

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 (M184V). 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 virus (HBV) infection, it has significant activity against HBV and it has been widely used in combination with tenofovir DF (and tenofovir alafenamide) to treat HBV in persons coinfecting with HIV. When concomitantly treating HIV and HBV, emtricitabine should be used in combination with another antiretroviral agent effective against HBV, since emtricitabine monotherapy leads to high rates of HBV resistance and failure.

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](#) and [THRIVE](#)], darunavir [[FLAMINGO](#)], raltegravir [[STARTMRK](#)], dolutegravir [[SPRING-2](#)], elvitegravir [[Study 103](#) and [Study 104/111](#)], and bictegravir [[GS-380-1489](#) and [GS-380-1490](#)]. In addition, emtricitabine has been studied in combination

with tenofovir DF for HIV preexposure prophylaxis [[iPrEx](#) and [Partners PrEP](#)].

Adverse Effects

Overall, emtricitabine is well tolerated. It may rarely cause side effects such as headache, diarrhea, nausea, or rash. It may be difficult to distinguish the cause of these side effects, since they are more commonly caused by other antiretrovirals in a regimen.

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. Tenofovir alafenamide-**emtricitabine** is designated Insufficient Data in Pregnancy to Recommend Routine Use in Initial Regimens for ART-Naive Women.

- For additional information regarding the safety and toxicity of emtricitabine in pregnancy see the HHS Perinatal Guidelines Emtricitabine ([Emtriva](#)) Summary.
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Class and Mechanism

Overall, emtricitabine tends to be well tolerated with few side effects. Side effects may include headache, diarrhea, nausea, or rarely rash; these may be difficult to distinguish from other antiretrovirals in a regimen. Hyperpigmentation of the palms and soles may occur; the risk is higher in persons with darker skin pigmentation.

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](#).

Key Drug Interactions

For complete information on emtricitabine-related drug interactions, see the [Drug Interactions section in the Emtricitabine \(Emtriva\) Prescribing Information](#).
