



Biktarvy (bictegravir + emtricitabine + tenofovir alafenamide)

WHAT IS BIKTARVY?

Biktarvy is a single-tablet regimen that contains three antiretroviral drugs (ARVs) used to treat HIV: bictegravir (GS-9883, or BIC); emtricitabine (Emtriva; see Fact Sheet 420); and tenofovir alafenamide (TAF). Biktarvy is the first approved medication that contains bictegravir, and the fourth single-pill regimen that includes TAF, a new version of tenofovir that has lower bone and kidney risks than tenofovir disoproxil fumarate (Viread; see Fact Sheet 419). Biktarvy is manufactured by Gilead Sciences, Inc.

Bictegravir is an integrase inhibitor (or INSTI). Emtricitabine and tenofovir alafenamide are both nucleoside reverse transcriptase inhibitors (or NRTIs). These drugs stop HIV from multiplying by preventing the virus' integrase and reverse transcriptase enzymes, respectively, from working. These enzymes change HIV's genetic material (RNA) into DNA and incorporate the viral genes into the human chromosome. These processes are shown on Fact Sheet 106, steps 4 and 5. The three drugs in Biktarvy block these processes and reduce the amount of HIV in the body of a person living with HIV.

WHO SHOULD TAKE BIKTARVY?

Biktarvy was approved in 2018 as a complete antiretroviral regimen for people who have never taken ARVs before, or who are currently on stable HIV treatment with a viral load that is less than 50 copies/mL for at least 3 months, and have no history of treatment failure or resistance to the medications in Biktarvy. People with severe liver or kidney problems may not be able to take Biktarvy.

While antiretroviral therapy (ART) is recommended for all people living with HIV, no matter what your symptoms or CD4 count (see Fact Sheet 124), you and your health care provider should

consider your CD4 cell count, your viral load (see Fact Sheet 125), any symptoms you are having, and your preferences regarding HIV medications. Fact Sheet 404 has more information about guidelines for the use of antiretroviral drugs.

If you take Biktarvy, you can reduce your viral load to extremely low levels, and increase your CD4 cell counts. This should mean staying healthier longer.

WHAT ABOUT DRUG RESISTANCE?

The HIV virus creates copies of itself in a process called replication. Sometimes the new copies of HIV contain mutations. They are slightly different from the original virus. Some mutations can keep multiplying even when you are taking ART. When this happens, the drug will stop working. This is called "developing resistance" to the drug. See Fact Sheet 126 for more information on resistance.

Sometimes, if your virus develops resistance to one drug, it will also have resistance to other ARVs. This is called "cross-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. The normal adult dose is one tablet, once per day, with or without food. Each tablet includes 50 milligrams (mg) of bictegravir, 200 mg of emtricitabine, and 25 mg of tenofovir alafenamide.

WHAT ARE THE SIDE EFFECTS?

When you start any ART, you may have temporary side effects such as headaches, nausea, indigestion, or just

feeling ill. These side effects usually get better or disappear over time.

Biktarvy is usually very well tolerated. The most commonly reported side effects seen among people taking Biktarvy are nausea, diarrhea, and headache.

Serious side effects of Biktarvy can include lactic acidosis (see Fact Sheet 556), a rare type of serious liver injury; immune reconstitution inflammatory syndrome or IRIS (see Fact Sheet 483), which sometimes occurs when the immune system begins to recover after starting ART; and new or worsening kidney or liver problems. People taking Biktarvy should have their liver and kidney health monitored. Be sure your health care provider knows if you have had problems with your kidneys or your liver, including hepatitis B.

HOW DOES IT REACT WITH OTHER DRUGS?

Biktarvy can interact with other drugs or supplements that you are taking. **These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are being identified all the time.**

Biktarvy should not be taken with the heart medication dofetilide or the tuberculosis drug rifampin. It also interacts with some medications for seizures. Biktarvy should not be taken at the same time as antacids, calcium supplements, or iron supplements.

Make sure that your health care providers know about ALL drugs and supplements you are taking.

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