GILEAD | Medical Information

BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide)

Can you give me general information regarding 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

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.

Stay under a healthcare provider's care during treatment with BIKTARVY.

BIKTARVY is **taken one time each day**, any time of day, with or without food, as directed by your healthcare provider.

Do not miss doses or stop taking BIKTARVY without talking first with your healthcare provider. Make sure to refill your prescription before you run out.

- **Dofetilide**, a drug used to support a normal heartbeat in people who have an irregular heartbeat.
- **Rifampin**, also known as rifampicin, an antibiotic used to treat or prevent tuberculosis.

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

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.

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 should I tell my healthcare provider before taking BIKTARVY?

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

- have liver problems, including HBV
- have kidney problems
- are pregnant or plan to become pregnant. Tell your healthcare provider if you become pregnant during treatment with BIKTARVY.

Pregnancy Registry: There is a pregnancy registry for those who take BIKTARVY during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. BIKTARVY passes to your baby in your breastmilk. Talk to your healthcare provider about the following risks to your baby from breastfeeding during treatment with BIKTARVY:
    - the HIV-1 virus may pass to your baby if your baby does not have HIV-1.
    - the HIV-1 virus may become harder to treat if your baby has HIV-1.
    - your baby may get side effects from BIKTARVY.

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

Some medicines may interact with BIKTARVY. 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 BIKTARVY.
- **Do not start a new medicine without telling your healthcare provider**. Your healthcare provider can tell you if it is safe to take BIKTARVY with other medicines.

How should I take BIKTARVY?

Take BIKTARVY exactly as your healthcare provider tells you to take it. BIKTARVY is taken by itself (not with other HIV-1 medicines) to treat HIV-1.

- **Take one BIKTARVY tablet once a day, as directed by your healthcare provider.** It can be taken with or without food, any time of day.
- For **children** unable to swallow a whole tablet, the tablet can be split and each part taken separately as long as all parts are swallowed within about 10 minutes.
- If you are on **dialysis**, take your daily dose of BIKTARVY following dialysis.
- If you take antacids that contain **aluminum** or **magnesium**, take BIKTARVY **at least 2 hours before** or **6 hours after** you take these antacids.
- If you take supplements or antacids that contain **iron** or **calcium**, take BIKTARVY **with food at the same time** that you take these supplements or antacids.
- If you are **pregnant** and take supplements or antacids that contain **aluminum**, **magnesium**, **iron**, or **calcium**, talk to your healthcare provider about how to take BIKTARVY along with these supplements or antacids.

Do not change your dose or stop taking BIKTARVY without first talking to your healthcare provider. Stay under a healthcare provider's care during treatment with BIKTARVY.

Do not miss a dose of BIKTARVY. Make sure to refill your prescription before you run out.

When your BIKTARVY supply starts to run low, get more from your healthcare provider or pharmacy. **This is very important** because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to BIKTARVY and become harder to treat. Resistance means a virus has mutated or changed in a way that might make some medicines not work as well.

If you take too much BIKTARVY, call your healthcare provider or go to the nearest hospital emergency room right away.

Do not take BIKTARVY if you also take a medication that contains**:**

- **Dofetilide**, a drug used to support a normal heartbeat in people who have an irregular heartbeat.
- **Rifampin**, also known as rifampicin, an antibiotic used to treat or prevent tuberculosis.

What are the side effects of BIKTARVY?

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 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 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 ingredients in BIKTARVY?

- One tablet contains three HIV medicines or **active ingredients**: bictegravir, emtricitabine, and tenofovir alafenamide.
- The tablet also contains other **inactive ingredients**: croscarmellose sodium, magnesium stearate, and microcrystalline cellulose. The tablet is film-coated with a coating material containing iron oxide black, iron oxide red, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Glossary

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

Dialysis: is a medical treatment that helps filter the and removes waste, extra fluid, and toxins from the blood when the kidneys are not working properly.

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

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

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.

Resistance: sometimes a virus can mutate or change. This change might make some medicines not work as well.

References

Approved for Use on 30 Jul 2025

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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