Tenofovir disoproxil fumarate-Emtricitabine (Truvada)

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Drug Summary

In the past decade, tenofovir disoproxil fumarate (DF)-emtricitabine has been the principal nucleoside reverse transcriptase inhibitor (NRTI) backbone for initial and salvage antiretroviral regimens; it is also the NRTI backbone component of three single-tablet regimens efavirenz-tenofovir DF-emtricitabine, rilpivirine-tenofovir DF-emtricitabine, and elvitegravir-cobicistat-tenofovir DF-emtricitabine. Tenofovir DF-emtricitabine is the recommended NRTI backbone for the treatment of chronic hepatitis B virus infection in persons coinfected with HIV and for most postexposure prophylaxis (PEP) regimens. It is also the first and only FDA-approved medication for HIV preexposure prophylaxis (PrEP). Tenofovir DF-emtricitabine is generally well tolerated, has few drug interactions, and has a more favorable lipid profile than other NRTIs. On the negative side, long-term use of tenofovir DF may cause renal adverse effects and greater bone mineral density loss than other antiretroviral agents. The future use of tenofovir DF-emtricitabine may diminish with the availability of tenofovir alafenamide-emtricitabine, a medication with similar virologic efficacy but less potential to cause long-term adverse renal and bone effects. The dosage of both tenofovir DF and emtricitabine must be adjusted in the setting of impaired renal function.

Guidelines for use in Antiretroviral-Naïve Patients

In the October 17, 2017 version of the HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV, tenofovir DF-emtricitabine is designated as listed below for treatment-naïve patients:

**Recommended Initial Regimens for Most People with HIV**

- Dolutegravir plus tenofovir DF-emtricitabine (AI)
- Elvitegravir-cobicistat-tenofovir DF-emtricitabine (AI)
- Raltegravir plus tenofovir DF-emtricitabine (AI)
Recommended Initial Regimens in Certain Clinical Situations

- Darunavir plus ritonavir plus tenofovir DF-emtricitabine (AI)
- Darunavir-cobicistat plus tenofovir DF-emtricitabine (AII)
- Atazanavir-cobicistat plus tenofovir DF-emtricitabine (BI)
- Atazanavir plus ritonavir plus tenofovir DF-emtricitabine (BI)
- Efavirenz plus tenofovir DF-emtricitabine (BI)
- Rilpivirine-tenofovir DF-emtricitabine (BI), if HIV RNA less than 100,000 copies/mL and CD4 count greater than 200 cells/mm³

Key Clinical Trials

Tenofovir DF-emtricitabine has been a part of numerous studies for treatment-naïve and treatment-experienced persons. In a trial that randomized participants to abacavir-lamivudine or tenofovir DF-emtricitabine, combined with efavirenz or ritonavir-boosted atazanavir, use of tenofovir DF-emtricitabine resulted in fewer virologic failures in the subset of participants with baseline HIV RNA greater than 100,000 copies/mL [ACTG 5202]. Tenofovir DF-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 [GS-236-0102 (Study 102)] and [GS-236-0103 (Study 103)], raltegravir [STARTMRK], boosted darunavir [ARTEMIS], efavirenz [GS-934], and rilpivirine [ECHO (C209)]. Tenofovir DF-emtricitabine has also shown to be effective in several preexposure prophylaxis trials, including those with serodiscordant heterosexual men and women [Partners PrEP] and men who have sex with men and transgender women [iPrEx].

Adverse Effects

The emtricitabine component of tenofovir DF-emtricitabine infrequently causes significant short-term or long-term adverse effects. Hyperpigmentation of the palms and soles has been reported with emtricitabine and the risk is higher in persons with darker pigmented skin. The primary adverse effects concerns with tenofovir DF-emtricitabine are those caused by tenofovir DF and include a renal proximal tubule wasting syndrome and a reduction in bone mineral density. Other NRTIs do not cause similar nephrotoxicity or as much bone mineral density loss. More general side effects may include fatigue, malaise, nausea, diarrhea, and rash. Tenofovir DF has a mild lipid-lowering effect.

Use In Pregnancy

In the HHS Perinatal Guidelines section Recommendations for Use of Antiretroviral Drugs During Pregnancy (last updated October 19, 2017), tenofovir DF-emtricitabine is designated as a Preferred Two-NRTI Backbone in the category Preferred Initial Regimens in Pregnancy.

- For additional information regarding the safety and toxicity of tenofovir DF and emtricitabine in pregnancy see the HHS Perinatal Guidelines summaries on Tenofovir DF and Emtricitabine.
**Resistance**

For a listing of the most common clinically significant mutations associated with tenofovir disoproxil fumarate-emtricitabine (TDF-FTC, Tenofovir DF-Emtricitabine) resistance, see the [NRTI Resistance Notes on the Stanford University HIV Drug Resistance Database](https://www.hiv.uw.edu/page/treatment/drugs/tenofovir-disoproxil-fumarate-emtricitabine)

**Key Drug Interactions**

For complete information on tenofovir disoproxil fumarate-emtricitabine-related drug interactions, see the [Drug Interactions section in the Tenofovir disoproxil fumarate-Emtricitabine (Truvada) Prescribing Information](https://www.hiv.uw.edu/page/treatment/drugs/tenofovir-disoproxil-fumarate-emtricitabine)

**No Clinical Trials Available**

We do not currently have any clinical trials on file for this drug.

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