

Elvitegravir-Cobicistat-Tenofovir disoproxil fumarate-Emtricitabine (*Stribild*)

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Drug Summary

Elvitegravir-cobicistat-tenofovir disoproxil fumarate (DF)-emtricitabine is a single-tablet regimen used predominantly for initial therapy. Elvitegravir-cobicistat-tenofovir DF-emtricitabine is generally well tolerated, but has some limitations, including gastrointestinal side effects caused by cobicistat and risk of renal toxicity and bone mineral density loss secondary to tenofovir DF. Initiation of elvitegravir-cobicistat-tenofovir DF-emtricitabine is not recommended in patients with an estimated creatinine clearance less than 70 mL/min. The cobicistat component also has significant drug interactions with certain other antiretroviral medications and with many non-HIV medications. The single tablet regimen elvitegravir-cobicistat-tenofovir DF-emtricitabine differs from the similar newer fixed dose combination elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine only by the tenofovir component. In many clinical settings, elvitegravir-cobicistat-tenofovir DF-emtricitabine is being replaced by elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine due to potential for reduced long term renal and bone adverse effects with the latter drug.

Key Clinical Trials

In treatment-naïve adults, elvitegravir-cobicistat-tenofovir DF-emtricitabine showed equivalent rates of virologic suppression when compared with efavirenz-tenofovir DF-emtricitabine [[GS-236-0102 \(Study 102\)](#)] and with atazanavir plus ritonavir plus tenofovir-DF-emtricitabine [[GS-236-0103 \(Study 103\)](#)]. In treatment-naïve adult women, elvitegravir-cobicistat-tenofovir DF-emtricitabine demonstrated superior virologic suppression rates, largely driven by better tolerability, when compared with atazanavir plus ritonavir plus tenofovir-DF-emtricitabine [[WAVES](#)]. Elvitegravir-cobicistat-tenofovir DF-emtricitabine and elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine were also compared as initial therapy, and study participants had equivalent virologic suppression rates, though the tenofovir alafenamide-containing regimen was favorable in terms of renal and bone adverse effects [[GS-292-0104/GS-292-0111 \(Study 104/111\)](#)]. Studies have also shown that patients with no history of virologic failure or HIV drug resistance can switch from a virologically suppressive regimen of tenofovir DF-emtricitabine plus an NNRTI [[STRATEGY-NNRTI](#)], tenofovir DF-emtricitabine plus a boosted protease inhibitor [[STRATEGY-PI](#)], or tenofovir DF-emtricitabine plus

raltegravir, to elvitegravir-cobicistat-tenofovir DF-emtricitabine and maintain virologic suppression [[GS-236-0123](#)].

Adverse Effects

Elvitegravir-cobicistat-tenofovir DF-emtricitabine can cause fatigue, headache, malaise, nausea, and diarrhea. The emtricitabine and elvitegravir components of the regimen generally cause few side effects. The gastrointestinal side effects, which are among the most common adverse events with this regimen, are likely caused by the cobicistat component. Tenofovir DF can cause decreased bone mineral density and renal toxicity, including proximal tubular injury. Elvitegravir-cobicistat-tenofovir DF-emtricitabine should be discontinued if the patient's estimated creatinine clearance decreases to less than 50 mL/min. Because elvitegravir-cobicistat-tenofovir DF-emtricitabine contains two medications (tenofovir DF and emtricitabine) that have activity against hepatitis B virus, discontinuation of elvitegravir-cobicistat-tenofovir DF-emtricitabine in patients with chronic hepatitis B infection can potentially cause a severe exacerbation of hepatitis B.

Use In Pregnancy

In the HHS Perinatal Guidelines section Recommendations for Use of Antiretroviral Drugs During Pregnancy (last updated October 19, 2017), **elvitegravir-cobicistat-tenofovir DF-emtricitabine** is designated in the category of Not Recommended for Initial ART in Pregnancy, 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-cobicistat-tenofovir DF-emtricitabine in pregnancy see the HHS Perinatal Guidelines summaries on [Elvitegravir](#), [Cobicistat](#), [Tenofovir DF](#), and [Emtricitabine](#).
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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](#).

For a listing of the most common clinically significant mutations associated with tenofovir DF (TDF) and/or emtricitabine (FTC) resistance, see the [NRTI Resistance Notes on the Stanford University HIV Drug Resistance Database](#).

Key Drug Interactions

For complete information on elvitegravir-cobicistat-tenofovir disoproxil fumarate-emtricitabine-related drug interactions, see the [Drug Interactions section in the Elvitegravir-Cobicistat-Tenofovir disoproxil fumarate-Emtricitabine \(Stribild\) Prescribing Information](#).
