PDF created November 20, 2018, 6:20 pm

Fosamprenavir *(Lexiva)*

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Drug Summary

Fosamprenavir is a prodrug of amprenavir, a previously licensed but now discontinued protease inhibitor. Fosamprenavir has largely been replaced by newer antiretroviral anchor drugs that involve fewer pills or lower rates of side effects. For treatment-naïve patients, fosamprenavir can be administered unboosted twice daily, boosted by ritonavir once daily, or boosted by ritonavir twice daily; for protease inhibitor-experienced individuals, twice-daily dosing with ritonavir boosting is recommended. Virologic failure of a regimen containing fosamprenavir can lead to resistance mutations that decrease the efficacy of darunavir. Fosamprenavir contains a sulfonamide moiety so should be used with caution in patients with a known sulfonamide allergy. In the current treatment era, clinicians generally have a low threshold to change fosamprenavir to a currently recommended anchor drug in order to lower the risk of adverse events and to reduce pill burden.

Key Clinical Trials

Fosamprenavir has primarily been studied in treatment-naïve individuals. In this setting, and combined with abacavir and lamivudine, both unboosted twice-daily fosamprenavir [NEAT (APV30001)] and once-daily boosted fosamprenavir [SOLO (APV30002)] showed similar virologic efficacy as nelfinavir with the same NRTIs; the boosted fosamprenavir regimen was associated with a lower incidence of diarrhea as compared to nelfinavir. Twice-daily boosted fosamprenavir showed similar rates of virologic suppression and tolerability as twice-daily lopinavir-ritonavir, both with abacavir plus lamivudine [KLEAN]. For treatment-naïve individuals, once-daily ritonavir-boosted fosamprenavir was found to be noninferior in terms of virologic efficacy as compared to twice-daily boosted fosamprenavir (both with abacavir-lamivudine) [APV109141]. In addition, once-daily fosamprenavir boosted with 100 mg ritonavir was found to be equivalent to 200 mg ritonavir boosting [LESS].

Adverse Effects

Side effects of fosamprenavir may include rash, nausea, diarrhea, elevated lipid levels, hyperglycemia, and increases in hepatic aminotransferase levels. Fosamprenavir contains a sulfonamide moiety and thus should be used cautiously in individuals with a known sulfonamide allergy.

Use In Pregnancy

In the HHS Perinatal Guidelines section Recommendations for Use of Antiretroviral Drugs During Pregnancy (last updated October 19, 2017), **fosamprenavir** is designated as Not Recommended for Initial ART in Pregnancy.

- For additional information regarding the safety and toxicity of fosamprenavir in pregnancy see the HHS Perinatal Guidelines summary on Fosamprenavir.

Resistance

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

Key Drug Interactions

For complete information on fosamprenavir-related drug interactions, see the Drug Interactions section in the Fosamprenavir (*Lexiva*) Prescribing Information.