

Symtuza® (darunavir/cobicistat/emtricitabine/tenofovir) – Expanded indication

- On March 2, 2020, the [FDA approved](#) Janssen's [Symtuza \(darunavir/cobicistat/emtricitabine/tenofovir\)](#), as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 40 kg: who have no prior antiretroviral treatment history or who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir.
 - Symtuza was previously approved for this indication in adults only.
- The pharmacokinetic profile, safety, and antiviral activity of the components of Symtuza were evaluated in open-label clinical studies in pediatric patients.
 - In one study, darunavir and cobicistat once daily with two nucleoside reverse transcriptase inhibitors (NRTIs) were evaluated in 7 virologically suppressed pediatric patients aged 12 to less than 18 years and weighing at least 40 kg. At week 48, the proportion of patients who maintained HIV-1 RNA < 50 copies/mL was 86%, and the median change in CD4+ cell count from baseline was -342 cells/mm³ (range -1,389 to 210 cells/mm³).
 - In a second study, cobicistat, emtricitabine, and tenofovir alafenamide, as part of a fixed-dose combination regimen together with elvitegravir, were evaluated in 50 treatment-naïve pediatric patients with HIV-1 aged 12 to less than 18 years and weighing at least 35 kg. At week 48, the proportion of patients who had HIV-1 RNA < 50 copies/mL was 92%, and the median increase in CD4+ cell count from baseline was 220 cells/mm³.
- Symtuza carries a boxed warning for post treatment acute exacerbation of hepatitis B.
- The most common adverse reactions (≥ 2%) with Symtuza use were diarrhea, rash, nausea, fatigue, headache, abdominal discomfort, and flatulence.
- The recommended dosage of Symtuza is one tablet taken orally once daily with food in adults and pediatric patients weighing at least 40 kg.
- Symtuza is a four-drug fixed dose combination product containing 800 mg of darunavir, 150 mg of cobicistat, 200 mg of emtricitabine, and 10 mg of tenofovir alafenamide.