

## Evotaz® (atazanavir/cobicistat) - Expanded indication

- On July 31, 2020, the <u>FDA approved</u> Bristol-Myers Squibb's <u>Evotaz (atazanavir/cobicistat)</u>, in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in adults and pediatric patients weighing at least 35 kg.
  - Previously, Evotaz was approved for this indication in adults only.
- The expanded indication for Evotaz was demonstrated in an open-label study enrolling 14 pediatric
  patients ages 12 years and older with HIV-1 infection who were virologically suppressed. Patients
  were switched from ritonavir to cobicistat 150 mg once daily and continued atazanavir and 2
  nucleoside/nucleotide reverse transcriptase inhibitors.
  - At week 48, 93% (13/14) of subjects remained suppressed (HIV-1 RNA < 50 copies/mL), and 1 subject experienced virologic failure.
  - From a median baseline CD4+ cell count and CD4+% of 770 cells/mm³ (range 486 to 1765 cells/mm³) and 33% (range 23% to 45%), respectively, the median change from baseline in CD4+ cell count and CD4+% at week 48 was -60 cells/mm³ (range -500 to 705 cells/mm³) and -0.3% (range -6% to 8%), respectively.
- The recommended dose of Evotaz for the treatment of adult and pediatric patients is one tablet (300 mg of atazanavir and 150 mg of cobicistat) taken once daily orally with food.
  - Evotaz should be administered in conjunction with other antiretroviral agents



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