

IMPORTANT DRUG WARNING

September 11, 2009

Dear Health Care Provider:

The purpose of this letter is to inform you of important safety information for VIBATIV™ (telavancin) for injection, a once-daily intravenous antibiotic 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*)
- *Enterococcus faecalis* (vancomycin-susceptible isolates only)

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

An informational program for healthcare providers has been established to help minimize the risks associated with the use of VIBATIV; the most important relates to the use of the product during pregnancy. Animal data indicate that use of VIBATIV during pregnancy is associated with reduced fetal weights and increased rates of digit and limb malformations in offspring, although these malformations were infrequent.

Women of child bearing potential should have a serum pregnancy test prior to administration of VIBATIV. Patients should be counseled on the risks and benefits of VIBATIV. Consideration should be given to using an alternative course of therapy, if a positive test result is obtained.

The use of VIBATIV should be avoided during pregnancy unless the potential benefit to the patient outweighs the risk to the fetus. Women of childbearing potential (those who have **not** had: complete absence of menses for at least 24 months or medically confirmed menopause, medically confirmed primary ovarian failure, a history of hysterectomy, bilateral oophorectomy, or tubal ligation) should use effective contraception during VIBATIV therapy. Patients should be instructed to notify their prescribing physician/healthcare provider if they become pregnant while taking VIBATIV.

A pregnancy registry has been established to collect information about the effects of VIBATIV use during pregnancy. Physicians are encouraged to register pregnant patients, or pregnant women may enroll themselves in the pregnancy registry by calling 1-888-658-4228.



The VIBATIV Medication Guide should be provided to all patients who receive a course of VIBATIV. The Medication Guide is included in every unit carton of VIBATIV as a tear off attachment to the package insert. Additional copies of the Medication Guide will also be available via sales and/or clinical representatives, the product website and by request through Astellas at 1-800-727-7003. Please refer to the enclosed full prescribing information and Medication Guide.

For additional information, please contact the Medical Information department at 1-800-727-7003, or visit www.vibativ.com.

Sincerely,

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Astellas Pharma US, Inc.