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Generic Name:
Dolutegravir and lamivudine
Trade Name:
Dovato
Company:
ViiV Healthcare
Notes:

FDA has approved dolutegravir and lamivudine as a complete regimen for treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with no antiretroviral treatment history and with no known or suspected substitutions associated with resistance to the individual components of the new agent. This is the first two-drug, fixed-dose, complete regimen approved for adults with HIV-1 who have never received treatment.

The labeling includes a boxed warning cautioning that patients infected with both HIV and hepatitis B should receive additional treatment for their hepatitis B or consider a different drug regimen.

Patients with both HIV and hepatitis B who take products containing lamivudine, an ingredient in the new combination drug, have developed hepatitis B variants associated with resistance to lamivudine. These patients may have severe liver problems, including liver failure, when they stop taking drugs containing lamivudine. Patients with both HIV and hepatitis B virus who stop using the drug should be closely monitored by their health care provider.

Efficacy and safety of one tablet of dolutegravir and lamivudine taken daily were demonstrated in two identical, randomized, double-blind, controlled clinical trials in 1,433 HIV-infected adults with no prior antiretroviral treatment history. Results were similar to a drug regimen that included dolutegravir, emtricitabine, and tenofovir in reducing the amount of HIV in the blood. Treatment was considered successful if the patient maintained low levels (<50 copies/mL) of HIV RNA in their blood for at least 48 weeks.

The most common adverse reactions were headache, diarrhea, nausea, insomnia, and fatigue.

As there is a known risk for neural tube defects with dolutegravir, patients are advised to avoid use of the new drug at the time of conception through the first trimester of pregnancy. In May 2018, FDA released a Drug Safety Communication about reported neural tube birth defects in babies born to women treated with dolutegravir.

Medication Monitor Categories:
New Drug Approvals

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