

MEDICATION GUIDE

VIBATIV (vy-'ba-tiv)

(telavancin)

for injection

Read this Medication Guide before you start taking VIBATIV and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about VIBATIV?

VIBATIV may harm your unborn baby. Women who can become pregnant should have a blood pregnancy test before taking VIBATIV.

- Talk to your healthcare provider if you are pregnant or plan to become pregnant. Your healthcare provider will decide if VIBATIV is the right medicine for you
- Do not become pregnant while taking VIBATIV. Women who can become pregnant should use effective birth control (contraception) while taking VIBATIV
- If you get pregnant while taking VIBATIV, tell your healthcare provider right away
- If you become pregnant while taking VIBATIV, talk to your healthcare provider about taking part in the VIBATIV Pregnancy Registry. This is a study to learn how VIBATIV affects pregnancy and babies. You can enroll in this registry by calling 1- 888-658-4228

What is VIBATIV?

VIBATIV is a prescription antibiotic medicine used in adults, alone or with other medicines to treat certain types of germs (bacteria) that cause serious skin infections.

It is not known if VIBATIV is safe or effective in children under 18 years of age.

What should I tell my healthcare provider before taking VIBATIV?

Before you take VIBATIV, tell your healthcare provider if you:

- have kidney problems
- have diabetes
- have heart problems, including QTC prolongation or a family history of it
- have high blood pressure
- have other medical conditions
- are breastfeeding or plan to breastfeed. It is not known if VIBATIV passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking VIBATIV

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. VIBATIV and other medicines can affect each other causing side effects.

Especially tell your healthcare provider if you take:

- a blood thinner
- medicine to control your heart rate or rhythm (antiarrhythmics)
- water pills (diuretics)
- a Non-Steroidal Anti-Inflammatory Drug (NSAID)
- certain blood pressure medicines called ACE Inhibitors or ARBs

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How will I receive VIBATIV?

- VIBATIV is injected into your vein (IV infusion) by your healthcare provider slowly over 1 hour, 1 time a day, for 7 to 14 days.
- Do not stop taking VIBATIV unless your healthcare provider tells you to even if you feel better.
- It is important that you receive **all of your VIBATIV doses**. Do not skip any doses.
- If you miss a dose or stop taking VIBATIV before getting all of your doses, contact your healthcare provider right away.
- If you skip doses or stop treatment too soon, the germs (bacteria) may grow again and VIBATIV may not work.
- Your healthcare provider will do tests before you start and while you take VIBATIV.

What are the possible side effects of VIBATIV?

VIBATIV may cause serious side effects, including:

See **“What is the most important information I should know about VIBATIV?”**

- **Kidney problems**
- **Infusion-related reactions.** Infusion-related reactions can include: red color (flushing) to your upper body, hives (raised bumps), itching or rash if VIBATIV is given too fast
- **Intestine infection.** Intestine infections can cause diarrhea or bloody stools, stomach cramps, and a fever. These infections can happen 2 or more months after you stop taking VIBATIV
- **Irregular heartbeat.**
- **Changes in blood and urine test.** Tell your healthcare provider if you plan to have any test of your blood or urine while taking VIBATIV

Call your healthcare provider right away if you have any of the serious side effects listed above.

The most common side effects of VIBATIV include:

- change in your sense of taste
- nausea
- vomiting
- foamy urine

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of VIBATIV. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store VIBATIV?

- Store VIBATIV in the original package
- Keep VIBATIV refrigerated between 35°F to 46°F (2°C to 8°C)
- Keep out of heat

Keep VIBATIV and all medicines out of the reach of children.

General Information about the safe and effective use of VIBATIV.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIBATIV for a condition for which it is not prescribed. Do not give VIBATIV to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about VIBATIV. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about VIBATIV that is written for health professionals.

For more information, go to www.vibativ.com or call 1-800-727-7003.

What are the ingredients in VIBATIV?

Active ingredient: telavancin hydrochloride

Inactive ingredients: hydroxypropylbetadex, Ph. Eur (hydroxypropyl-beta-cyclodextrin), mannitol, sodium hydroxide, and hydrochloric acid

Manufactured for:

Theravance, Inc.

South San Francisco, CA 94080

Marketed by:

Astellas Pharma US, Inc.

Deerfield, IL 60015

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This Medication Guide has been approved by the U.S. Food and Drug Administration
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