VIBATIV®
(telavancin) for injection

DOSING GUIDE

VIBATIV: the *only* once-daily antibiotic indicated for cSSSI and HABP/VABP due to MRSA and MSSA[1]

VIBATIV® (telavancin) Indications

VIBATIV is a lipoglycopeptide antibacterial drug indicated for the treatment of the following infections in adult patients caused by susceptible bacteria:

Complicated Skin and Skin Structure Infections (cSSSIs)

VIBATIV is indicated for the treatment of adult patients with cSSSIs 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 Bacterial Pneumonia/Ventilator-Associated Bacterial Pneumonia (HABP/VABP)

VIBATIV is indicated for the treatment of adult patients with HABP/VABP, caused by susceptable isolates of Staphylococcus aureus (including 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.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN HABP/VABP PATIENTS WITH PRE-EXISTING MODERATE OR SEVERE RENAL IMPAIRMENT, NEPHROTOXICITY, POTENTIAL ADVERSE DEVELOPMENTAL OUTCOMES

- 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 (HABP/VABP) 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 in females of reproductive potential prior to initiating VIBATIV. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with VIBATIV and for 2 days after the final dose.

Please see additional Important Safety Information and usage and accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

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Dosing adjustment for patients with renal impairment

As with vancomycin, patients with renal impairment may require dosage adjustments.[1]

Creatinine clearance* (mL/min)	VIBATIV dose adjustments
>50	10 mg/kg every 24 hours
30-50	7.5 mg/kg every 24 hours
10-<30	10 mg/kg every 48 hours

Monitor renal function (ie, serum creatinine, creatinine clearance) in all patients receiving VIBATIV.
Values should be obtained:

– Prior to initiation of treatment
– During treatment (at 48-72-hour intervals, or more frequently if clinically indicated)
– At the end of therapy

*Calculate using the Cockcroft-Gault formula and ideal body weight (IBW). Use actual body weight if it is less than IBW.

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No therapeutic drug-level monitoring or loading dose needed

Recommended dosing for VIBATIV: 10 mg/kg administered over a 60-minute period in patients ≥18 years of age by intravenous infusion once every 24 hours.[1]

Duration of dosing	
HABP/VABP	7-21 days
cSSSI	7-14 days

- The duration of therapy should be guided by the severity of the infection and the patient's clinical progress

Learn more about the benefits of VIBATIV in patients with cSSSI or HABP/VABP due to *S. aureus*, including MRSA and MSSA

Consider the critical benefits of VIBATIV

		VIBATIV
Proven	Indicated for cSSSI and HABP/VABP due to *S. aureus*, including MRSA and MSSA, and includes data for concurrent *S. aureus* bacteremia in both[1]	✓
Potent *In Vitro*	MIC_{90} values >16X lower than MIC_{90} values for vancomycin and linezolid against both MRSA and MSSA (0.06 µg/mL for both, 100% of pathogens susceptible)[2,3]	✓
	MIC_{90} values >8X lower than daptomycin MIC_{90} against MRSA (0.06 µg/mL, 100% of pathogens susceptible)[3]	✓
Timely	Bactericidal action against *S. aureus*—reduced MRSA CFU/mL by approximately 5 log-units at 6 hours[4]	✓
Bioavailable	Plasma, AM, ELF, and blister fluid levels at least 16X higher than MIC_{90} for *S. aureus* over full dosing period[5,6]	✓
Convenient	Once-daily dosing without therapeutic drug-level monitoring[1]	✓

Please see additional Important Safety Information.

Important Safety Information (Continued from front cover)

Contraindication

Intravenous unfractionated heparin sodium is contraindicated with VIBATIV administration due to artificially prolonged activated partial thromboplastin time (aPTT) test results for up to 18 hours after VIBATIV administration. VIBATIV is contraindicated in patients with a known hypersensitivity to the drug.

Warnings and Precautions

There is decreased efficacy among patients treated for skin and skin structure infections with moderate/severe pre-existing renal impairment. Consider these data when selecting antibacterial therapy for patients with baseline CrCl ≤50 mL/min. Telavancin 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. VIBATIV should be used 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 has been reported and may range from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs. Avoid use in patients at risk for QTc prolongation. Use with caution in patients taking drugs known to prolong the QT interval.

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.

Geriatric Use

Telavancin is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection in this age group.

Most Common Adverse Reactions

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.

Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

Remember the convenient once-daily dosing of VIBATIV

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.

Usage (Continued from front cover)

Combination therapy may be clinically indicated if the documented or presumed pathogens include Gram-negative organisms.

Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative pathogens and to determine their susceptibility to telavancin. VIBATIV may be initiated as empiric therapy before results of these tests are known. To reduce the development of drug-resistant bacteria and maintain the effectiveness of VIBATIV and other antibacterial drugs, VIBATIV should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. 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.

References: 1. VIBATIV® [package insert]. Nashville, TN: Cumberland Pharmaceuticals Inc.; December 2020. **2.** Duncan LR, Smart JI, Flamm RK, Sader HS, Jones RN, Mendes RE. Telavancin activity tested against a collection of Staphylococcus aureus isolates causing pneumonia in hospitalized patients in the United States (2013-2014). *Diagn Microbiol Infect Dis.* 2016;86(3):300-302. 3. Mendes RE, Farrell DJ, Sader HS, Flamm RK, Jones RN. Baseline activity of telavancin against Gram-positive clinical isolates responsible for documented infections in U.S. hospitals (2011-2012) as determined by the revised susceptibility testing method. Antimicrob Agents Chemother. 2015;59:702-706. 4. Data on file. Cumberland Pharmaceuticals Inc. 5. Gotfried MH, Shaw JP, Benton BM, 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. 6. Sun HK, Duchin K, Nightingale CH, Shaw JP, Seroogy J, Nicolau DP. Tissue penetration of telavancin after intravenous administration in healthy subjects. Antimicrob Agents Chemother. 2006;50(2):788-790.

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CUMBERLAND® PHARMACEUTICALS

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