

Prezista® (darunavir) - Expanded Indication

- On July 18, 2016, <u>Janssen Therapeutics announced</u> the <u>FDA approval</u> of an expansion to the prescribing information for <u>Prezista (darunavir)</u> to include dosing recommendations for pregnant women with human immunodeficiency virus (HIV-1) and results from a study investigating the use of Prezista during pregnancy and the postpartum period.
- Prezista, co-administered with Norvir® (ritonavir), in combination with other antiretroviral (ARV) agents, is indicated for the treatment of HIV-1 infection in adult and pediatric patients 3 years of age and older.
- Approximately 8,500 women living with HIV give birth annually. Mother-to-child HIV transmission is the most common way young children become infected with HIV.
- The expanded indication for Prezista is based on an analysis of 34 pregnant women and available data from the antiretroviral pregnancy registry (APR).
 - Pharmacokinetic data demonstrate that exposure to darunavir and ritonavir at either 600 mg/100 mg twice daily or 800 mg/100 mg once daily as part of an ARV regimen was lower during pregnancy compared with the postpartum period.
 - Virologic response was preserved throughout the trial in both arms.
 - No mother to child transmission occurred in the infants born to the 29 patients who stayed on the ARV treatment through delivery.
 - Based on reports to the APR, there was no difference in rate of overall birth defects for darunavir compared with the background rate for major birth defects in a U.S. reference population.
- The recommended dose of Prezista in pregnant women is 600 mg taken orally with ritonavir 100 mg twice daily with food.
 - Prezista 800 mg taken with ritonavir 100 mg once daily should only be considered in certain pregnant patients who are already on a stable Prezista 800 mg with ritonavir 100 mg once daily regimen prior to pregnancy, are virologically suppressed (HIV-1 RNA < 50 copies/mL), and in whom a change to twice daily Prezista 600 mg with ritonavir 100 mg may compromise tolerability or compliance.</p>
- The Prezista prescribing information should be consulted for dosage recommendations for treatmentnaïve and treatment-experienced adults, and pediatric patients.



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