lamivudine (Epivir)

WHAT IS LAMIVUDINE?

Lamivudine, also known as 3TC, (brand name Epivir) is a drug used as part of antiretroviral therapy (ART). The FDA approved lamivudine in 1995 as an antiretroviral drug (ARV) for people with HIV infection. Generic versions have been approved under PEPFAR. Lamivudine is manufactured by ViiV Healthcare.

Lamivudine is a type of drug called a non-nucleoside reverse transcriptase inhibitor (NNRTI). NNRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, lamivudine may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Lamivudine does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE LAMIVUDINE?

Lamivudine is a prescription HIV medicine used in combination with other ARVS to treat HIV infection in adults and children 3 months old and older. The safety and effectiveness of lamivudine has not been established in children under 3 months of age. Lamivudine has not been carefully studied in the elderly (65 years of age and older).

All people living with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE LAMIVUDINE?

Do not take lamivudine if you are allergic to lamivudine or any of the ingredients in this drug.

Do not take lamivudine if you take medications that contain sorbitol.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING LAMIVUDINE?

Before you take lamivudine, tell your healthcare provider if you:

- Have or have had liver problems, including hepatitis B virus (HBV) or hepatitis C virus (HCV) infection.
- Have kidney problems.
- Have diabetes (each 15-mL dose (150 mg) of lamivudine oral solution contains 3 grams of sucrose).

Talk to your healthcare provider if you are pregnant or plan to become pregnant during treatment with lamivudine. Taking lamivudine during pregnancy has not been associated with an increased risk of birth defects. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with lamivudine. Do not breastfeed if you take lamivudine. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS LAMIVUDINE TAKEN?

Lamivudine is taken by mouth as a tablet or oral solution. The recommended dosage of lamivudine for adults is 300 mg daily taken orally as either 150 mg twice daily or 300 mg once daily, in combination with other ARVs. If lamivudine is taken by a person with both HIV and HBV, the dosage for HIV therapy should be used as part of an appropriate combination regimen. The recommended dosage of lamivudine for children varies based on the child's weight and age. Your healthcare provider will determine the correct dosage.

Lamivudine can be taken without or without food.

You need to take lamivudine in combination with other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

Lamivudine is also available in several combination medications. Combination HIV medicines contain 2 or more HIV medicines from 1 or more drug classes.

- abacavir/dolutegravir/lamivudine (Triumeq)
- abacavir/lamivudine (Epzicom)
- dolutegravir/lamivudine (Dovato)
- doravirine/lamivudine/tenofovir DF (Delstrigo)
- efavirenz/lamivudine/tenofovir DF (Symfi and Symfi Lo)
- lamivudine/tenofovir (Cimduo)

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of lamivudine in adults are headaches, nausea, generally not feeling well, fatigue, nasal signs and symptoms, diarrhea, and cough. The most common side effects of lamivudine in children include fever and cough.

Lamivudine can cause serious side effects including:

Worsening of HBV infection Your healthcare provider will test you for HBV infection before you start treatment with lamivudine. If you have HBV infection and take lamivudine, your HBV infection may get worse (flare-up) if you stop taking lamivudine. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not run out of lamivudine. Refill your prescription or talk to your healthcare provider before your lamivudine is all gone. Do not stop taking lamivudine without first talking to your healthcare provider. If you stop taking lamivudine, your healthcare provider will need to check your health often and do blood tests regularly to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking lamivudine.

Resistant HBV infection. If you have HIV and HBV, HBV can change (mutate) during your treatment with lamivudine and become harder to treat (resistant).

Too much lactic acid in your blood (lactic acidosis). Lactic acidosis is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- Feel very weak or tired
- Unusual (not normal) muscle pain
- Trouble breathing
- Stomach pain with nausea and vomiting
- Feel cold, especially in your arms and legs
- Feel dizzy or light-headed
- Have a fast or irregular heartbeat

Severe liver problems. In rare cases, severe liver problems can happen that can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). Tell your healthcare provider right away if you get these symptoms:

- Your skin or the white part of your eyes turns yellow (jaundice)
- Dark or "tea-colored" urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea
- Pain, aching, or tenderness on the right side of your stomach area

You may be more likely to get lactic acidosis or serious liver problems if you are assigned female at birth (AFAB) or very overweight (obese).

Risk of inflammation of the pancreas (pancreatitis). Children may be at risk for developing pancreatitis during treatment with lamivudine if they have taken nucleoside analogue medicines in the past (NRTIs or NNRTIs), have a history of pancreatitis, or have other risk factors for pancreatitis. Call your healthcare provider right away if your child develops signs and symptoms of pancreatitis including severe upper stomach-area pain, with or without nausea and vomiting. Your healthcare provider may tell you to stop giving lamivudine to your child if their symptoms and blood test results show that your child may have pancreatitis.

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting lamivudine.

These are not all the possible side effects of lamivudine. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES LAMIVUDINE REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug or substance in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take lamivudine with other medicines.

Co-administration of lamivudine and sorbitol may decrease lamivudine concentrations. When possible, avoid chronic coadministration.

MORE INFORMATION

Download the full Prescribing Information, including Patient Information leaflet

Check out the ViiV Healthcare Patient Assistance Program

Get a ViiV Healthcare Savings Card

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