

Pifeltro® (doravirine) – Expanded indication

- On September 19, 2019, the <u>FDA approved</u> Merck's <u>Pifeltro (doravirine)</u>, in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in adult patients to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to doravirine.
- Pifeltro is also approved in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history.
- The expanded indication for Pifeltro was approved based on the open-label DRIVE-SHIFT study enrolling 670 adult patients with virologically-suppressed HIV-1. Patients were randomized to either switch to Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate) at baseline (Immediate Switch Group [ISG]), or stay on their baseline regimen until week 24, at which point they switched to Delstrigo (Delayed Switch Group [DSG]).
 - Based on the percentage of patients with HIV-1 RNA ≥ 50 copies/mL, the ISG group was shown to be non-inferior to the DSG group (2% vs. 1%, difference = 0.7%; 95% CI: -1.3, 2.6).
- The recommended dose of Pifeltro for either indication in adults is one 100 mg tablet orally once daily with or without food



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.