



# BIKTARVY<sup>®</sup> (bictegravir, emtricitabine, and tenofovir alafenamide)

## How do I take 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](https://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_patient_pi.pdf)

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## The short answer

**How to 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.

BIKTARVY is taken as one pill once a day, every day, as directed by your doctor. It can be taken with or without food, at any time of day.

**Missed dose:** Do not miss a dose of BIKTARVY. Make sure to refill your prescription before you run out. If you stop taking BIKTARVY, even for a short time, the amount of virus in your blood may increase. In that case, 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.

**Taking with other medications:** Do not take BIKTARVY if you also take a medication that contains dofetilide or rifampin, also known as rifampicin.

If you take antacids that contain aluminum or magnesium, or antacids or supplements that contain iron or calcium, you will need to follow special instructions for how to take BIKTARVY. These instructions can be found within this document.

Before starting BIKTARVY, please tell your doctor about all prescription and over-the-counter medications, antacids, laxatives, vitamins, herbal products, and dietary supplements that you take. Some medications may interact with BIKTARVY

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## 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.

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## 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).

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## What should I know before taking BIKTARVY?

**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.

**Please tell your healthcare provider about all medications and dietary supplements** that you take, including prescription and over-the-counter medicines, antacids, laxatives, vitamins, and herbal supplements.

- Some medications 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 these medications.
- 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.

**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.**



- 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.



**Pregnancy Registry: There is a pregnancy registry for women who take BIKTARVY 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.**

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## How should I take BIKTARVY?



You should take one pill by mouth once a day, every day, as directed by your doctor. It can be taken with or without food, at any time of day.

**BIKTARVY is a prescription medication** used to treat HIV-1 in adults and children who weigh at least 31 pounds. It is taken by itself without any other HIV-1 medications.

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## Are there any other instructions I should follow?

Prescribing Information states the following on how to take BIKTARVY:



It can be taken with or without food. Please see below for instructions about when BIKTARVY has to be taken with food.

- 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.



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.



**DO NOT MISS A DOSE OF BIKTARVY.** If you stop taking BIKTARVY, even for a short time, the amount of virus in your blood may increase. In that case, 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



Do not run out of BIKTARVY. Refill your prescription or talk to your doctor before your BIKTARVY is all gone.



Do not change your dose or stop taking BIKTARVY without speaking to your doctor first.



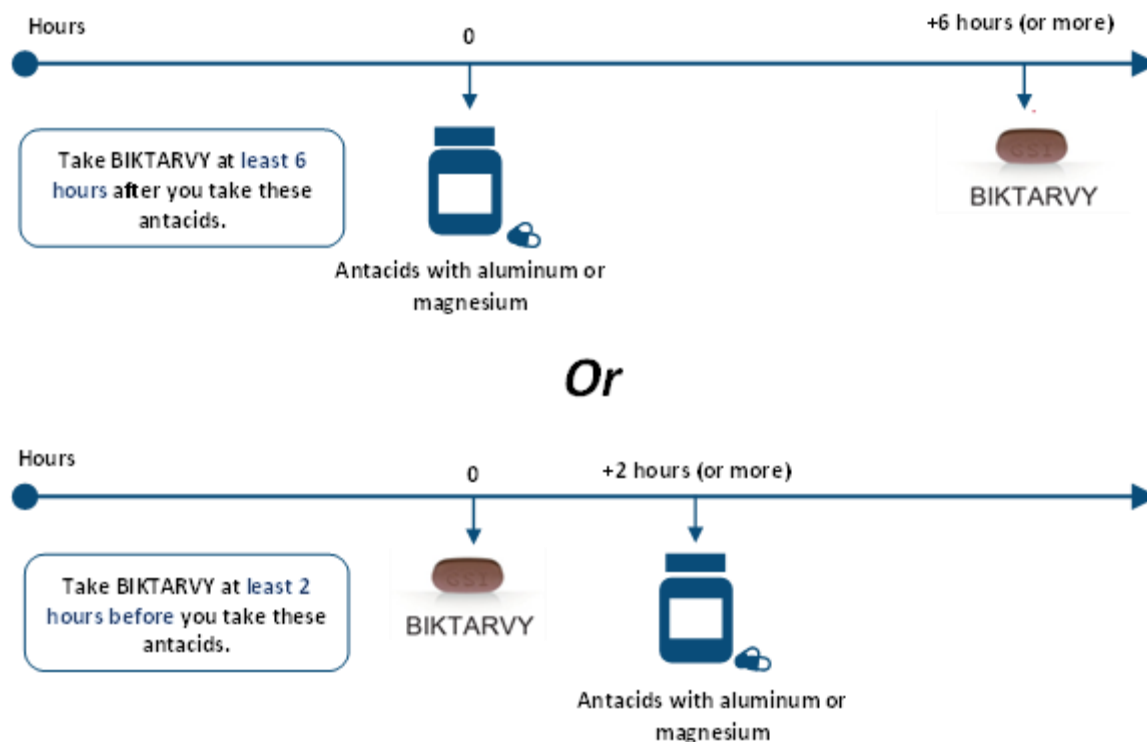
It is important to keep seeing your doctor while you are taking BIKTARVY.



