



Tybost[®] (cobicistat) – Expanded indication

- On August 22, 2019, the [FDA approved](#) Gilead's [Tybost \(cobicistat\)](#), to increase systemic exposure of [atazanavir](#) in combination with other antiretroviral agents in the treatment of human immunodeficiency virus (HIV)-1 infection in pediatric patients weighing at least 35 kg.
 - Tybost was previously approved for this indication in adults only.
 - Tybost is also approved to increase systemic exposure of [Prezista[®] \(darunavir\)](#) (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection in adults.
- The approval of Tybost for the expanded indication was based on an open-label study evaluating the pharmacokinetics, safety, and efficacy of Tybost coadministered with atazanavir in 14 pediatric patients ages 12 years and older with virologically suppressed HIV-1 infection.
 - Overall, 93% (13/14) of patients remained suppressed (HIV-1 RNA < 50 copies/mL), and 1 subject experienced virologic failure at week 48.
- The recommended dose of Tybost for the treatment of HIV-infection in pediatric patients is 150 mg orally once daily. Tybost should be used in combination with atazanavir 300 mg orally once daily.
- Refer to the Tybost drug label for adult and additional dosing recommendations.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.