Product Sheet BIKTARVY

Product Name: BIKTARVY

Form: Tablets, for oral use

Indications and Usage
BIKTARVY is a combination of three medications:

- Bictegravir (BIC), an integrase strand transfer inhibitor for human immunodeficiency virus type 1 (HIV-1)
- Emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors

It is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg:

- Without a history of antiretroviral treatment
- To replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.

Dosage and Administration

- **Recommended Dose:**
    - Adults and pediatric patients weighing at least 25 kg: One tablet containing 50 mg of BIC, 200 mg of FTC, and 25 mg of TAF, once daily with or without food.
    - Pediatric patients weighing between 14 kg and less than 25 kg: One tablet containing 30 mg of BIC, 120 mg of FTC, and 15 mg of TAF, once daily with or without food.
    - Pregnant individuals who are virologically suppressed: One tablet containing 50 mg of BIC, 200 mg of FTC, and 25 mg of TAF, once daily with or without food.
- **Renal Impairment:** Not recommended in patients with an estimated creatinine clearance between 15 and less than 30 mL/min, or in those with creatinine clearance below 15 mL/min who are not receiving chronic hemodialysis.
- **Hepatic Impairment:** Not recommended in patients with severe hepatic impairment.

Forms and Concentrations

- Tablets: 50 mg of BIC, 200 mg of FTC, and 25 mg of TAF
- Tablets: 30 mg of BIC, 120 mg of FTC, and 15 mg of TAF

Contraindications

- Dofetilide
- Rifampin

Warnings and Precautions

- **Immune Reconstitution Syndrome:** May require further evaluation and treatment.
- **New or Worsening Renal Impairment:** Assess serum creatinine, creatinine clearance, urine glucose, and urine protein at baseline and during treatment as clinically appropriate.
- **Lactic Acidosis/Severe Hepatomegaly with Steatosis:** Discontinue treatment in patients who develop symptoms or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity.

Adverse Reactions
The most common adverse reactions (incidence ≥5%, all grades) are diarrhea, nausea, and headache.

Drug Interactions

- Co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.
- Refer to the Full Prescribing Information before and during treatment for important information on drug interactions.