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 patients 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.

Guidelines for use in Antiretroviral-Naïve Patients

In the July 14, 2016 version of the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, **dolutegravir** is designated as listed below for treatment-naïve patients:

RECOMMENDED Regimen Options

- **Dolutegravir**-abacavir-lamivudine—only for patients who are HLA-B*5701 negative (**AI**)
- **Dolutegravir** plus tenofovir disoproxil fumarate-emtricitabine (**AI**)
- **Dolutegravir** plus tenofovir alafenamide-emtricitabine (**AII**)

ALTERNATIVE Regimen Options

- NOT listed

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]. Based on promising preliminary results of dual maintenance therapy with dolutegravir and rilpivirine, a phase 3 program [SWORD-1] and [SWORD-2] is investigating the efficacy, safety, and tolerability of switching to dolutegravir plus rilpivirine in patients with virologic suppression on a standard three- or four-drug antiretroviral regimen; preliminary data from this program have shown the same (95%) virologic suppression rates in th switch and maintenance groups at week 48. Based on this data, an application for FDA approval of a dolutegravir-rilpivirine combination tablet has been submitted.

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.

Use In Pregnancy

In the October 26, 2016 version of the HHS Perinatal Guidelines, **dolutegravir** is designated in the category of Insufficient Data in Pregnancy to Recommend Routine Use in Initial Regimens for Antiretroviral-Naïve Women. This recommendation is based on the limited data on dolutegravir in pregnancy.

- 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.

No Clinical Trials Available

We do not currently have any clinical trials on file for this drug.

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The most up to date version of this content may be obtained from:
https://www.hiv.uw.edu/page/treatment/drugs/dolutegravir