

Tybost® (cobicistat) – Expanded indication

- On October 3, 2019, the FDA approved Gilead Sciences' **Tybost (cobicistat)**, to increase systemic exposure of **atazanavir** or **Prezista® (darunavir)** (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of human immunodeficiency virus (HIV)-1 infection in adults and in pediatric patients: weighing at least 35 kg co-administered with atazanavir or weighing at least 40 kg co-administered with darunavir.
 - Previously, Tybost's pediatric indication was limited to increasing systemic exposure of atazanavir in combination with other antiretroviral agents in the treatment of HIV-1 infection in pediatric patients weighing at least 35 kg.
 - Tybost is not interchangeable with **ritonavir** to increase systemic exposure of darunavir 600 mg twice daily, **fosamprenavir**, **Invirase® (saquinavir)**, or **Aptivus® (tipranavir)** due to lack of exposure data. The use of Tybost is not recommended with darunavir 600 mg twice daily, fosamprenavir, saquinavir, or tipranavir.
 - Complex or unknown mechanisms of drug interactions preclude extrapolation of ritonavir drug interactions to certain Tybost interactions. Tybost and ritonavir when administered with either atazanavir or darunavir may result in different drug interactions when used with concomitant medications.
- The approval of the expanded indication for Tybost is based on an open-label study of 7 HIV-1 infected virologically suppressed pediatric patients aged 12 years and older. Patients were switched from ritonavir to Tybost and continued darunavir and two nucleotide reverse transcriptase inhibitors.
 - In patients who switched to Tybost co-administered with darunavir, 86% (6/7) of subjects remained suppressed (HIV-1 RNA < 50 copies/mL), and 1 subject had missing data at week 48.
- The recommended doses of Tybost and atazanavir or darunavir in pediatric patients are given with food and based on weight as follows:

Tybost dosage	Co-administered agent dosage	Patient populations and weight
150 mg orally once daily (co-administered at the same time as atazanavir or darunavir)	atazanavir 300 mg orally once daily	Treatment-naïve or treatment-experienced weighing at least 35 kg
	darunavir 800 mg orally once daily	Treatment-naïve or treatment-experienced with no darunavir resistance-associated substitutions weighing at least 40 kg

- Consult the Tybost drug label for adult dosing and further administration recommendations.
- Consult the prescribing information for atazanavir or darunavir for further administration rec