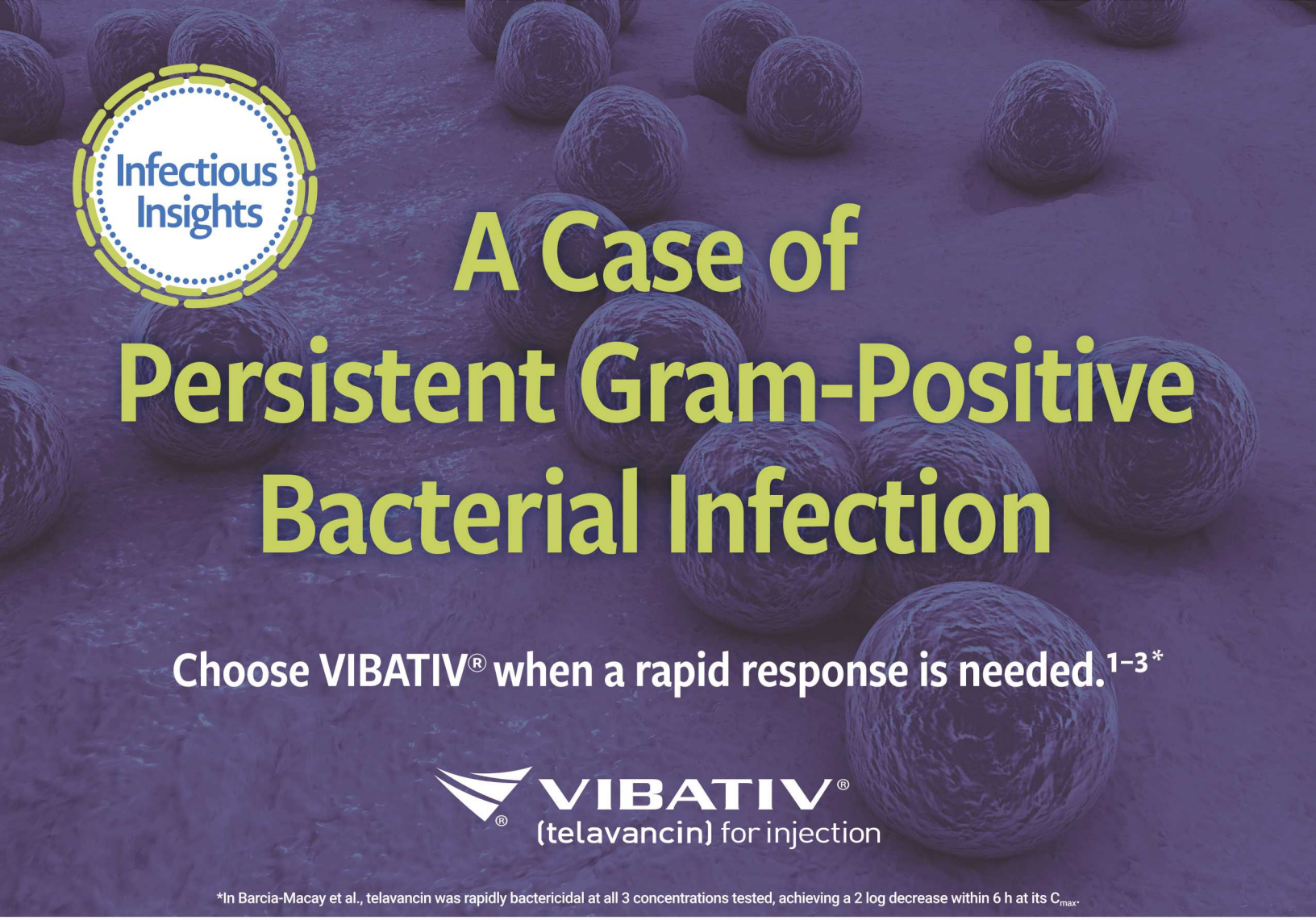

Vibativ® (telavancin) Injection

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.

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.

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

CHARLIE S. | 49 y/o male, 6'1", 105 kg, Financial Banker

(Not an actual patient. For illustration only.)

MEDICAL HISTORY

- History of depression, hypertension, deep vein thrombosis with inferior vena cava filter, and lower extremity non-healing wound.
- NKDA

CURRENT MEDICATIONS

- Duloxetine 30mg daily
- Losartan 100mg daily
- Amlodipine 10mg daily

HISTORY OF PRESENT ILLNESS

- CS admitted to hospital with fever, chills, and swelling of lower extremities.
- Tmax 39.2ºC, BP 165/95, HR 105
- WBC 19,000/mm^3, BUN 18 mg/dL, SCr 0.7 mg/dL
- Ultrasound uncovered thrombosed IVC filter
- Blood cultures obtained
- CS admitted to hospital and started on piperacillin/tazobactam 3.375g IV q6h and vancomycin dosed per hospital protocol.

HOSPITAL COURSE

- Day 2: Bacteremia secondary to non-healing lower extremity was identified.
- Blood cultures grew MRSA with MIC = 1 vancomycin; 0.25 = daptomycin; 0.06 = telavancin
- Piperacillin/tazobactam discontinued and vancomycin continued; blood cultures obtained daily and remained positive for next 7 days.
- Day 9: vancomycin discontinued and daptomycin 10 mg/kg daily; daily blood cultures obtained and remained positive for next 8 days.
- Day 17: daptomycin discontinued and VIBATIV® (telavancin) 10 mg/kg IV daily initiated; daily blood cultures continued.
- On hospital day 20: blood cultures NGTD from cultures drawn on hospital day 18.
- Lower extremity ulcer has improved granulation and epithelialization, no purulence, mild erythema resolving.
- CS defervesced
- WBC 7,500/mm^3, BUN 15 mg/dL, SCr 1.1 mg/dL

CLINICAL COURSE

- CS was successfully treated for 6 weeks with VIBATIV for bacteremia secondary to lower extremity wound with concern for infected endovascular hardware.

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. *Infectious Dis.* 2015;1-6.
2. Barcia-Macay M, et al. *J Antimicrob Chemother.* 2006; 58:1177-1184.
3. Vibativ® [Package Insert]. Nashville, TN: Cumberland Pharmaceuticals; November 2023.

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

CUMBERLAND® PHARMACEUTICALS

POT4300225

Infectious Insights

A Case of Persistent Gram-Positive Bacterial Infection

A short three-part video series with case study and commentary by Andrew Dold, DO

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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

- Importance of Rapid Clearance and Treatment Options
- Treating Obese Patients
- Addressing Biofilm in Endovascular Infections

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

CUMBERLAND® PHARMACEUTICALS

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