

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**22-110**

**REMS**

**NDA 22-110 VIBATIV™ (telavancin)**

**[Lipoglycopeptide]**

**Theravance, Inc.  
901 Gateway Boulevard, South San Francisco, CA 94080  
[650-808-6076]**

**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOALS**

The goal of the VIBATIV REMS is to avoid unintended exposure of pregnant women to VIBATIV by:

- Educating healthcare professionals (HCPs) and patients on the potential risk of fetal developmental toxicity if women are exposed to VIBATIV while pregnant.
- Informing HCPs that a serum pregnancy test should be performed before initiating therapy with VIBATIV in women of childbearing potential.
- Informing HCPs that women of childbearing potential, including those being treated in the outpatient setting, should be counseled about pregnancy prevention and use of effective contraception during VIBATIV use.
- Informing HCPs and patients about the Pregnancy Registry for patients exposed to VIBATIV during pregnancy.

**II. REMS ELEMENTS**

**A. Medication Guide**

Theravance will ensure that a Medication Guide will be distributed with each VIBATIV prescription in accordance with 21 CFR 208.24. VIBATIV is packaged as a single unit of use and the Medication Guide is inserted inside the carton.

Additional copies of the Medication Guide will also be available via sales and/or clinical representatives, the product website, and by request at 1-800-727-7003.

Please see appended Medication Guide.

**B. Communication Plan**

In accordance with FDCA 505-1(e)(3), Theravance will implement a communication plan to targeted healthcare providers and pharmacists to support the implementation of the VIBATIV REMS. The communication plan consists of the following:

1. A Dear Healthcare Provider (HCP) Letter describing the fetal effects of VIBATIV seen in animals and pregnancy prevention measures. The letter will include Pregnancy Registry Information. The letter will be accompanied by the VIBATIV Package Insert (PI) and the Medication Guide.
2. The Dear HCP Letter will be distributed to targeted HCPs and pharmacists at the specified timeframes:
  - a. Prior to commercial distribution
  - b. 6 months after product approval
  - c. 1 and 2 years after product approval

3. The Dear HCP Letter will be distributed either through hardcopy mailings by U.S. mail or email to reach the target audience. The letter will also be available on the product website. The website will also include information about the Pregnancy Registry and the toll-free number to call to enroll in the Registry.

The email will target physicians based on the American Medical Association database. The email distribution list for other healthcare providers will be based on other databases and secured through a private contractor.

Providers that have an email address on file will receive the Dear HCP Letter via email. If the intended recipient does not open the Dear HCP Letter within 72 hours, the materials will be distributed hardcopy via U.S. mail. The healthcare providers on the target audience list who do not have an email on file will receive a hardcopy via U.S. mail.

All distributions, hardcopy and electronic will include the designation "Important Drug Warning" according to 21 CFR 200.5.

4. The Dear HCP Letter will be sent to the following targeted Healthcare Providers:

*Physician Groups*

Infectious Disease  
Emergency Medicine  
Critical Care Medicine  
Hospitalist  
General Surgery  
Obstetrics and Gynecology  
Family Practice

*Other Healthcare Professionals*

Health System Pharmacists / Hospital Pharmacists  
Outpatient Infusion Providers

*Organizational Headquarters*

Infectious Disease Society of America  
American College of Emergency Physicians

Society of Critical Care Medicine  
 Society of Hospital Medicine  
 Surgical Infection Society  
 American Thoracic Society (critical care)  
 American College of Chest Physicians (critical care)  
 American College of Obstetrics and Gynecology  
 American Society of Health System Pharmacists  
 Society of Infectious Disease Pharmacists  
 American College of Clinical Pharmacists  
 Outpatient Parenteral Antimicrobial Therapy  
 American Medical Association

The Dear HCP Letter will be distributed with the VIBATIV Package Insert and Medication Guide.

Please see appended Dear HCP Letter.

**C. Elements to Assure Safe Use**

VIBATIV can be approved without any elements to assure safe use.

**D. Implementation System**

VIBATIV can be approved without any elements to assure safe use, therefore an implementation system is not required.

**E. Timetable for Submission of Assessments**

Theravance will submit REMS Assessments at 18 months, 3 years, and 7 years following the approval of the REMS (see table below). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Theravance will submit each assessment so that it will be received by the FDA on or before the due date.

Timetable for Submission of Assessments	
Assessment	Month/Year of Submission
1 <sup>st</sup> Assessment (18 months from approval)	March 2011
2 <sup>nd</sup> Assessment (3 years from approval)	September 2012
3 <sup>rd</sup> Assessment (7 years from approval)	September 2016

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-22110

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ORIG-1

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THERAVANCE INC

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TELAVANCIN

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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EDWARD M COX  
09/11/2009