



VEMLIDY® (tenofovir alafenamide)

What are the possible side effects of VEMILIDY?

This information is provided in response to your question. It is not treatment advice on how to use VEMILIDY. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the **VEMLIDY Patient Information** for more details, including approved use(s) and important warnings. https://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.pdf

The short answer¹

The **most common side effect** of VEMILIDY during clinical trials was **headache**. This side effect happened in 12% of people in the study which is 12 in every 100 people.

VEMLIDY may cause **serious side effects** such as:



Worsening of hepatitis B virus infection, also called HBV. Your HBV infection may get worse or flare up if you take VEMILIDY and suddenly stop taking it.



Kidney problems, including kidney failure.



Too much lactic acid in your blood; this is a rare but serious side effect that can lead to death.



In rare cases, **severe liver problems** that can lead to death.

These are not all the possible side effects of VEMILIDY. Please tell your healthcare provider if you have any side effects.

What is the most important information I should know about VEMLIDY?¹

Some medications have important warnings that are designed to alert you of serious or life-threatening risks that come with taking the medication.

VEMLIDY has an important warning for: Worsening of hepatitis B virus (HBV) infection. Your HBV infection may get worse (flare-up) if you take VEMLIDY and then stop taking it. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

- Do not run out of VEMLIDY. Refill your prescription or talk to your healthcare provider before your VEMLIDY is all gone.
- Do not stop taking VEMLIDY without first talking to your healthcare provider.
- If you stop taking VEMLIDY, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking VEMLIDY.

Who is VEMLIDY for?¹

VEMLIDY is a prescription medicine used to treat **chronic (long-lasting) HBV in adults and children 6 years of age and older** who weigh **at least 55 pounds (25 kg)** with stable (compensated) liver disease.

- VEMLIDY may lower the amount of HBV in your body.
- VEMLIDY may improve the condition of your liver.
- It is not known if VEMLIDY is safe and effective in children with chronic HBV infection who are under 6 years of age or weigh less than 55 pounds (25 kg).

What are the common side effects?¹

- The most **common side effect** of VEMLIDY in clinical studies was **headache**. This side effect happened in 12% of people in the study which is 12 in every 100 people.

- There were other common side effects – stomach pain, cough, back pain, feeling tired, nausea, joint pain, diarrhea, indigestion – but they happened in fewer people (9 out of 100 people or fewer).

What are the serious side effects?¹

VEMLIDY may cause **serious side effects** such as:



- **Worsening of hepatitis B virus (HBV) infection if you stop taking VEMLIDY.** Your HBV may flare up if you take VEMLIDY and then stop taking it. A “flare-up” is when your HBV suddenly returns in a worse way than before.

Do not run out of VEMLIDY. Refill your prescription or talk to your healthcare provider before your VEMLIDY runs out.

Do not stop taking VEMLIDY without first talking to your healthcare provider. Your healthcare provider will need to check your health regularly after you stop taking VEMLIDY.



- **New or worsening kidney problems**, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys when starting and during treatment with VEMLIDY. Your healthcare provider may tell you to stop taking VEMLIDY if you develop new or worsening kidney problems.



- **Too much lactic acid** in your blood, also called lactic acidosis. This is a rare but serious medical emergency that can lead to death. **Tell your healthcare provider right away if you get these symptoms:**
 - Weakness or being more tired than usual
 - Unusual muscle pain
 - Shortness of breath or fast breathing
 - Stomach pain with nausea and vomiting
 - Cold or blue hands and feet
 - Dizziness or lightheadedness

- Fast or abnormal heartbeat



- **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. **Tell your healthcare provider right away if you get these symptoms:**
 - Skin or the white part of the eyes turns yellow
 - Dark “tea-colored” pee
 - Light-colored stools
 - Loss of appetite for several days or longer
 - Feeling sick to your stomach
 - Pain in and around your stomach

These are not all of the possible side effects of VEMLIDY.

Contact your healthcare provider right away if you are concerned about any symptoms you are experiencing or if you think that you might have any of these side effects.

What should I tell my healthcare provider before taking VEMLIDY?¹

Before taking VEMLIDY, tell your healthcare provider about all your medical conditions, including if you:

- **have human immunodeficiency virus-1 (HIV-1) infection.** Your healthcare provider may test you for HIV-1 infection before you start VEMLIDY. If you have both HBV and HIV-1, and you only take VEMLIDY, the HIV-1 virus may develop resistance and become harder to treat.
- **have end-stage renal disease (ESRD).**
- **are pregnant or plan to become pregnant.** It is not known if VEMLIDY will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with VEMLIDY.

What should I tell my healthcare provider if I am pregnant?¹



Pregnancy Registry: There is a pregnancy registry for women who take VEMLIDY during pregnancy. This registry collects information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

- Talk to your healthcare provider if you are breastfeeding or plan to breastfeed. VEMLIDY may pass into your breastmilk. Talk with your healthcare provider about the best way to feed your baby.

What should I tell my healthcare provider about the medicines I take before taking VEMLIDY?¹

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Some medicines may affect how VEMLIDY works. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.
- You can ask your healthcare provider or pharmacist for a list of medicines that interact with VEMLIDY.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take VEMLIDY with other medicines.

Glossary

Chronic: long-term; continuing for a long time, ongoing.

Clinical trial: a study in people. It may help to find how well a medicine works and how safe it is.

Compensated liver disease: means the liver is damaged but still working well enough to perform its essential functions.

Diarrhea: frequent, loose watery stools, which can cause dehydration and may require hospitalization and treatment with intravenous fluids.

FDA (Food and Drug Administration): is a government agency responsible for ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

Hepatitis B Virus (HBV): a type of virus (HBV) that can cause serious liver infection.

Human Immunodeficiency Virus (HIV): HIV is a virus that attacks the body's immune system. If HIV is not treated, it can lead to AIDS.

Hives: are red, itchy bumps or raised patches that appear on the skin.

Lactic acid: is a natural substance your body makes when it turns sugar into energy, especially during exercise.

Nausea: feeling sick to the stomach; stomach discomfort and the sensation of wanting to vomit.

Resistance: when a disease or infection has "resistance" to a medication, it means that the medication does not work well to fight the infection anymore.

Supplements: products people take to add extra nutrients to their diet, like vitamins, minerals, or other helpful substances.

Reference

1. Enclosed. Gilead Sciences Inc, VEMLIDY® (tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.

More information about VEMLIDY

If you would like more detailed information about VEMLIDY, please visit:

https://www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.pdf.

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for VEMLIDY. It will tell you about the uses, warnings, and other important safety information about VEMLIDY.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for VEMLIDY. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of VEMLIDY in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 <https://www.patient.askgileadmedical.com/>

Reporting side effects

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 www.accessdata.fda.gov/scripts/medwatch

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