

## IMPORTANT DRUG WARNING

May 2016

**Subject: Increased Risk of Mortality in Patients with Pre-existing Renal Impairment, Risk of Nephrotoxicity and Risk of Fetal Developmental Toxicity with VIBATIV® (telavancin)**

Dear Health Care Provider:

This letter is to inform you of the serious risks associated with the use of VIBATIV® (telavancin).

VIBATIV is indicated for:

1. 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).
2. 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.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure the benefits of VIBATIV outweigh the risks.

VIBATIV has a **Boxed Warning** that includes the following risks:

### **Increased Mortality in Patients with Pre-existing Renal Impairment**

- Patients with pre-existing moderate/severe renal impairment ( $\text{CrCl} \leq 50 \text{ mL/min}$ ) who were treated with VIBATIV for hospital-acquired and ventilator-associated bacterial pneumonia had increased mortality observed versus vancomycin. Use of VIBATIV in patients with pre-existing moderate/severe renal impairment ( $\text{CrCl} \leq 50 \text{ mL/min}$ ) 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.

### **Risk of Fetal Developmental Toxicity**

- Women of child bearing 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 3 animal species at clinically relevant doses raise concerns about potential adverse developmental outcomes in humans.

### **Reporting Adverse Events**

To report any adverse events with the use of VIBATIV contact:

- Theravance Biopharma at 1-855-633-8479 or by email at [MedInfo@theravance.com](mailto:MedInfo@theravance.com) and/or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

This letter is not intended as a complete description of the benefits and risks associated with the use of VIBATIV. For additional information, including the complete Indication and Warnings & Precautions, please review the enclosed full Prescribing Information.

Sincerely,



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Vice President, Clinical Development and Medical Affairs, Anti-Infectives

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