

MEDICATION GUIDE
VIBATIV® (vy-'ba-tiv)
(telavancin)
for injection

Read this Medication Guide before you receive VIBATIV. 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 can cause serious side effects, including:

- **Increased risk of death.** VIBATIV was associated with an increased risk of death compared to vancomycin in people who already had kidney problems and were treated for bacterial pneumonia that you can get when you are in the hospital.
- **New or worsening kidney problems.** Your healthcare provider should do a blood test to check your kidneys before you start, while you receive, and after you stop receiving VIBATIV.
- **VIBATIV may harm your unborn baby. Women who can become pregnant should have a blood pregnancy test before receiving 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.
 - Women who can become pregnant should use effective birth control (contraception) while receiving VIBATIV.
 - If you become pregnant while receiving VIBATIV, tell your healthcare provider right away. 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 1-855-633-8479.

What is VIBATIV?

VIBATIV is a prescription antibacterial medicine used alone, or with other medicines, to treat adults with certain types of germs (bacteria) that cause:

- Serious skin infections
- Hospital-Acquired Bacterial Pneumonia (HABP)
- Ventilator-Associated Bacterial Pneumonia (VABP)

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

Who should not take VIBATIV?

Do not take VIBATIV if you:

- are allergic to telavancin or any of the ingredients in VIBATIV. See the end of this Medication Guide for a complete list of ingredients in VIBATIV.

What should I tell my healthcare provider before receiving VIBATIV?

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

- have had a serious allergic reaction to VIBATIV or vancomycin
- have kidney problems
- have diabetes
- have or have had heart problems, including QTc prolongation or a family history of it
- have high blood pressure
- have any other medical conditions
- are breastfeeding or plan to breastfeed. It is not known if VIBATIV passes into breast milk. You and your healthcare provider should decide if you will breastfeed while receiving 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 Non-Steroidal Anti-Inflammatory Drug (NSAID)
- certain blood pressure medicines called ACE Inhibitors or ARBs
- water pills (diuretics)
- a blood thinner
- medicine to control your heart rate or rhythm (antiarrhythmics)

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 given by your healthcare provider through a needle placed into your vein (IV infusion) slowly over 1 hour, 1 time each day, for 7 to 21 days.
- **Do not** stop receiving VIBATIV unless your healthcare provider tells you to, even if you feel better.
- Your healthcare provider will do blood tests before you start and while you receive 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?”

- **Serious allergic reactions.** Allergic reactions can happen in people who take VIBATIV, even after only one dose. Stop taking VIBATIV and get emergency medical help right away if you get any of the following symptoms of a severe allergic reaction:
 - hives
 - trouble breathing or swallowing
 - swelling of the lips, tongue, face
 - throat tightness, hoarseness
 - rapid heartbeat
 - faint
- **Infusion-related reactions.** People who receive VIBATIV too quickly can have a certain type of skin reaction called “Red-man Syndrome”. Signs and symptoms of Red-man Syndrome can include:
 - red color (flushing)
 - rash
 - itching
- **Problems with the electrical system of your heart (QTc prolongation).** Tell your healthcare provider right away if you have a change in your heartbeat such as a fast or irregular heartbeat or if you had a fainting episode.

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
- diarrhea

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 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.

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 1-855-633-8479.

What are the ingredients in VIBATIV?

Active ingredient: telavancin hydrochloride

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

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

Manufactured by:

Theravance Biopharma Antibiotics, Inc.

Marketed by:

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