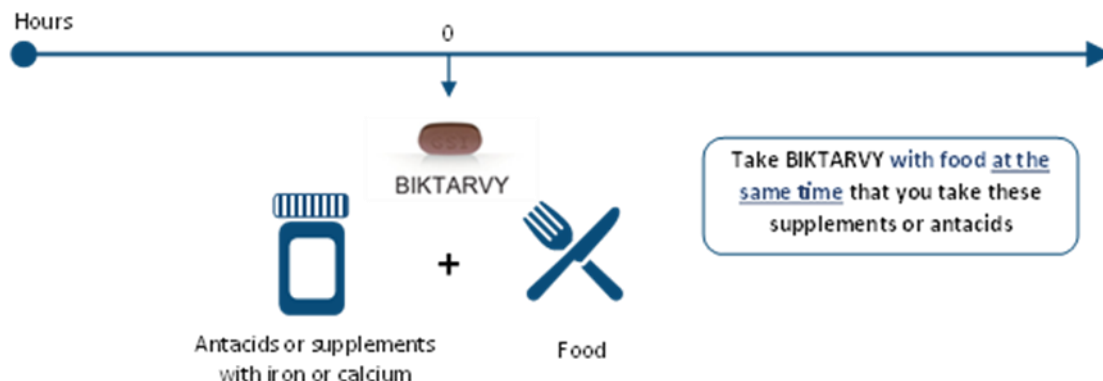
If you take too much BIKTARVY, call your doctor or go to the nearest hospital emergency room right away.

## What should I know if I take supplements or antacids while taking BIKTARVY?

If you take supplements or antacids that contain aluminum or magnesium:



## If you take supplements or antacids that contain iron or calcium:



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## Glossary

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

**Antacid:** is a medicine that helps reduce the acid in your stomach.

**Dialysis:** is a medical treatment that helps do the job of the kidneys when they are not working properly. Kidneys remove waste, extra fluid, and toxins from the blood, but when they fail, dialysis helps by filtering the blood and removing these substances.

**HBV (hepatitis B virus):** HBV is an illness caused by the hepatitis B virus. It affects the liver and can make it swollen and damaged. People can get it through contact with infected blood, unprotected sex, or from an infected mother to her baby at birth. Some people recover from it on their own, while others can have long-term liver problems if not treated.

**HIV-1 (Human Immunodeficiency Virus type 1):** is a virus that attacks the body's immune system. If this is not treated, it can lead to AIDS (acquired immunodeficiency syndrome).

**Interact:** when two or more drugs react together and possibly cause a side effect.

**Laxative:** is a type of medicine or food that helps you pass stool when you are constipated.

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**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.

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

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## References

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



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## 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](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](http://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](http://www.accessdata.fda.gov/scripts/medwatch)

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