

Dolutegravir-Rilpivirine (*Juluca*)

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Drug Summary

Dolutegravir-rilpivirine is a two-drug, single-tablet regimen that may be used to replace an existing antiretroviral regimen in persons who have suppressed HIV RNA levels on a stable antiretroviral regimen for at least 6 months; the dolutegravir-rilpivirine two-drug regimen should only be used in persons with no history of antiretroviral treatment failure and no known mutations associated with resistance to either dolutegravir or rilpivirine. The primary use of dolutegravir-rilpivirine is likely to be as a nucleoside-reverse transcriptase inhibitor (NRTI)-sparing regimen for maintenance therapy in appropriate situations in persons with stable suppressed HIV. Note that dolutegravir-rilpivirine is not approved for use as initial antiretroviral therapy.

Key Clinical Trials

The [[SWORD-1](#)] and [[SWORD-2](#)] trials were phase 3, open-label, international trials with identical designs that evaluated the safety and efficacy of switching virologically suppressed individuals taking combination antiretroviral therapy regimen to the two-drug regimen of dolutegravir (50 mg once daily) plus rilpivirine (25 mg once daily). Enrollment required participants to have been taking the same combination antiretroviral regimen for at least 6 months with documented HIV RNA levels less than 50 copies/mL for at least 12 months. The baseline combination antiretroviral therapy was either a 3-drug regimen with a non-nucleoside reverse transcriptase inhibitor (54%) anchor drug, a three-drug regimen with an integrase inhibitor (20%) anchor drug, or a 4-drug regimen that had a protease inhibitor plus a boosting agent (26%) as the anchor. Individuals were required to be taking only their first or second antiretroviral regimen and were excluded if they had a history of virologic failure or hepatitis B infection. At week 48 after enrollment, in a pooled analysis of the data for SWORD-1 and SWORD-2, the same rate of virologic suppression (HIV RNA level less than 50 copies/mL) was observed in the two study arms: 95% (486/513) in the dolutegravir plus rilpivirine arm and 95% (485/511) in the arm that continued the standard antiretroviral regimen.

Adverse Effects

Adverse effects to dolutegravir are uncommon, and usually mild. Headaches, insomnia, and psychiatric symptoms have been reported, as have rash and hypersensitivity reaction. Dolutegravir inhibits tubular secretion of creatinine and may increase serum creatinine (average increase of 0.12 mg/dL); it has no effect on actual (measured) glomerular filtration rate (GFR). Creatinine elevation may occur in the early weeks after initiation of dolutegravir and does not worsen with time.

Rilpivirine is generally well tolerated, but adverse effects can include headache, insomnia, depression, rash, or elevated hepatic aminotransferase levels. Supratherapeutic doses of rilpivirine can cause QT prolongation; therefore, caution should be used when coadministering rilpivirine-containing therapy with other QT prolonging agents, and QT should be monitored in this setting.

Dolutegravir Safety Alert: On May 18, 2018, an [FDA Safety Alert](#) was posted that warned of potential serious neural tube birth defects in infants born to mothers who received dolutegravir at the time of becoming pregnant or early in the first trimester. On May 30, 2018, the HHS Antiretroviral Guideline Panels issued [Recommendations Regarding Dolutegravir](#) that address the use of dolutegravir in adults and adolescents with HIV who are pregnant or of child-bearing potential.

Use In Pregnancy

Note: On May 18, 2018, an [FDA Safety Alert](#) was posted that warned of potential serious neural tube birth defects in infants born to mothers who received dolutegravir at the time of becoming pregnant or early in the first trimester. On May 30, 2018, the HHS Antiretroviral Guideline Panels issued [Recommendations Regarding Dolutegravir](#) that address the use of dolutegravir in adults and adolescents with HIV who are pregnant or of child-bearing potential.

There are no recommendations for the use of the fixed-drug dolutegravir-rilpivirine in pregnancy and there are no data to support use of the 2-drug maintenance regimen dolutegravir-rilpivirine at any time during pregnancy.

- For additional information regarding the safety and toxicity of dolutegravir-abacavir-lamivudine in pregnancy see the HHS Perinatal Guidelines summaries on [Dolutegravir](#) and [Rilpivirine](#).

Key Drug Interactions

For complete information on dolutegravir-rilpivirine-related drug interactions, see the [Drug Interactions section in the Dolutegravir-Rilpivirine \(Juluca\) Prescribing Information](#).

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<https://www.hiv.uw.edu/page/treatment/drugs/dolutegravir-rilpivirine>