Generic Name:
Doravirine, lamivudine, tenofovir disoproxil fumarate; doravirine
Trade Name:
Delstrigo; Pifeltro
Company:
Merck
Notes:

Merck announced FDA approval of two new HIV-1 medications for adult patients with no prior antiretroviral treatment experience: a once-daily fixed-dose combination tablet of doravirine 100 mg, lamivudine (3TC) 300 mg, and tenofovir disoproxil fumarate (TDF) 300 mg, approved under the trade name Delstrigo; and doravirine 100 mg, a new nonnucleoside reverse transcriptase inhibitor that is administered in combination with other antiretroviral medicines and was approved under the trade name Pifeltro.

Both drugs are administered orally once daily with or without food.

Approval was based on findings from two pivotal, randomized, multicenter, double-blind, active controlled Phase III trials, DRIVE-AHEAD and DRIVE-FORWARD.

Delstrigo is contraindicated in patients with a previous hypersensitivity reaction to 3TC.

Delstrigo and Pifeltro are contraindicated when coadministered with drugs that are strong CYP450 3A enzyme inducers because significant decreases in doravirine plasma concentrations may occur and lessen their effectiveness.

Immune reconstitution syndrome can occur, including autoimmune disorders with variable time to onset, which may necessitate further evaluation and treatment.

Renal impairment, including acute renal failure and Fanconi syndrome, has been reported with use of TDF. Delstrigo should be avoided with concurrent or recent use of a nephrotoxic agent, as cases of acute renal failure after initiation of high-dose or multiple NSAIDs have been reported in patients with risk factors for renal dysfunction who appeared stable on TDF.

Common adverse reactions in clinical trials included dizziness (7%), nausea (5%) and abnormal dreams (5%).

Delstrigo and Pifeltro do not cure HIV-1 infection or AIDS.

Medication Monitor Categories:
New Drug Approvals