

First two-drug regimen approved for HIV-1 treatment

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(HealthDay)—The U.S. Food and Drug Administration has announced

the approval of Dovato (dolutegravir and lamivudine), the first approved two-drug, fixed-dose, complete regimen for adults with HIV-1 who have not been previously treated with antiretroviral medication.

Dovato is indicated for [patients](#) with no known or suspected substitutions associated with resistance to the drug's individual components. As opposed to the standard-of-care three-drug regimen, Dovato provides patients with the option of a two-drug regimen in a single tablet without the additional toxicity and potential drug interactions carried by a third drug.

Data from two randomized, double-blind, controlled [clinical trials](#) demonstrated the efficacy and safety of one daily tablet of Dovato in 1,433 HIV-infected adults who had no history of antiretroviral treatment. Researchers found that a regimen of dolutegravir and lamivudine similarly reduced the amount of HIV in the blood compared with a drug regimen of dolutegravir, emtricitabine, and tenofovir. Treatment was successful if patients maintained less than 50 copies/mL of HIV RNA in their blood for at least 48 weeks. Commonly reported [adverse reactions](#) included headache, diarrhea, nausea, insomnia, and fatigue.

Patients should not use Dovato from conception through the first trimester of pregnancy because of a known risk for neural tube defects with dolutegravir. The boxed warning on the Dovato labeling indicates that patients who have both HIV and hepatitis B should add treatment for hepatitis B or consider a different drug regimen. Patients infected with both HIV and hepatitis B who take lamivudine-containing products have developed resistance to lamivudine and may have severe liver problems when they cease taking these drugs. Patients with both HIV and hepatitis B who stop taking Dovato should be closely monitored.

Approval of Dovato was granted to ViiV Healthcare.

More information: [More Information](#)

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