



Viread[®] (tenofovir disoproxil fumarate) – Expanded indication

- On December 11, 2018, the FDA approved [Viread \(tenofovir disoproxil fumarate\)](#) for the treatment of chronic hepatitis B virus (HBV) in adults and pediatric patients 2 years of age and older weighing at least 10 kg.
 - Previously Viread was approved for use in patients 12 years of age and older for this indication.
 - Viread is also indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients 2 years of age and older weighing at least 10 kg.
- The expanded indication is based on data from a clinical study of 89 pediatric patients 2 years to less than 12 years of age with chronic HBV infection. Patients were treated with Viread 8 mg/kg up to a maximum dose of 300 mg or placebo once daily for 48 weeks.
 - At week 48, there was an overall higher proportion in the Viread group with HBV DNA < 400 copies/mL (77% vs. 7%, respectively) and alanine aminotransferase normalization rate (66% vs. 15%, respectively) vs. the placebo group.
 - There was no difference between the Viread and placebo groups in those who achieved hepatitis B e-antigen (HBeAg) loss (30% vs. 28%, respectively) or HBeAg seroconversion (25% vs. 24%, respectively).
- Viread carries a boxed warning for posttreatment acute exacerbation of hepatitis B.
- The most common adverse reactions with Viread use in pediatric patients were consistent with those observed in adults.
- In addition to the expanded indication, information regarding early virologic failure in HIV-infected patients was removed from the *Warnings and Precautions* section of the Viread drug label.
- The recommended dosage in pediatric patients at least 2 years of age and adults for both indications is weight based:
 - For patients weighing ≥ 17 kg who can swallow an intact tablet: one Viread tablet (150 mg, 200 mg, 250 mg, or 300 mg based on body weight) once daily taken orally without regard to food.
 - For patients ≥ 10 kg and unable to swallow a tablet: 8 mg/kg of Viread oral powder (up to a maximum of 300 mg) taken once daily with food.
 - For patients weighing ≥ 35 kg: one 300 mg tablet once daily without regard to food.



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