

Doravirine-Tenofovir DF-Lamivudine (*Delstrigo*)

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Drug Summary

Doravirine-tenofovir DF-lamivudine is a single-tablet regimen dosed once daily with or without food that is approved for use in persons with no antiretroviral history. The non-nucleoside reverse transcriptase inhibitor (NNRTI) anchor drug in this regimen—doravirine—retains activity in the presence of common NNRTI drug-resistant mutations (e.g. K103N, Y181C, G190A) and thus may have clinical utility for individuals with resistance to other NNRTI's. Treatment failure with doravirine can result in emergence of resistance associated substitutions that may confer cross-resistance to efavirenz, etravirine, nevirapine, and rilpivirine. Unlike the NNRTI rilpivirine, there are no CD4 count or HIV RNA level restriction for the use of doravirine. In addition, doravirine does not have restrictions for use in combination with proton pump inhibitors. The single-tablet regimen doravirine-tenofovir DF-lamivudine is potent and well-tolerated NNRTI single-tablet regimen, but its use may be somewhat limited by the FDA approval only for antiretroviral-naïve persons, since current recommendations to use integrase strand transfer inhibitors as the anchor drug when initiating antiretroviral therapy.

Key Clinical Trials

- The phase 3 DRIVE AHEAD study compared virologic efficacy and tolerability of two single-tablet coformulated regimens: doravirine-tenofovir DF-lamivudine and efavirenz-tenofovir DF-emtricitabine [[DRIVE AHEAD](#)]. In this trial 364 individuals were randomized to each arm and at 48 weeks results demonstrated non-inferiority of the doravirine regimen by FDA snapshot (proportion with HIV RNA below 50 copies/mL was 84.3% in the doravirine arm versus 80.8% in the efavirenz arm by intention-to-treat analysis). Results also showed that less rash, central nervous side effects, and lipid changes occurred in the doravirine arm and there were overall fewer treatment discontinuations due to adverse effects as compared to the efavirenz arm.
- The ongoing phase 3 trial (DRIVE SHIFT) trial is evaluating the effectiveness of switching from other antiretroviral regimens to doravirine-tenofovir DF-lamivudine [[DRIVE SHIFT](#)].
- The phase 2a DRIVE BEYOND trial is evaluating the efficacy of doravirine-tenofovir DF-lamivudine in treatment-naïve subjects who have NNRTI-transmitted resistance mutations [[DRIVE BEYOND](#)].

Adverse Effects

The adverse effects that occurred in trials in more than 5% of participants consisted of dizziness, nausea, and abnormal dreams. Tenofovir DF may cause nephrotoxicity and decreases in bone mineral density. Doravirine-tenofovir DF-lamivudine should not be used in persons with a creatinine clearance less than 50 mL/min.

Use In Pregnancy

There are insufficient data on the use of doravirine-tenofovir DF-lamivudine in pregnancy.

Key Drug Interactions

For complete information on doravirine-tenofovir df-lamivudine-related drug interactions, see the [Drug Interactions section in the Doravirine-Tenofovir DF-Lamivudine \(Delstrigo\) Prescribing Information](#).