# Pifeltro (doravirine)


NEW PRODUCT SLIDESHOW

MPR

# Introduction

- **Brand name:** Pifeltro
- **Generic name:** Doravirine
- **Pharmacological class:** Non-nucleoside reverse transcriptase inhibitor
- **Strength and Formulation:** 100mg; tablets
- **Manufacturer:** Merck
- **How supplied:** Bottle—30
- **Legal Classification:** Rx

# Indication

- In combination with other antiretroviral agents for **HIV-1 infection** in antiretroviral treatment-naïve adult patients

# Pifeltro


NDC 0006-3069-01
Pifeltro™
(doravirine) tablets
100 mg
Each tablet contains 100 mg doravirine.
ALERT: Find out about medicines that should NOT be taken with Pifeltro™.
Rx only
30 Tablets
USUAL DOSAGE: See Package Insert.
700
700

# Dosage & Administration

- ≥18yrs: 100mg once daily
- Concomitant rifabutin: 100mg twice daily (approx. 12hrs apart)

# Considerations for Special Populations

- **Pregnancy:** No adequate human data to establish risk
- **Nursing mothers:** Not recommended
- **Pediatric:** <18yrs: not established
- **Elderly:** Use caution
- **Renal impairment:** No dosage adjustment required; no adequate studies in end-stage renal disease or in dialysis patients
- **Hepatic impairment:** No dosage adjustment in mild or moderate impairment; has not been studied in severe impairment

# Contraindications

- Concomitant strong CYP3A inducers (eg, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, enzalutamide, rifampin, rifapentine, mitotane, St. John's wort): discontinue for ≥4wks prior to starting Pifeltro

# Warnings/Precautions

- Immune reconstitution syndrome

# Interactions

- Concomitant efavirenz, etravirine, nevirapine: not recommended
- May be antagonized by CYP3A inducers (see Contraindications)
- May be potentiated by CYP3A inhibitors

# Adverse Reactions

- Nausea
- Dizziness
- Headache
- Fatigue
- Diarrhea
- Abdominal pain
- Abnormal dreams

# Mechanism of Action

- Doravirine is a pyridinone non-nucleoside reverse transcriptase inhibitor of HIV-1 and inhibits HIV-1 replication by non-competitive inhibition of HIV-1 reverse transcriptase

# Clinical Studies

- The efficacy of Pifeltro is based on the analyses of 48-week data from 2 randomized, multicenter, double-blind, active controlled Phase 3 trials (DRIVE-FORWARD and DRIVE-AHEAD) in HIV-1 infected patients with no antiretroviral treatment history (N=1494)

# Clinical Studies

- In **DRIVE-FORWARD**, 766 patients were randomized and received at least 1 dose of either Pifeltro once daily or darunavir 800mg + ritonavir 100mg (DRV+r) once daily each in combination with emtricitabine/tenofovir DF (FTC/TDF) or abacavir/lamivudine (ABC/3TC) selected by the investigator

# Clinical Studies

- At Week 48, 84% of patients in the Pifeltro arm had HIV-1 RNA <50 copies/mL compared with 80% of patients in the DRV+r group (treatment difference: 3.9%)
- The mean CD4+ T-cell counts in the Pifeltro and DRV+r groups increased from baseline by 193 and 186 cells/$mm^3$, respectively

# Clinical Studies

- In **DRIVE-AHEAD**, 728 patients were randomized and received at least 1 dose of either doravirine, lamivudine, tenofovir disoproxil fumarate fixed-dose tablets (Delstrigo) or efavirenz (EFV) 600mg/FTC 200mg/TDF 300mg once daily

# Clinical Studies

- At Week 48, 84% of the Delstrigo arm had HIV-1 RNA <50 copies/mL compared with 81% of patients in the EFV/FTC/TDF group (treatment difference: 3.5%)
- The mean CD4+ T-cell counts in the Delstrigo and EFV/FTC/TDF groups increased from baseline by 198 and 188 cells/mm$^3$, respectively
- For more clinical trial data, see full labeling

# New Product Monograph

- For more information view the product monograph available at:

  www.empr.com/pifeltro/drug/34877/