



PDL NEW DRUG REVIEW

Proprietary Name: Stribild®

Common Name: elvitegravir, cobicistat, emtricitabine, tenofovir, disoproxil

PDL Category: Antiretrovirals

<u>Comparable Products</u>	<u>Recommended Drug List Status</u>
Isentress	Recommended
Truvada	Recommended

Summary

Indications and Usage: Complete regimen for the treatment of HIV-1 infection in adults who are antiretroviral treatment-naïve. Stribild® is a complete treatment regimen for HIV-1 infection, and thus it should not be administered with other antiretroviral medications for the treatment of HIV-1 infection. This is a pregnancy category B medication. The safety and efficacy of use in children under the age of 18 have not been established.

Drug-Drug Interactions: Elvitegravir and cobicistat are both metabolized by CYP3A4, and cobicistat is also metabolized to a minor extent by CYP2D6. A substantial list of significant drug interactions for which dosage changes are recommended can be found in the prescribing information.

Dosage Forms: Capsule-shaped tablets: 150mg of elvitegravir, 150mg of cobicistat, 200mg of emtricitabine, and 300mg of tenofovir disoproxil fumarate (tenofovir DF, equivalent to 245mg tenofovir disoproxil).

Recommended Dosage: Take one tablet once daily with food. Dose adjustment is not required in those with mild or moderate hepatic impairment. Use is not recommended in those with severe hepatic impairment. Use should not be initiated in those with an estimated creatinine clearance (CrCl) <70ml/min. Furthermore, treatment should be discontinued if estimated CrCl declines to <50ml/min during treatment.

Common Adverse Drug Reactions: The most common adverse events reported with Stribild® included ocular icterus (<1%), diarrhea (12%), flatulence (2%), nausea (16%), fatigue (5%), headache (7%), somnolence (1%), dizziness (3%), rash (3%), abnormal dreams (9%), and insomnia (3%).

Cobicistat inhibits secretion of creatinine in the renal tubules which will lead to a 0.1 to .02 mg/dl increase in serum creatinine that does NOT correspond to an actual decrease in GFR, but will lead to a decrease in *estimated* GFR. More significant elevations in serum creatinine may indicate actual renal toxicity which can also occur.

Contraindications: The concomitant use with drugs that are highly dependent on CYP3A4 for clearance, and for which increased plasma levels are associated with serious and/or life threatening events. These drugs include alfuzosin, rifampin, dihydroergotamine, ergotamine, methylergonovine, cisapride, St. John's wort, lovastatin, simvastatin, pimozone, sildenafil when dosed as Revatio for the treatment of PAH, triazolam, and midazolam (oral).

Manufacturer: Gilead Sciences

