

DOSING GUIDE

VIBATIV: the *only* once-daily antibiotic indicated for cSSSI and HABP/VABP due to MRSA and MSSA¹

Indication

HABP/VABP

VIBATIV[®] is indicated for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of *Staphylococcus aureus* (including methicillin-susceptible and -resistant isolates). VIBATIV should be reserved for use when alternative treatments are not suitable.

cSSSI

VIBATIV is indicated for the treatment of adult patients with 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)

Important Safety Information

Mortality

Patients with pre-existing moderate/severe renal impairment (CrCl \leq 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 \leq 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 occurred in patients who received VIBATIV. Renal adverse events were more likely to occur in patients with baseline comorbidities known to predispose patients to kidney dysfunction and in patients who received concomitant medications known to affect

kidney function. Monitor renal function in all patients receiving VIBATIV prior to initiation of treatment, during treatment, and at the end of therapy. If renal function decreases, the benefit of continuing VIBATIV versus discontinuing and initiating therapy with an alternative agent should be assessed.

Fetal Risk

Women of childbearing potential should have a serum pregnancy test prior to administration of VIBATIV. Avoid use of VIBATIV during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus. Adverse developmental outcomes observed in three animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans. If not already pregnant, women of childbearing potential should use effective contraception during VIBATIV treatment.

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

Dosing adjustment for patients with renal impairment¹

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.

Please see additional Important Safety Information on front and back cover and accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

No therapeutic drug-level monitoring or loading dose needed¹

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 <i>S. aureus</i> , including MRSA and MSSA, and includes data for concurrent <i>S. aureus</i> 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 <i>S. aureus</i> —reduced MRSA CFU/mL by approximately 5 log-units at 6 hours ⁴	✓
Available	Plasma, AM, ELF, and blister fluid levels at least 16X higher than MIC ₉₀ for <i>S. aureus</i> over full dosing period ^{5,6}	✓
Friendly	Patient-friendly once-daily dosing without therapeutic drug-level monitoring ¹	✓

Please see reverse side for 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.

Hypersensitivity Reactions

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.

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.

Infusion Related Reactions

VIBATIV is a lipoglycopeptide antibacterial agent and should be administered over a period of 60 minutes to reduce the risk of infusion-related reactions. Rapid intravenous infusions of the glycopeptide class of antimicrobial agents can cause “Red-man Syndrome” like reactions including: flushing of the upper body, urticaria, pruritus, or rash.

QTc Prolongation

Caution is warranted when prescribing VIBATIV to patients taking drugs known to prolong the QT interval. In a study involving healthy volunteers, VIBATIV prolonged the QTc interval. Use of VIBATIV should be avoided in patients with congenital long QT syndrome, known prolongation of the QTc interval, uncompensated heart failure, or severe left ventricular hypertrophy.

Most Common Adverse Reactions

The most common adverse reactions (greater than or equal to 10% of patients treated with VIBATIV) were diarrhea, taste disturbance, nausea, vomiting, and foamy urine.

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

References: 1. VIBATIV® (telavancin) Prescribing Information. Theravance Biopharma Antibiotics, Inc. May 2016. 2. Duncan LR, Smart JJ, 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. Theravance Biopharma Antibiotics, Inc. 5. Gottfried 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.

Remember the patient-friendly dosing of once-daily VIBATIV¹

Indication (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.

Important Safety Information (Continued from front cover)

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Reference: 1. VIBATIV[®] (telavancin) Prescribing Information. Theravance Biopharma Antibiotics, Inc. May 2016.



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