Tenoforvir DF (Viread)

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Drug Summary

Tenoforvir disoproxil fumarate (tenoforvir DF; TDF) has been a cornerstone of initial and salvage antiretroviral regimens for more than a decade, based on its excellent virologic efficacy and a better safety profile than older nucleoside reverse transcriptase inhibitors (NRTIs). Tenoforvir DF can be a component of regimens for treatment of HIV, for treatment of hepatitis B virus in persons coinfected with HIV, and for postexposure prophylaxis (PEP). The fixed-dose combination tenoforvir DF-emtricitabine is the first and only FDA-approved medication for HIV preexposure prophylaxis (PrEP). Tenoforvir DF is generally well tolerated, has few drug-drug interactions, and is included in several single-tablet combinations. Its principal limitations are potential nephrotoxicity, including a proximal tubule wasting syndrome, and amplified bone mineral density loss. Use of tenoforvir DF has diminished with the availability of tenoforvir alafenamide, a medication with similar virologic efficacy but less potential for long-term adverse renal and bone effects. Most clinicians in the United States favor tenoforvir alafenamide over tenoforvir DF for these reasons. The dosage of tenoforvir DF must be adjusted in the setting of impaired renal function. Tenoforvir DF has a favorable mild lipid-lowering effect.

Key Clinical Trials

Initial approval of tenoforvir DF was based on a study of treatment-experienced individuals in which the addition of tenoforvir DF to the current regimen led to a decrease in viral load and increase in CD4 count as compared to placebo [GS-99-907]. Tenoforvir DF has been a part of numerous studies for treatment-naïve and treatment-experienced persons. In a trial that randomized treatment-naïve participants to abacavir-lamivudine or tenoforvir DF-emtricitabine, combined with efavirenz or ritonavir-boosted atazanavir, use of tenoforvir DF-emtricitabine resulted in fewer virologic failures than abacavir-lamivudine in the subset of participants with baseline HIV RNA greater than 100,000 copies/mL [ACTG 5202]. Tenoforvir DF, in combination with emtricitabine, has been studied for treatment-naïve individuals as a part of combination therapy with anchor drugs from multiple classes; it has proven effective when combined with dolutegravir [SPRING-2], elvitegravir-cobicistat [Study 102 and Study 103], raltegravir [STARTMRK], boosted darunavir [ARTEMIS], efavirenz [GS-934], and rilpivirine [ECHO]. Tenoforvir DF, either alone or in combination with emtricitabine, has also shown to be effective in several preexposure prophylaxis trials, including those with serodifferent heterosexual couples [Partners PrEP], men who have sex with men and transgender
women [iPrEx], and persons who inject drugs [Bangkok Tenofovir].

**Adverse Effects**

Tenofovir DF can cause renal and bone adverse effects, including renal proximal tubule injury and reduction in bone mineral density. For example, some patients have developed the proximal tubular disorder Fanconi's syndrome, characterized by renal loss of protein, phosphate, bicarbonate, and glucose. Tenofovir DF can also cause fatigue, malaise, nausea, diarrhea and other gastrointestinal complaints.

**Resistance**

For a listing of the most common clinically significant mutations associated with tenofovir df (TDF, tenofovir disoproxil fumarate) resistance, see the NRTI Resistance Notes on the Stanford University HIV Drug Resistance Database.

**Key Drug Interactions**

For complete information on tenofovir df-related drug interactions, see the Drug Interactions section in the Tenofovir DF (Viread) Prescribing Information.