



BIKTARVY[®] (bictegravir, emtricitabine, and tenofovir alafenamide)

What are the possible side effects of BIKTARVY?

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

Download the **BIKTARVY Patient Information** for more details, including approved use(s) and important warnings: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_patient_pi.pdf

The short answer

The most common side effects of BIKTARVY during clinical trials were diarrhea, nausea, and headache. Each of these side effects affected at least 5 out of 100 people.

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



Worsening of hepatitis B virus, also called HBV. If you have HBV and take BIKTARVY, your HBV may get worse if you suddenly stop taking BIKTARVY.



Changes in your immune system, or immune reconstitution syndrome, can happen when you start taking HIV-1 medicines.



Kidney problems, including kidney failure.



Too much lactic acid in your blood, also called lactic acidosis; 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 BIKTARVY. Please tell your healthcare provider if you have any side effects.

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

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

BIKTARVY has an important warning for: Worsening of hepatitis B virus (HBV).

Your healthcare provider will test you for HBV before or when you start treatment with BIKTARVY. If you have HBV and take BIKTARVY, your HBV may get worse (flare-up) if you stop taking BIKTARVY. A “flare-up” is when your HBV suddenly returns in a worse way than before.

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

Who is BIKTARVY for?

BIKTARVY is a prescription medicine that is used without other human immunodeficiency virus-1 (HIV-1) medicines to treat HIV-1 in adults and children who weigh at least 31 pounds (14 kg):

- who have not received HIV-1 medicines in the past, or
- who have received HIV-1 medicines in the past, or to replace their current HIV-1 medicines, and whose healthcare provider determines that they meet certain requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

It is not known if BIKTARVY is safe and effective in children who weigh less than 31 pounds (14 kg).

What are the common side effects?

The most **common side effects** of BIKTARVY in clinical trials were **diarrhea, nausea, and headache**. Each of these side effects happened in at least 5 out of 100 adults.

BIKTARVY caused other side effects that happened in 4 out of 100 people or fewer. These side effects were:

- | | |
|-------------------------------------|----------------|
| o Tiredness | o Vomiting |
| o Strange dreams | o Flatulence |
| o Feeling dizzy | o Indigestion |
| o Trouble staying or falling asleep | o Stomach pain |
| o Bloating | o Rash |
| | o Depression |

In clinical trials, very few people stopped taking BIKTARVY because of these side effects.

Nearly 9 out of 10 of the side effects in clinical trials caused by BIKTARVY were mild.

What are the rare side effects?

Suicidal thoughts, attempted suicide, or suicidal depression happened in 2 out of 100 adults.

- Most of these patients had a history of depression, attempted suicide, or psychiatric illness before taking BIKTARVY.

If you experience this, call your healthcare provider right away.

What are the serious side effects?

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



- **Worsening of hepatitis B virus (HBV).** Your healthcare provider will test you for HBV before or when you start treatment with BIKTARVY. If you have HBV and take BIKTARVY, your HBV may get worse (flare-up) if you stop taking BIKTARVY. A “flare-up” is when your HBV suddenly returns in a worse way than before.



- **Changes in your immune system**, or immune reconstitution syndrome, can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you have any new symptoms after starting your HIV-1 medicine.



- **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 BIKTARVY. Your healthcare provider may tell you to stop taking BIKTARVY 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, also known as nausea
 - Pain in and around your stomach

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

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 are the side effects in children?

BIKTARVY can be used to treat children with HIV-1 who weigh at least 31 pounds (14 kg).

In clinical trials, about 11 out of 100 children who took BIKTARVY had side effects. The only side effect reported by more than one child was stomach discomfort. The types of side effects in children were similar to those experienced by adults and most were mild.

Where can I get more information on the side effects of BIKTARVY?

Before a medicine is approved by the US Food and Drug Administration or FDA, researchers do clinical trials in groups of patients to see if the medicine works and how safe it is. Clinical trials are carried out in hospitals and clinics, and only some patients are eligible to take part. This means that the side effects seen in clinical trials may not be exactly the same as the side effects that people experience in the “real world”.

Clinical trials give us a very good idea of the most common or serious side effects that a medicine causes. However, they may not find all of the side effects that a medicine can cause.

Please talk to your healthcare provider if you have a side effect that is bothering you or that is not going away.

What were the side effects observed after the BIKTARVY clinical trials?

After a medicine is approved by the FDA, information on the side effects that the medicine causes in the “real world” is collected. Because of the way this information is collected, it is not always possible to know for sure how common these side effects are, or if they are caused by the medicine.

Since BIKTARVY was approved, some people have reported having kidney disorders, swelling under the skin, hives, a serious skin reaction that causes painful rashes, blisters, and sores of the skin and mucous membranes, especially in the mouth, and weight increased after taking BIKTARVY.

Glossary

AIDS (Acquired Immunodeficiency Syndrome): most advanced stage of HIV.

Clinical trial: a study in people. They may help to find out how well a medicine works or how safe it is.

Depression: a feeling of sadness and loss of interest.

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.

Flatulence: Commonly known as farting, passing wind, or having gas, flatulence is a medical term for releasing gas from the digestive system through the anus.

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

HIV (Human Immunodeficiency Virus): 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.

Immune system: is your body's defense team. It protects you from germs like bacteria and viruses that can make you sick.

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.

Psychiatric illness: is a condition that affects how a person thinks, feels, or behaves, making it hard to cope with daily life. It is like when your mind is not feeling well, just like your body can get sick. Examples include depression, anxiety, or conditions like schizophrenia.

Rash: an area of irritated or swollen skin.

References

1. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. US Prescribing Information. Foster City, CA.

More information about BIKTARVY

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

https://www.gilead.com/~media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.pdf

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

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 BIKTARVY. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of BIKTARVY 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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