



# Biktarvy

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## WHAT IS BIKTARVY?

Biktarvy is a complete HIV regimen used as part of [antiretroviral therapy \(ART\)](#). Biktarvy contains three [antiretroviral drugs \(ARVs\)](#) combined in one tablet:

- bicitgravir
- [emtricitabine \(FTC, Emtriva\)](#)
- tenofovir alafenamide fumarate (tenofovir AF, TAF, Vemlidy)

The FDA approved Biktarvy in 2018 as an ARV for people with HIV infection. Biktarvy is manufactured by [Gilead Sciences](#).

One of the drugs in Biktarvy, bicitgravir, is a type of drug called an [integrase inhibitor](#). Integrase inhibitors block integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of host CD4 cells. Blocking integrase prevents HIV from replicating. The other two drugs, emtricitabine and tenofovir AF, are [nucleoside reverse transcriptase inhibitors \(NRTIs\)](#). NRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used alone as a complete regimen to treat HIV infection, Biktarvy may help:

- Reduce the amount of HIV in your blood. This is called [viral load](#).
- Increase the number of [CD4 cells](#) in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting [opportunistic infections \(OIs\)](#) that can happen when your immune system is weak. [Read more about viral suppression](#).

Biktarvy does not cure HIV infection or [AIDS](#). You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

## WHO SHOULD TAKE BIKTARVY?

Biktarvy is a prescription three-drug fixed-dose combination medication to treat HIV infection in adults and children who weigh at least 55 pounds (25 kg):

- who have not received HIV medicines in the past
- OR**
- to replace their current HIV medicines when their healthcare provider determines that they meet certain requirements.

The safety and effectiveness of Biktarvy has not been established in children weighing less than 55 pounds (25 kg). Biktarvy has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. [Read more about U.S. ART guidelines](#).

Biktarvy provides three drugs in one pill. It can be more convenient to use Biktarvy than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Biktarvy is used as a complete regimen for the treatment of HIV infection.**

## WHO SHOULD NOT TAKE BIKTARVY?

Do not take Biktarvy if you are allergic to bicitgravir, emtricitabine, tenofovir AF, or any of the ingredients in this drug.

Do not take Biktarvy if you are taking any of the following medicines. Taking Biktarvy with these medicines may affect how Biktarvy works. Biktarvy may cause serious or life-threatening side effects or death when used with these medicines:

- [Tuberculosis \(TB\)](#) medicine: rifampin
- Heart medicine: dofetilide

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any

of these medicines in the past 4 weeks, talk to your healthcare provider or pharmacist before starting treatment with Biktarvy.

Biktarvy is not recommended in people with moderate to severe kidney or liver disease.

### **WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING BIKTARVY?**

Before you take Biktarvy, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have liver problems, including [hepatitis B virus \(HBV\)](#) infection
- Have [kidney problems](#)

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with Biktarvy. It is not known if Biktarvy can harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. [Read more about pregnancy and HIV.](#)

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Biktarvy. At least one of the medicines in Biktarvy can pass to your baby in your breastmilk. It is not known if the other medicines in Biktarvy can pass into your breastmilk. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

### **WHAT ABOUT DRUG RESISTANCE?**

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. [Read more about HIV drug resistance.](#)

***Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.***

### **HOW IS BIKTARVY TAKEN?**

Biktarvy is taken by mouth as a tablet. Each Biktarvy tablet contains 50 mg of bicitgravir, 200 mg of emtricitabine, and 25 mg of tenofovir AF. The recommended dosage of Biktarvy for adults and children weighing at least 55 pounds (25 kg) is one tablet once daily.

You should take Biktarvy at the same time each day with or without food. 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.

### **WHAT ARE THE SIDE EFFECTS?**

When you start any ARV, you may have temporary [side effects](#) such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Biktarvy are [diarrhea](#), nausea, and headaches.

Some patients may experience weight gain, particularly in the first year of use. This appears to be part of a broader trend seen with INSTI- and TAF-based regimens.

Biktarvy can cause serious side effects including:

**Worsening of HBV infection.** Your healthcare provider will test you for HBV before starting treatment with Biktarvy. If you have HBV infection and take Biktarvy, your HBV may get worse (flareup) if you stop taking Biktarvy. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not stop taking Biktarvy without first talking to your healthcare provider. Do not run out of Biktarvy. Refill your prescription or talk to your healthcare provider before your Biktarvy is all gone. 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 HBV infection, or give you a medication to treat HBV. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking Biktarvy.

**Immune Reconstitution Inflammatory Syndrome (IRIS).** [IRIS](#) is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting treatment with Biktarvy.

**New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with Biktarvy. Your healthcare provider may tell you to stop taking

Biktarvy if you develop new or worse kidney problems during treatment with Biktarvy.

**Too much lactic acid in your blood (lactic acidosis).** [Lactic acidosis](#) is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- Weakness or being more tired than usual
- Being short of breath or fast breathing
- Cold or blue hands and feet
- Fast or abnormal heartbeat
- Unusual muscle pain
- Stomach pain with nausea and vomiting
- Feel dizzy or lightheaded

**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 your eyes turns yellow
- Dark or “tea-colored” urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea or vomiting
- Stomach-area pain

These are not all the possible side effects of Biktarvy. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **HOW DOES BIKTARVY REACT WITH OTHER DRUGS?**

All ARVs can [interact](#) with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Biktarvy with other medicines.

See above for a list of medicines that should not be taken with Biktarvy.

Biktarvy is a complete regimen for the treatment of HIV infection; therefore, taking Biktarvy with other ARVs for the treatment of HIV infection is not recommended.

#### **MORE INFORMATION**

Visit the [Biktarvy website](#).

Visit the [Biktarvy healthcare professional website](#).

Download the full [Prescribing Information](#).

Download the [Patient Information](#) leaflet.

Apply for the [Gilead Advancing Access Program](#).

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