Generic Name:
Bictegravir/emtricitabine/tenofovir alafenamide
Trade Name:
Biktarvy
Company:
Gilead Sciences
Notes:

Gilead Sciences announced FDA approval of bictegravir 50 mg/emtricitabine 200 mg/tenofovir alafenamide 25 mg ([BIC/FTC/TAF] Biktarvy?Gilead), a once-daily, single-tablet regimen (STR) for treatment of HIV-1 infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 c/mL) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the product?s individual components.

It combines bictegravir, a novel unboosted integrase strand transfer inhibitor (INSTI), with emtricitabine 200 mg/tenofovir alafenamide 25 mg (Descovy?Gilead), a dual nucleoside reverse transcriptase inhibitor (NRTI). It is the smallest INSTI-based triple-therapy STR available.

No dosage adjustment of BIC/FTC/TAF is required in patients with estimated creatinine clearance greater than or equal to 30 mL/min.

BIC/FTC/TAF does not require testing for HLA-B*5701, has no food intake requirements, and has no baseline viral load or CD4 count restrictions.

Before or when initiating treatment, health care providers should test for hepatitis B virus (HBV) infection and renal function, as well as monitor renal function as clinically appropriate during therapy. The agent does not cure HIV infection or AIDS.

A boxed warning cautions on the risk of acute exacerbation of HBV posttreatment.

Medication Monitor Categories:
New Drug Approvals