

PATIENT INFORMATION  
Lamivudine Tablets (HBV)  
(la miv' ue deen)

What is the most important information I should know about lamivudine tablets (HBV)?

Lamivudine tablets (HBV) can cause serious side effects, including:

- **Worsening liver disease.** Your hepatitis B infection may become worse after stopping treatment with lamivudine tablets (HBV). Worsening liver disease can be serious and may lead to death. If you stop treatment with lamivudine tablets (HBV), your healthcare provider will need to check your health and do blood tests to check your liver for at least several months after you stop taking lamivudine tablets (HBV).
- **Risk of HIV-1 resistance in people with unknown HIV-1 infection or in people with untreated HIV-1 infection.** If you have or get HIV-1 (Human Immunodeficiency Virus type 1) that is not being treated with medicines while taking lamivudine tablets (HBV), the HIV-1 virus may develop resistance to certain HIV-1 medicines and become harder to treat.

Your healthcare provider should offer you counseling and testing for HIV-1 infection before you start treatment for hepatitis B with lamivudine tablets (HBV) and during treatment.

Lamivudine tablets (HBV) contain a lower dose of lamivudine than other medicines that contain lamivudine and are used to treat HIV-1 infection.

- **Resistant Hepatitis B Virus (HBV).** The hepatitis B virus can change (mutate) during your treatment with lamivudine tablets (HBV) and become harder to treat (resistant). If this happens, your liver disease can become worse and may lead to death. Tell your healthcare provider right away if you have any new symptoms.
- For more information about side effects, see "What are the possible side effects of lamivudine tablets (HBV) ?"

What is lamivudine tablets (HBV)?

Lamivudine tablets (HBV) is a prescription medicine used to treat long-term (chronic) hepatitis B virus (HBV) when the disease is progressing and there is liver swelling (inflammation).

It is not known if lamivudine tablets (HBV) is safe and effective in:

- people with chronic HBV who have a severely damaged liver that is unable to work properly (decompensated liver disease)
- people with HIV-1, hepatitis C virus , or hepatitis D (delta) virus
- people who have had a liver transplant
- children with chronic HBV less than 2 years of age

Lamivudine tablets (HBV) does not stop you from spreading HBV to others by sex, sharing needles, or being exposed to your blood. Avoid doing things that can spread HBV infection to others.

Do not take lamivudine tablets (HBV):

- If you are allergic to lamivudine or any of the ingredients in lamivudine tablets (HBV). See the end of this Patient Information leaflet for a complete list of ingredients in lamivudine tablets (HBV).

Before taking lamivudine tablets (HBV), tell your healthcare provider about all of your medical conditions, including if you:

- have HIV-1 infection
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if lamivudine tablets (HBV) will harm your unborn baby.

**Pregnancy Registry.** There is a pregnancy registry for women who take antiviral 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. Lamivudine can pass into your breast milk and may harm your baby. You and your healthcare provider should decide if you will take lamivudine tablets (HBV) or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with lamivudine tablets (HBV). **Keep a list of your medicines to show your healthcare provider and pharmacist.**

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with lamivudine tablets (HBV).
- **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 tablets (HBV) with other medicines.

Lamivudine tablets (HBV) should not be taken if you also take other medicines that contain lamivudine or emtricitabine.

How should I take lamivudine tablets (HBV)?

- Take lamivudine tablets (HBV) exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking lamivudine tablets (HBV) without talking with your healthcare provider
- If you miss a dose of lamivudine tablets (HBV) , 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 tablets (HBV)
- Lamivudine tablets (HBV) may be taken with or without food.
- Your healthcare provider may prescribe a lower dose if you have problems with your kidneys.
- For children 2 to 17 years of age, your healthcare provider will prescribe a dose of lamivudine tablets (HBV) based on your child's body weight.
- Tell your healthcare provider if you or your child has trouble swallowing tablets.
- If you take too much lamivudine tablets (HBV), call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of lamivudine tablets (HBV)?

- Lamivudine tablets (HBV) may cause serious side effects, including:
- See "What is the most important information I should know about lamivudine tablets (HBV)?"

**Too much lactic acid in your blood (lactic acidosis).** Lactic acidosis is a serious medical emergency that can lead to death. **Call your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:**

- o feel very weak or tired
- o unusual (not normal) muscle pain
- o trouble breathing
- o stomach pain with nausea and vomiting
- o feel cold, especially in your arms and legs
- o feel dizzy or light-headed
- o have a fast or irregular heartbeat

**Severe liver problems.** Severe liver problems can happen in people who take lamivudine tablets (HBV) or similar medicines. In some cases, these severe liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis) when you take lamivudine tablets (HBV).

**Call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:**

- o your skin or the white part of your eyes turns yellow (jaundice)
- o dark or "tea-colored" urine
- o light-colored stools (bowel movements)
- o loss of appetite for several days or longer
- o nausea
- o pain, aching, or tenderness on the right side of your stomach area

**You may be more likely to get lactic acidosis or severe liver problems if you are female or very overweight (obese).**

**The most common side effects of lamivudine tablets (HBV) include** ear, nose, and throat infections; sore throat; and diarrhea.

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 tablets (HBV).

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 tablets (HBV)?

- Store lamivudine tablets (HBV) at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep lamivudine tablets (HBV) and all medicines out of the reach of children.**

**General information about the safe and effective use of lamivudine tablets (HBV)**

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

You can ask your pharmacist or healthcare provider for information about lamivudine tablets (HBV) that is written for health professionals.

What are the ingredients in lamivudine tablets (HBV)?

**Active ingredient:** lamivudine

**Inactive ingredients:** anhydrous lactose, crospovidone, colloidal silicon dioxide, ferric oxide red, ferric oxide yellow, hypromellose, hydroxypropyl cellulose, magnesium stearate, polyethylene glycol and titanium dioxide.

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

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APOTEX INC.  
LAMIVUDINE TABLETS (HBV)  
100 mg

**Manufactured by**  
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Toronto, Ontario  
Canada M9L 1T9

**Manufactured for**  
Apotex Corp.  
Weston, Florida  
USA 33326

Revised: February 2022  
Revision: 7