

PATIENT INFORMATION

Lamivudine (la miv' ue deen) Oral Solution, USP

What is the most important information I should know about lamivudine oral solution?

Lamivudine oral solution can cause serious side effects, including:

- **Worsening of hepatitis B virus in people who have HIV-1 infection.** If you have HIV-1 (Human Immunodeficiency Virus type 1) and hepatitis B virus (HBV) infection, your HBV may get worse (flare-up) if you stop taking lamivudine oral solution. A “flare-up” is when your HBV infection suddenly returns in a worse way than before. Worsening liver disease can be serious and may lead to death.
 - Do not run out of lamivudine oral solution. Refill your prescription or talk to your healthcare provider before your lamivudine oral solution is all gone.
 - Do not stop lamivudine oral solution without first talking to your healthcare provider.
 - If you stop taking lamivudine oral solution, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver.

 - **Resistant Hepatitis B Virus (HBV).** If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with lamivudine oral solution and become harder to treat (resistant).
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What is lamivudine oral solution?

Lamivudine oral solution is a prescription medicine used together with other antiretroviral medicines to treat Human Immunodeficiency Virus (HIV-1) infection.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

Lamivudine oral solution (used to treat HIV-1 infection) contains a higher dose of the same active ingredient (lamivudine) than is in the medicine EPIVIR-HBV tablets and oral solution (used to treat HBV). If you have both HIV-1 and HBV, you should not use EPIVIR-HBV to treat your infections.

The safety and effectiveness of lamivudine oral solution have not been established in children under 3 months of age.

Who should not take lamivudine oral solution?

Do not take lamivudine oral solution if you are allergic to lamivudine or any of the ingredients in lamivudine oral solution. See the end of this Patient Information leaflet for a complete list of ingredients in lamivudine oral solution.

What should I tell my healthcare provider before taking lamivudine oral solution?

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

- have or have had liver problems, including hepatitis B or C virus infection.
 - have kidney problems.
 - have diabetes. Each 15-mL dose (150 mg) of lamivudine oral solution contains 3 grams of sucrose.
 - are pregnant or plan to become pregnant. Taking lamivudine oral solution during pregnancy has not been associated with an increased risk of birth defects. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
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Pregnancy Registry. There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take lamivudine oral solution.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
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Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medications interact with lamivudine oral solution. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. You can ask your healthcare provider or pharmacist for a list of medicines that interact with lamivudine oral solution.

Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take lamivudine oral solution with other medicines.

How should I take lamivudine oral solution?

- **Take lamivudine oral solution exactly as your healthcare provider tells you to take it.**
 - If you miss a dose of lamivudine oral solution, take it as soon as you remember. Do not take 2 doses at the same time or take more than what your healthcare provider tells you to take.
 - Stay under the care of a healthcare provider during treatment with lamivudine oral solution.
 - Lamivudine oral solution may be taken with or without food.
 - For children 3 months and older, your healthcare provider will prescribe a dose of lamivudine oral solution based on your child's body weight.
 - Do not run out of lamivudine oral solution. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.
 - If you take too much lamivudine oral solution, call your healthcare provider or go to the nearest hospital emergency room right away.
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What are the possible side effects of lamivudine oral solution?

- **Lamivudine oral solution can cause serious side effects including:**
- **See "What is the most important information I should know about lamivudine oral solution?"**
- **Build-up of an acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take lamivudine oral solution. Lactic acidosis is a serious medical emergency that can cause death. **Call your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:**
 - 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
- **Serious liver problems** can happen in people who take lamivudine oral solution. In some cases, these serious liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:**
 - 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 female or very overweight (obese).

- **Risk of inflammation of the pancreas (pancreatitis).** Children may be at risk for developing pancreatitis during treatment with lamivudine oral solution if they:
 - have taken nucleoside analogue medicines in the past
 - have a history of pancreatitis
 - 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 oral solution to your child if their symptoms and blood test results show that your child may have pancreatitis.

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after you start taking lamivudine oral solution.

The most common side effects of lamivudine oral solution in adults include:

- headache
- nausea
- generally not feeling well
- tiredness
- nasal signs and symptoms
- diarrhea
- cough

The most common side effects of lamivudine oral solution in children include fever and cough.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of lamivudine oral solution. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store lamivudine oral solution?

- Store lamivudine oral solution at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep bottles of lamivudine oral solution tightly closed.

Keep lamivudine oral solution and all medicines out of the reach of children.

General information about the safe and effective use of lamivudine oral solution.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use lamivudine oral solution for a condition for which it was not prescribed. Do not give lamivudine oral solution to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about lamivudine oral solution that is written for health professionals.

For more information, call Chartwell RX, LLC. at 1-845-232-1683.

What are the ingredients in lamivudine oral solution?

Active ingredient: lamivudine

Inactive ingredients: alcohol (5% v/v), edetate disodium, artificial strawberry flavor, citric acid (anhydrous), methylparaben, propylene glycol, propylparaben, sodium citrate (dihydrate), sucrose (200 mg per mL) and purified water.

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Manufactured for:

Chartwell RX, LLC.

Congers, NY 10920

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This Patient Information has been approved by the U.S. Food and Drug Administration.