Elvitegravir (Vitekta)

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Drug Summary

Elvitegravir is available as a single medication, but in clinical practice is almost always used as a component of a single tablet regimen—either elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine or elvitegravir-cobicistat-tenofovir disoproxil fumarate (DF)-emtricitabine. Elvitegravir requires pharmacokinetic “boosting” with cobicistat or ritonavir, and the accompanying booster has drug interactions with many medications. Elvitegravir should be taken with food. Failure of a regimen containing elvitegravir often results in drug resistance mutations that confer resistance to both elvitegravir and raltegravir; cross-resistance to dolutegravir also may be present, particularly with more extensive elvitegravir resistance.

Key Clinical Trials

In antiretroviral-naïve individuals with wild-type virus, elvitegravir has only been studied in fixed-dose single tablet regimens: elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine or elvitegravir-cobicistat-tenofovir DF-emtricitabine. These two coformulations have been shown to be equivalent to each other [GS-292-0104/GS-292-0111 (Study 104/111)] in terms of HIV suppression. The coformulated single tablet regimen elvitegravir-cobicistat-tenofovir DF-emtricitabine was shown to be noninferior to 2 NRTIs plus efavirenz [GS-236-0102 (Study 102)] or two NRTIs plus atazanavir plus ritonavir [GS-236-0103 (Study 103)] in treatment-naïve patients. In treatment-experienced patients who have virologic suppression, switching to elvitegravir-cobicistat-tenofovir DF-emtricitabine maintained virologic suppression in patients switching from ritonavir-boosted PIs [STRATEGY-PI] or NNRTIs [STRATEGY-NNRTI]. In carefully selected patients with drug-resistant HIV, but no previous exposure to integrase inhibitors, elvitegravir plus a ritonavir-boosted PI and at least 1 other active ARV resulted in equivalent rates of HIV control as raltegravir plus comparable background regimens [GS-183-0145]. In an open label trial that enrolled patients with extensive resistance and at least two prior treatment failures, patients had excellent virologic success with a switch to a convenient two pill, once a day regimen of elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine plus darunavir [GS-292-0119 (Study 119)].


**Adverse Effects**

Elvitegravir is generally very well tolerated and the most common adverse effect is diarrhea. Uncommon adverse effects include rash, abdominal pain, psychiatric disorders, and elevated hepatic aminotransferase levels. Note that cobicistat (usually given with elvitegravir) inhibits tubular secretion of creatinine, which causes an increase in serum creatinine and a decrease in estimated glomerular filtration rate (eGFR). Cobicistat, however, does not affect actual (measured) GFR. During the first 4 to 8 weeks after initiating cobicistat, patients typically have an elevation in serum creatinine of about 0.10 to 0.14 mg/dL and these changes typically stabilize by 8 weeks. Cobicistat-related increases in serum creatinine of up to 0.4 mg/dL are considered acceptable; increases above this level warrant further evaluation.

**Use In Pregnancy**

In the HHS Perinatal Guidelines section Recommendations for Use of Antiretroviral Drugs During Pregnancy (last updated October 19, 2017), elvitegravir, elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine, and elvitegravir-cobicistat-tenofovir DF-emtricitabine all are in the category Not Recommended for Initial ART in Pregnancy in the category because of concerns of virologic breakthrough due to lowered levels of elvitegravir and cobicistat in the second and third trimesters of pregnancy.

For additional information regarding the safety and toxicity of elvitegravir in pregnancy see the HHS Perinatal Guidelines summary on Elvitegravir.

**Resistance**

For a listing of the most common clinically significant mutations associated with elvitegravir (EVG) resistance, see the INSTI Resistance Notes on the Stanford University HIV Drug Resistance Database.

**Key Drug Interactions**

For complete information on elvitegravir-related drug interactions, see the Drug Interactions section in the Elvitegravir (Vitekta) Prescribing Information.