



Descovy® (emtricitabine/tenofovir alafenamide) – Expanded indication, new strength

- On January 7, 2022, the [FDA approved](#) Gilead's [Descovy \(emtricitabine/tenofovir alafenamide\)](#), in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor, for the treatment of HIV-1 infection in pediatric patients weighing *at least 14 kg and less than 35 kg*.
 - Descovy was previously approved for this use in pediatric patients weighing *at least 25 kg and less than 35 kg*.
- Descovy is also approved:
 - In combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg.
 - In at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP.
- In addition to the expanded indication, the FDA approved a new tablet strength of Descovy: 120 mg of emtricitabine and 15 mg of tenofovir alafenamide.
 - Descovy was previously available as a 200 mg emtricitabine and 25 mg tenofovir alafenamide tablet.
- The approval of Descovy for the expanded indication was based on open-label, single arm study in 24 virologically suppressed HIV-1 infected children at least 2 years of age and weighing at least 14 to less than 25 kg. Patients received emtricitabine/tenofovir alafenamide with bicitegravir. Overall, 91% (20/22) of patients remained virologically suppressed at week 24.
- Descovy carries a boxed warning for post-treatment acute exacerbation of hepatitis B and risk of drug resistance with use of Descovy for HIV-1 PrEP in undiagnosed early HIV-1 infection.
- The recommended dosage of Descovy in pediatric patients weighing at least 14 kg to less than 25 kg is one tablet (containing 120 mg emtricitabine and 15 mg tenofovir alafenamide) orally once daily.
 - Refer to the Descovy drug label for dosing for its other uses.



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