Lamivudine *(Epivir)*

Table of Contents

- Lamivudine *Epivir* Editor's Summary
- Drug Summary
- Guidelines for use in Antiretroviral-Naïve Patients
- Key Clinical Trials
- Adverse Effects
- Use In Pregnancy
- Resistance
- Key Drug Interactions

Drug Summary

Lamivudine has been extensively used for treatment of HIV infection since the mid-1990s, in both initial therapy and salvage therapy. Currently it is most frequently used as a component of the combination tablets dolutegravir-abacavir-lamivudine or abacavir-lamivudine. Two other coformulations with lamivudine (lamivudine-zidovudine and lamivudine-zidovudine-abacavir) have fallen out of favor due to toxicity from the zidovudine component of these combinations. Lamivudine is well-tolerated, rarely causes adverse effects, and has few drug interactions. Lamivudine is nearly identical to emtricitabine and the two generally are 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). Either lamivudine or emtricitabine is included as one of two nucleoside analogues in all antiretroviral regimens recommended for initial therapy. Lamivudine has a relatively low barrier to resistance and if a patient develops virologic failure while taking a regimen that includes lamivudine, the first NRTI resistance mutation to occur is generally a lamivudine resistance mutation. Lamivudine has activity against hepatitis B, though it should only be used in combination with another anti-hepatitis B antiretroviral for treatment of hepatitis B because lamivudine monotherapy leads to high rates of hepatitis B resistance and treatment failure. The lamivudine dose should be reduced in the setting of renal insufficiency.

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, lamivudine is designated as listed below for treatment-naïve patients:

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

- Dolutegravir-abacavir-lamivudine *(AI)*—if HLA-B*5701*negative
Recommended Initial Regimens in Certain Clinical Situations

- Darunavir-cobicistat plus abacavir-**lamivudine** (BII)—if HLA-B*5701 negative
- Darunavir plus ritonavir plus abacavir-**lamivudine** (BII)—if HLA-B*5701 negative
- Atazanavir-cobicistat plus abacavir-**lamivudine** (CIII)—if HLA-B*5701 negative and HIV RNA less than 100,000 copies/mL
- Atazanavir plus ritonavir plus abacavir-**lamivudine** (CI)—if HLA-B*5701 negative and HIV RNA less than 100,000 copies/mL
- Raltegravir plus abacavir-**lamivudine** (CII)—if HLA-B*5701 negative and HIV RNA less than 100,000 copies/mL
- Lopinavir-ritonavir plus **lamivudine** (CI)

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

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Key Clinical Trials

In the early era of antiretroviral therapy, before initial 3-drug ART became the standard of care, lamivudine was added to other NRTIs, such as a zidovudine or stavudine, for dual therapy and this strategy demonstrated immunologic benefit as compared to continued zidovudine or stavudine monotherapy [NUCA 3001], [NUCA 3002], and [ACTG 306]. Subsequently, lamivudine was studied in combination with another NRTI plus an early protease inhibitor or NNRTI for 3-drug therapy and found to be effective at achieving virologic suppression; for example, lamivudine was studied in combination with zidovudine and efavirenz [GS-934], as well as with abacavir and either ritonavir-boosted fosamprenavir [KLEAN] or lopinavir [HEAT]. More recently, lamivudine was shown to be safe and effective in combination therapy with abacavir and the integrase inhibitors raltegravir [SHIELD] or dolutegravir [SINGLE]. It is also being studied as part of 2-drug initial or simplification regimens, such as lamivudine plus dolutegravir PADDLE, or lamivudine plus a boosted protease inhibitor [GARDEL], [OLE], [SALT] and [AtLaS].

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Adverse Effects

Overall, lamivudine tends to be 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.

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Use In Pregnancy

In the HHS Perinatal Guidelines section Recommendations for Use of Antiretroviral Drugs During Pregnancy (last updated October 19, 2017), abacavir-**lamivudine** is designated as a Preferred Two-NRTI Backbone in the category Preferred Initial Regimens in Pregnancy; abacavir-lamivudine should only be used in women who are HLAB*5701 negative. In addition, abacavir-lamivudine is not recommended in combination with either efavirenz or atazanavir boosted with ritonavir if the
pretreatment HIV RNA is greater than 100,000 copies/mL. Tenofovir DF plus lamivudine is a Preferred Two-NRTI Backbone in the category Preferred Initial Regimens in Pregnancy. Zidovudine-lamivudine is an Alternative Two-NRTI Backbone in the category Alternative Initial Regimens in Pregnancy.

- For additional information regarding the safety and toxicity of lamivudine in pregnancy see the HHS Perinatal Guidelines Lamivudine (Epivir) Summary.

## Resistance

For a listing of the most common clinically significant mutations associated with lamivudine (3TC) resistance, see the NRTI Resistance Notes on the Stanford University HIV Drug Resistance Database.

## Key Drug Interactions

For complete information on lamivudine-related drug interactions, see the Drug Interactions section in the Lamivudine (Epivir) Prescribing Information.

## No Clinical Trials Available

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