

Doravirine (*Pifeltro*)

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Drug Summary

Doravirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that is well tolerated and dosed once daily, with or without food. Doravirine is indicated in combination with other antiretroviral agents for the treatment of adult patients with HIV who have no prior antiretroviral treatment history. 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 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. Doravirine is a potent and well-tolerated NNRTI that currently is indicated for use only in antiretroviral-naïve individuals. In the future, it is likely that doravirine will be used more often for antiretroviral-experienced individuals, especially those with resistance to NNRTIs.

Key Clinical Trials

- In a phase 2 trial, 216 treatment-naïve adults were randomized 1:1 to doravirine or efavirenz, each with two NRTI's, and at 48 weeks an equivalent proportion had suppressed HIV RNA level (77.8% in the doravirine arm and 78.7% in the efavirenz arm) [[MK-1439-007](#)]. Side effects were less frequent with doravirine, particularly central nervous system side effects.

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- In the phase 3 DRIVE FORWARD study, doravirine was compared to ritonavir-boosted darunavir as initial antiretroviral therapy, each with two NRTI's [[Drive Forward](#)]. In the primary analysis, there were 383 participants in each arm; at 48 weeks, doravirine was non-inferior to ritonavir-boosted darunavir (HIV RNA obtained from: <https://www.hiv.uw.edu/page/treatment/drugs/doravirine>)