Biktarvy (bictegravir, emtricitabine, tenofovir alafenamide)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Biktarvy
- **Generic name:** Bictegravir, emtricitabine, tenofovir alafenamide
- **Pharmacological class:** HIV-1 integrase strand transfer inhibitor + nucleoside analog reverse transcriptase inhibitors
- **Strength and Formulation:** 50mg/200mg/25mg; tabs
- **Manufacturer:** Gilead Sciences
- **How supplied:** Tabs—30
- **Legal Classification:** Rx

Biktarvy


30 tablets
Biktarvy®
(bictegravir, emtricitabine, and
tenofovir alafenamide) tablets
50 mg / 200 mg / 25 mg
GSI

Indications

- A **complete regimen** for the treatment of HIV-1 infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for ≥3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy

Dosage & Administration

- Test for HBV infection prior to initiation
- 1 tab once daily

Considerations for Special Populations

- **Pediatric:** <18yrs: not established
- **Pregnancy:** Insufficient human data to establish drug-associated risk
- **Nursing mothers:** Not recommended
- **Elderly:** Insufficient number of subjects studied
- **Renal impairment:** Severe (CrCl <30mL/min): not recommended
- **Hepatic impairment:** Severe (Child-Pugh Class C): not recommended

Contraindications

- Concomitant dofetilide, rifampin

Warnings/Precautions

- **Test for HBV** before starting therapy and closely monitor patients co-infected with HBV and HIV for several months after stopping treatment (discontinuing therapy may exacerbate HBV infection); if appropriate, anti-hepatitis B therapy may be warranted (esp. in those with advanced liver disease or cirrhosis)

Warnings/Precautions

- Suspend therapy if **lactic acidosis** or **hepatotoxicity** (eg, hepatomegaly, steatosis) occurs
- **Monitor** serum creatinine, CrCl, urine glucose, urine protein, and serum phosphorus (in patients at risk for chronic renal disease); discontinue if significant renal dysfunction or Fanconi syndrome occurs

Interactions

- **See Contraindications**
- Concomitant other antiretrovirals: not recommended
- May potentiate concomitant OCT2 and MATE1 substrates (eg, dofetilide)
- May be affected by drugs that induce or inhibit CYP3A and UGT1A1
- Concomitant drugs that strongly affect P-gp and BCRP activity may lead to changes in TAF absorption

Interactions

- May be potentiated by drugs that decrease renal function or compete for active tubular secretion (eg, acyclovir, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides, NSAIDs)
- May be antagonized by anticonvulsants (eg, carbamazepine, oxcarbazepine, phenobarbital, phenytoin); consider alternatives
- Concomitant rifabutin, rifapentine, St. John's wort: not recommended

Interactions

- Concomitant cation-containing antacids, laxatives, sucralfate, and buffered drugs: give Biktarvy 2hrs before
- Concomitant oral iron/calcium supplements: may take together with food
- Routine coadministration with, or 2hrs after, cation-containing antacids or oral iron/calcium supplements: not recommended
- May potentiate metformin (refer to metformin labeling)

Adverse Reactions

- Diarrhea
- Nausea
- Headache
- HBV exacerbation
- New onset or worsening renal impairment
- Immune reconstitution syndrome
- Lactic acidosis
- Hepatomegaly

Mechanism of Action

- **Bictegravir**, an HIV-1 integrase strand transfer inhibitor, prevents integration of linear HIV-1 DNA into host genomic DNA, blocking the transformation of the HIV-1 provirus and propagation of the virus
- **Emtricitabine** inhibits the activity of HIV-1 reverse transcriptase by competing with the natural substrate deoxycytidine 5'-triphosphate and by being incorporated into nascent viral DNA, resulting in chain termination

Mechanism of Action

- **Tenofovir alafenamide** is a prodrug of tenofovir, which is phosphorylated to the active tenofovir diphosphate
- It inhibits HIV-1 replication through incorporation into viral DA by the HIV reverse transcriptase, resulting in chain termination

Clinical Studies

- Biktarvy was evaluated in 2 studies of adults with no antiretroviral treatment history (**Trials 1489 and 1490**) and 2 studies of virologically-suppressed adults (**Trials 1844 and 1878**)

Clinical Studies

- **Trial 1489** was a randomized, double-blind, active-controlled trial that randomized patients to Biktarvy (N=314) or ABC/DTG/3TC (N=315) once daily
- **Trial 1490** was a randomized, double-blind, active-controlled trial that randomized patients to Biktarvy (N=320) or DTG + FTC/TAF (N=325) once daily

Clinical Studies

- In **Trial 1489**, HIV-1 RNA <50 copies/mL was achieved in **92%** of Biktarvy patients vs **93%** of ABC/DTG/3TC patients at Week 48 (difference -0.6%, 95% CI: -4.8% to 3.6%)
- In **Trial 1490**, HIV-1 RNA <50 copies/mL was achieved in **89%** of Biktarvy patients vs **93%** of DTG + FTC/TAF patients at Week 48 (difference -3.5%, 95% CI: -7.9% to 1.0%)

Clinical Studies

- **Trial 1844** evaluated the safety and efficacy of switching from DTG + ABC/3TC or ABC/DTG/3TC to Biktarvy in virologically-suppressed adults (N=563)
- **Trial 1878** evaluated the safety and efficacy of switching from either ABC/3TC or FTC/TDF + ATV or DRV to Biktarvy in virologically-suppressed adults (N=577)

Clinical Studies

- In **Trial 1844**, HIV-1 RNA ≥50 copies/mL was seen in 1% of Biktarvy patients vs <1% of ABC/DTG/3TC patients (difference 0.7%, 95% CI: -1.0% to 2.8%)
- In **Trial 1878**, HIV-1 RNA ≥50 copies/mL was seen in 2% of patients in both treatment groups (difference 0.0%, 95% CI: -2.5% to 2.5%)

Clinical Studies

- Treatment outcomes were similar across subgroups by age, sex, race, baseline viral load, and baseline CD4+ count for Trials 1489 and 1490
- Treatment outcomes between groups were similar across subgroups by age, sex, race, and region for Trials 1844 and 1878

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/biktarvy/drug/34794/