

Doravirine (DOR, Pifeltro)

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Formulations	
Tablet: 100 mg Fixed-Dose Combination (FDC) Tablet [Delstrigo] Doravirine 100 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg When using FDC tablets, refer to other sections of Appendix A: Pediatric Antiretroviral Drug Information for information about the individual components of the FDC. See also Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets and Co-packaged Formulations: Minimum Body Weights and Considerations for Use in Children and Adolescents. For additional information, see Drugs@FDA or DailyMed.	
Dosing Recommendations	Selected Adverse Events
Child and Adolescent (Weighing ≥ 35 kg) and Adult Dose - DOR 100 mg once daily in antiretroviral (ARV)-naïve and ARV-experienced people who have been virologically suppressed (HIV RNA < 50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known mutations associated with resistance to DOR [Delstrigo] DOR/Lamivudine (3TC)/Tenofovir Disoproxil Fumarate (TDF) <i>Child and Adolescent (Weighing ≥ 35 kg) and Adult Dose</i> - One tablet once daily in ARV-naïve and ARV-experienced people who have been virologically suppressed (HIV RNA < 50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known mutations associated with resistance to the individual components of Delstrigo	- Nausea - Abdominal pain - Diarrhea - Abnormal dreams - Insomnia, somnolence
	Special Instructions
	- DOR can be taken with or without food. - Screen children for hepatitis B virus (HBV) infection before using Delstrigo, which contains 3TC and TDF. Severe acute exacerbation of HBV can occur when 3TC or TDF are discontinued; therefore, hepatic function and HBV viral load should be monitored for several months after halting therapy with 3TC or TDF.
	Metabolism/Elimination
	- DOR is metabolized by the enzyme cytochrome (CYP) P450 3A. - DOR has multiple interactions with several drugs (see the Drug Interactions section below). DOR Dosing in Children With Hepatic Impairment - Dose adjustment is not required in children with mild or moderate hepatic impairment. DOR has not been studied in people with severe hepatic impairment.