

Edurant[®] (rilpivirine) – Expanded indication and new formulation

- On March 15, 2024, the [FDA announced](#) the approval of Janssen’s [Edurant and Edurant PED \(rilpivirine\)](#), in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in treatment-naïve patients 2 years of age and older and weighing at least 14 kg with HIV-1 RNA less than or equal to 100,000 copies/mL.
 - Previously, Edurant was approved for the same indication in patients 12 years of age and older.
- Edurant is also approved in combination with [Vocabria[®] \(cabotegravir\)](#), for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.
- In addition, the [FDA approved](#) Edurant PED 2.5 mg tablet for oral suspension.
- The approval of Edurant and Edurant PED for the expanded use was based on a single-arm, open-label study in 18 antiretroviral treatment-naïve HIV-1 infected pediatric subjects 6 to less than 12 years of age and weighing at least 17 kg. Patients were treated with Edurant and an investigator-selected background regimen containing two nucleoside reverse transcriptase inhibitors.
 - At week 48, the number of patients with HIV-1 RNA \leq 50 copies/mL was 13/18 (72%) while 3/18 (17%) patients had HIV-1 RNA \geq 50 copies/mL. Two out of the 18 patients had missing data at week 48.
- The safety and efficacy of Edurant and Edurant PED in treatment naïve pediatric subjects 2 to less than 6 years of age is supported by evidence from adequate and well-controlled studies of Edurant in adults with additional population pharmacokinetic data from adults and pediatric subjects 6 years and older.
- The recommended dose of Edurant and Edurant PED for the treatment of expanded indication in pediatric patients 2 years of age and older and weighing at least 14 kg is based on body weight and given orally once daily as shown in the chart below:

Body Weight (kg)	Edurant 25 mg Tablet	Edurant PED 2.5 mg Tablet for Oral Suspension	Total Daily Dose
14 kg to less than 20 kg	Not recommended	5 tablets once daily	12.5 mg Edurant PED once daily
20 kg to less than 25 kg	Not recommended	6 tablets once daily	15 mg Edurant PED once daily
Greater than or equal to 25 kg	1 tablet once daily	Not recommended	25 mg Edurant once daily

- Refer to the Edurant drug label for dosing for all its other indications.

- Janssen’s launch plans for Edurant PED are pending. Edurant PED will be available as a 2.5 mg tablet for oral suspension.



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