Emtricitabine (Emtriva)

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Drug Summary

Emtricitabine is a component of the nucleoside reverse transcriptase inhibitor (NRTI) backbone of many initial and salvage antiretroviral regimens. Advantages of emtricitabine are high tolerability, few drug interactions, and coformulation as part of a number of combination tablets and single-tablet regimens. Emtricitabine is highly similar to lamivudine and the two are generally considered to be equivalent; they are used interchangeably but never together (since these two drugs have no significant additive potency and have equivalent resistance profiles). Emtricitabine has a relatively low barrier to resistance and if a patient develops virologic failure while taking a regimen that includes emtricitabine, the first NRTI resistance mutation to occur is generally an emtricitabine resistance mutation. Emtricitabine is also a component of the only FDA approved medication for HIV preexposure prophylaxis, tenofovir DF-emtricitabine. Although emtricitabine does not have an FDA approval to treat hepatitis B infection, it has significant activity against hepatitis B and it has been widely used in combination with tenofovir DF to treat hepatitis B in persons coinfected with HIV. When concomitantly treating HIV and hepatitis B, emtricitabine should be used in combination with another antiretroviral agent effective against hepatitis B, since emtricitabine monotherapy leads to high rates of hepatitis B resistance and failure. The dose of emtricitabine should be reduced in the setting of renal insufficiency.

Guidelines for use in Antiretroviral-Naïve Patients

In the July 14, 2016 version of the DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, emtricitabine is classified as listed below for treatment-naïve patients:

RECOMMENDED Regimen Options

- Dolutegravir plus tenofovir DF-emtricitabine (AI)
- Dolutegravir plus tenofovir alafenamide-emtricitabine (AII)
- Elvitegravir-cobicistat-tenofovir DF-emtricitabine (AI)
Elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine (AI)
Raltegravir plus tenofovir DF-emtricitabine (AI)
Raltegravir plus tenofovir alafenamide-emtricitabine (AII)
Darunavir plus ritonavir plus tenofovir DF-emtricitabine (AI)
Darunavir plus ritonavir plus tenofovir alafenamide-emtricitabine (AII)

ALTERNATIVE Regimen Options
Efavirenz-tenofovir DF-emtricitabine (BI)
Efavirenz plus tenofovir alafenamide-emtricitabine (BII)
Rilpivirine-tenofovir DF-emtricitabine- only if HIV RNA less than 100,000 copies/ml and CD4 count greater than 200 cells/mm$^3$ (BI)
Rilpivirine-tenofovir alafenamide-emtricitabine-only if HIV RNA less than 100,000 copies/ml and CD4 count greater than 200 cells/mm$^3$ (BII)
Darunavir plus ritonavir plus tenofovir DF-emtricitabine (BI)
Darunavir plus ritonavir plus tenofovir alafenamide-emtricitabine (BII)
Atazanavir-cobicistat plus tenofovir DF-emtricitabine (BI)
Atazanavir-cobicistat plus tenofovir alafenamide-emtricitabine (BII)
Darunavir-cobicistat plus tenofovir DF-emtricitabine (BII)
Darunavir-cobicistat plus tenofovir alafenamide-emtricitabine (BII)

NOTE: lamivudine may be substituted for emtricitabine, or vice versa, if a non-fixed dose combination is desired

Key Clinical Trials
An early, randomized, double-blind, double-dummy trial compared emtricitabine to stavudine (each given with didanosine and efavirenz); the emtricitabine arm demonstrated higher virologic efficacy and tolerability [FTC-301A]. Another trial of individuals with stable virologic suppression on lamivudine-containing regimens randomized participants to continue lamivudine or switch from lamivudine to emtricitabine; rates of virologic suppression were equivalent in the two arms [FTC-303/FTC-350]. Since that time, emtricitabine has been shown to be effective in initial therapy in combination with tenofovir DF or tenofovir alafenamide plus a number of different anchor drugs, including efavirenz [GS-934], rilpivirine [ECHO (C209)] and [THRIVE (C215)], darunavir [FLAMINGO], raltegravir [STARTMRK], or dolutegravir [SPRING-2], or elvitegravir [GS-236-0103 (Study 103)] and [GS-292-0104/GS-292-0111 (Study 104/111)]. In addition, emtricitabine has been studied in combination with tenofovir DF for HIV preexposure prophylaxis [iPrEx] and [Partners PrEP].

Use In Pregnancy

In the October 26, 2016 version of the HHS Perinatal Guidelines for Initial Combination Regimens in Antiretroviral-Naïve Pregnant Women, 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 emtricitabine in pregnancy see the HHS Perinatal Guidelines Emtricitabine (Emtriva) Summary.
**Resistance**

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

**Key Drug Interactions**

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

**No Clinical Trials Available**

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