

Patient Information
BIKTARVY® (bik-TAR-vee)
(bictegravir, emtricitabine,
and tenofovir alafenamide)
tablets

Important: Ask your healthcare provider or pharmacist about medicines that should not be taken with BIKTARVY. For more information, see “What should I tell my healthcare provider before taking BIKTARVY?”

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

BIKTARVY can cause serious side effects, including:

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

For more information about side effects, see “What are the possible side effects of BIKTARVY?”

What is BIKTARVY?

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

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

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

BIKTARVY contains the medicines bictegravir, emtricitabine, and tenofovir alafenamide.

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

Do not take BIKTARVY if you also take a medicine that contains:

- dofetilide
- rifampin

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 infection
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if BIKTARVY can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with BIKTARVY.

Pregnancy Registry: There is a pregnancy registry for women 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. Do not breastfeed if you take BIKTARVY.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - At least one of the medicines in BIKTARVY can pass to your baby in your breast milk. It is not known if the other medicines in BIKTARVY can pass into your breast milk.

Talk with your healthcare provider about the best way to feed your baby.

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 infection.
- Take BIKTARVY 1 time each day with or without food.
- 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 change your dose or stop taking BIKTARVY without first talking with your healthcare provider. Stay under a healthcare provider's care during treatment with BIKTARVY.
- 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.
- Do not miss a dose of BIKTARVY.
- If you take too much BIKTARVY, call your healthcare provider or go to the nearest hospital emergency room right away.
- 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.

What are the possible side effects of BIKTARVY?

BIKTARVY may cause serious side effects, including:

- **See “What is the most important information I should know about BIKTARVY?”**
- **Changes in your immune system (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 start having any new symptoms after starting your HIV-1 medicine.
- **New or worse 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 worse kidney problems.
- **Too much lactic acid in your blood (lactic acidosis).** Too much lactic acid is a serious but rare 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, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a 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 your eyes turns yellow, dark “tea-colored” urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.

The most common side effects of BIKTARVY are diarrhea, nausea, and headache.

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BIKTARVY?

- Store BIKTARVY bottle below 86 °F (30 °C).
- Keep the bottle tightly closed.
- BIKTARVY contains a desiccant packet to help keep your medicine dry (protect it from moisture). Keep the desiccant packet in the bottle. **Do not eat the desiccant packet.**
- Store BIKTARVY blister pack at room temperature between 68 °F to 77 °F (20 °C to 25 °C).
- Keep BIKTARVY in its original bottle or blister pack.
- BIKTARVY comes in a child-resistant package.

Keep BIKTARVY and all medicines out of reach of children.

General information about the safe and effective use of BIKTARVY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use BIKTARVY for a condition for which it was not prescribed. Do not give BIKTARVY to other people, even if they have the

same symptoms you have. It may harm them. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about BIKTARVY that is written for health professionals.

What are the ingredients in BIKTARVY?

Active ingredients: bictegravir, emtricitabine, and tenofovir alafenamide.

Inactive ingredients: croscarmellose sodium, magnesium stearate, and microcrystalline cellulose.

The tablets are film-coated with a coating material containing iron oxide black, iron oxide red, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Manufactured and distributed by: Gilead Sciences, Inc. Foster City, CA 94404

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For more information, call 1-800-445-3235 or go to www.BIKTARVY.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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