

Generic: Bictegravir, emtricitabine, and tenofovir alafenamide (FDA approved 02/07/2018)

Company: Gilead Sciences

Agent for: Human Immunodeficiency Virus Type 1 (HIV-1) Infection

Indications: Complete regime for treatment of HIV-1 in adults with no antiretroviral treatment history or patients who are virologically suppressed on a stable antiretroviral regimen for at least 3 months with no history of treatment failure.

Mechanism of Action: Bictegravir is an integrase strand transfer inhibitor. This prevents the HIV-1 DNA from integrating with the host DNA, which prevents the virus from propagating. Emtricitabine and tenofovir alafenamide are HIV nucleoside analog reverse transcriptase inhibitors. These compete with the natural substrates and result in DNA chain termination.

COMPARABLE DRUGS: Triumeq, Juluca, Genvoya, Descovy, Tivicay, and Prezista.

COST PER MONTH (WAC)

BIKTARVY: \$2,945.65

TRIUMEQ: \$ 2,805.20

JULUCA: \$2,579.00

GENVOYA: \$2,945.65

DESCOVY: \$1,675.79

TIVICAY 50MG: \$1,657.61

PREZISTA 800MG: \$1,580.64

ADVANTAGES:

- Patients can start after 3 months of being undetectable on another medication.
- No other HIV drugs need to be co-administered.

DISADVANTAGES:

- Patients need to be tested for hepatitis B before starting treatment.
- Not recommended for patients with creatine clearance below 30 mL/min or patients with severe hepatic impairment.

MOST IMPORTANT RISKS/ADVERSE EVENTS: Severe acute exacerbations of Hepatitis B have been reported in patients that are coinfecting with both HIV and hepatitis B who discontinued products containing

emtricitabine or tenofovir disoproxil fumarate. Worsening renal impairment has also been seen in some patients using tenofovir prodrugs. A buildup of lactic acid in blood may also occur.

MOST COMMON ADVERSE EVENTS: Common side effects include diarrhea, nausea and headache.

USUAL DOSAGE: The recommended dose is one tablet once daily with or without food. If a dose is missed, take the missed dose as soon as the patient remembers. If it is almost time for the next dose, skip the missed dose and take next dose at regular time. Do not take two doses at the same time to make up for a missed dose.

PRODUCT: Tablets contain 50 mg of bictegravir, 200 mg of emtricitabine, and 25 mg of tenofovir alafenamide. The tablets are brown, capsule-shaped and debossed with "GSI" one side and "9883" on the other side. The medication should be stored below 30°C (86°F), kept tightly closed and in the original container.

COMMENTS: HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). HIV is transmitted through contact with infected body fluids. It targets the immune system and invades T-cells, which normally fight infection. The virus replicates and destroys the immune system. There is no known cure for HIV. The current medications help manage HIV by preventing it from replicating. Medications do not prevent the spread of HIV. Most treatments involve more than one drug to prevent resistance and attack the virus from different angles. Biktarvy aims to reduce the amount of HIV-1 in the patients' blood to an "undetectable" amount (< 50/mL) and increase the CD4+ T- cells to help the body fight the infection and improve the immune system. In two clinical trials conducted over 48 weeks that focused on patients with no antiretroviral treatment history, patients on Biktarvy had an increased CD4+ count compared to patients on another regimen of antiviral medications. When two different trials were conducted with patients who switched to Biktarvy, similar results were also seen when compared to patients on another regimen of antiviral medications.