Generic Name:
Elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide
Trade Name:
Genvoya
Company:
Gilead Sciences
Notes:

FDA approved a fixed-dose combination tablet containing elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide under the trade name Genvoya for use in adults and children ages 12 years and older who are infected with HIV-1, weigh at least 35 kg (77 pounds), and have never taken HIV therapy (treatment-naive) and in adults whose HIV-1 virus is currently suppressed.

While Genvoya is not recommended for patients with severe renal impairment, those with moderate renal impairment can take the drug.

Genvoya?s safety and efficacy in adults were evaluated in 3,171 participants enrolled in four clinical trials. Depending on the trial, participants were randomly assigned to receive Genvoya or another FDA-approved HIV treatment. Results showed Genvoya was effective in reducing viral loads and comparable to the other treatment regimens.

Genvoya contains a new form of tenofovir that has not been previously approved. This new form of tenofovir provides lower levels of drug in the bloodstream but higher levels within the cells where HIV-1 replicates. It was developed to help reduce some drug adverse effects.

Genvoya appears to be associated with less kidney toxicity and decreases in bone density than previously approved tenofovir-containing regimens, based on laboratory measures. Patients receiving Genvoya experienced greater increases in serum lipids (total cholesterol and low-density lipoprotein) than patients receiving other treatment regimens in the studies.

Genvoya carries a boxed warning alerting patients and health care providers that the drug can cause a buildup of lactic acid in the blood and severe liver problems, both of which can be fatal. The boxed warning also states that Genvoya is not approved to treat chronic hepatitis B virus infection.

The most common adverse effect associated with Genvoya is nausea. Serious adverse effects include new or worsening kidney problems, decreased bone mineral density, fat redistribution, and changes in the immune system. Health care providers are advised to monitor patients for kidney and bone adverse effects. Genvoya should not be given with other antiretroviral products and may have drug interactions with a number of other commonly used medications.

Medication Monitor Categories:
Supplemental Approvals