

Dolutegravir (*Tivicay*)

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Drug Summary

Dolutegravir is a widely used and very important medication both for initial antiretroviral therapy and for the treatment of persons with HIV drug resistance. It has high potency against susceptible virus, a high genetic barrier to drug resistance, excellent tolerability for most patients, no food requirements, and few significant drug interactions. Dosage adjustment is required if certain integrase mutations are present, or if certain interacting medications are given concurrently.

Key Clinical Trials

In antiretroviral therapy-naïve individuals with wild-type virus, dolutegravir plus either abacavir-lamivudine or tenofovir DF-emtricitabine has been shown to be noninferior to or superior to regimens of two NRTIs plus efavirenz [[SINGLE](#)], darunavir plus ritonavir [[FLAMINGO](#)], or raltegravir [[SPRING-2](#)]. In patients with HIV drug resistance to antiretroviral medications other than integrase inhibitors, use of dolutegravir (once daily) plus an optimized background regimen was more effective than a combination of raltegravir plus optimized background regimen [[SAILING](#)]. In patients with HIV resistance to the integrase inhibitors raltegravir or elvitegravir, dolutegravir was not effective if certain specific integrase mutations were present at baseline [[VIKING-3](#)].

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.

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.

The information in the May 30, 2018 HHS Antiretroviral Guideline Panels recommendations regarding dolutegravir should take priority over content listed below as outlined in the October 19, 2017 version in the HHS Perinatal Guidelines.

In the HHS Perinatal Guidelines section Recommendations for Use of Antiretroviral Drugs During Pregnancy (last updated October 19, 2017), **dolutegravir** plus a preferred Two NRTI Backbone and the single table regimen **dolutegravir**-abacavir-lamivudine are designated as Alternative Integrase Inhibitor Regimens in the category Alternative Initial Regimens in Pregnancy. Note that dolutegravir-abacavir-lamivudine should not be used in persons who test positive for HLA-B*5701.

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

Resistance

For a listing of the most common clinically significant mutations associated with dolutegravir (DTG) resistance, see the [INSTI Resistance Notes on the Stanford University HIV Drug Resistance Database](#).

Key Drug Interactions

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