



Prezcobix® (darunavir/cobicistat) – Expanded indication

- On July 31, 2020, the [FDA approved](#) Janssen's [Prezcobix \(darunavir/cobicistat\)](#), in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in treatment naïve and treatment-experienced adults and pediatric patients weighing at least 40 kg with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V)
 - Previously, Prezcobix was approved for this indication in adults only.
- The expanded indication for Prezcobix was demonstrated in a Phase 2/3 multicenter, open-label trial to evaluate the pharmacokinetics, safety, and efficacy of darunavir co-administered with cobicistat in adolescents aged 12 years and older with HIV-1 infection who were virologically suppressed and had a baseline estimated creatinine clearance ≥ 90 mL/min/1.73 m².
 - Patients were on a stable antiretroviral regimen (for at least 3 months), consisting of darunavir administered with ritonavir, combined with 2 nucleoside reverse transcriptase inhibitors (NRTIs). Patients (N=7) were switched from ritonavir to cobicistat 150 mg once daily and continued darunavir and 2 NRTIs.
 - The median age of patients was 14 years (range 12-16 years), median weight was 60 kg (range 45-78 kg), and 43% were male. At baseline, all patients had plasma HIV-1 RNA < 50 copies/mL) and one subject had missing data.
 - From a median baseline CD4+ cell count and CD4+% of 1,117 cells/mm³ (range 658 to 2,416 cells/mm³) and 45% (range 28% to 56%), respectively, the median change from baseline in CD4+ cell count and CD4+% at Week 48 was -342 cells/mm³ (range -1,389 to 219 cells/mm³) and -6% (range -12% to 5%), respectively.
 - All 6 patients with available data had CD4+ cell counts above 800 cells/mm³ at Week 48.
- The recommended dose of Prezcobix for the treatment of adult and pediatric patients is one tablet taken once daily with food in adults and pediatric patients weighing at least 40 kg.
 - Prezcobix should be administered in conjunction with other antiretroviral agents.



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