

## Tivicay<sup>®</sup> (dolutegravir), Tivicay PD (dolutegravir) – Expanded indication, New formulation approval

- On June 12, 2020, the [FDA announced](#) the approval of [ViiV Healthcare's Tivicay \(dolutegravir\)](#) tablets and Tivicay PD (dolutegravir) tablets for suspension, in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults (treatment-naïve or -experienced) and in pediatric patients (treatment-naïve or -experienced but integrase strand transfer inhibitor [INSTI]-naïve) aged at least 4 weeks and weighing at least 3 kg.
  - Tivicay was previously approved for a similar indication in adults and in pediatric patients weighing at least 30 kg.
  - Tivicay PD is a newly approved formulation of dolutegravir.
- Tivicay is also approved in combination with [rilpivirine \(Edurant<sup>®</sup>\)](#) as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral agent.
- According to the Centers for Disease Control and Prevention, at the end of 2016, there were 2,238 children younger than 13 years old living with HIV in the U.S. and dependent areas, with 99 new HIV-1 infections diagnosed in this age group in 2017.
- The efficacy of Tivicay and Tivicay PD was established in IMPAACT P1093, an ongoing, open-label study evaluating the pharmacokinetic parameters, safety, tolerability, and efficacy of Tivicay and Tivicay PD in combination treatment regimens in 75 HIV-1-infected infants, children, and adolescents aged at least 4 weeks to 18 years. Virologic outcomes are included from patients who received either Tivicay tablets or Tivicay PD tablets for oral suspension as per the dosing recommendations for their weight band and who had reached week 24 or week 48.
  - At week 24, 62% of patients achieved HIV-1 RNA less than 50 copies per mL and 86% achieved HIV-1 RNA less than 400 copies per mL.
  - At week 48, 69% of subjects achieved HIV-1 RNA less than 50 copies per /mL and 79% achieved HIV-1 RNA less than 400 copies per mL.
- Tivicay and Tivicay PD are contraindicated in patients:
  - With previous hypersensitivity reaction to dolutegravir
  - Receiving [dofetilide](#) due to the potential for increased dofetilide plasma concentrations and the risk for serious and/or life-threatening events.
- Warnings and precautions for Tivicay and Tivicay PD include hypersensitivity reactions, hepatotoxicity, embryo-fetal toxicity, risk of adverse reactions or loss of virologic response due to drug interactions, immune reconstitution syndrome, and different formulations are not interchangeable.
- The most common adverse reactions of moderate to severe intensity and incidence at least 2% (in those receiving Tivicay in any one adult trial) with Tivicay and Tivicay PD use were insomnia, fatigue, and headache.

- The recommended weight-based oral dosage of Tivicay PD in pediatric patients weighing 3 to 14 kg (4 weeks and older, treatment-naïve or treatment-experienced but naïve to INSTI treatment) is described in the table below.

— Tivicay tablets should not be used in patients weighing 3 to 14 kg.

Body weight	Tivicay PD	
	Daily dosage	Number of 5-mg tablets
3 kg to less than 6 kg	5 mg once daily	1
6 kg to less than 10 kg	15 mg once daily	3
10 kg to less than 14 kg	20 mg once daily	4

- For pediatric patients weighing 14 kg or greater (4 weeks and older, treatment-naïve or treatment-experienced but naïve to INSTI treatment) administer either: Tivicay PD (preferred in pediatric patients weighing less than 20 kg) or Tivicay tablets.

— Tivicay and Tivicay PD are not bioequivalent and are not interchangeable on a milligram-per-milligram basis.

Body weight	Tivicay PD	
	Daily dosage	Number of 5-mg tablets
14 kg to less than 20 kg	25 mg once daily	5
20 kg and greater	30 mg once daily	6

Body weight	Tivicay	
	Daily dosage	Number of 5-mg tablets
14 kg to less than 20 kg	40 mg once daily	4 x 10-mg
20 kg and greater	50 mg once daily	1 x 50-mg

- Refer to the Tivicay drug label for adult dosing recommendations.
- ViiV Healthcare's launch plans for Tivicay PD are pending. Tivicay PD will be available as a 5 mg tablet for oral suspension.



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