Each film coated tablet contains 100 mg of lamivudine USP

USUAL DOSAGE: See prescribing information for Dosage and Administration

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]

Do not use if printed safety seal under cap is broken or missing

US Contact Number: 866 495 1995

Lamivudine Tablets (HBV)

100 mg

Pharmacist: Dispense the Patient Information Leaflet provided separately to each patient

Rx only

60 Tablets

Manufactured by HETERO LABS LIMITED
Unit V, Polepally, Jadcherla, Mahaboob Nagar 509 301, India

Reference ID: 3429747
Each film coated tablet contains 100 mg of lamivudine USP.

**USUAL DOSAGE:** See prescribing information for Dosage and Administration.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Do not use if printed safety seal under cap is broken or missing.

**US Contact Number:** 866-495-1995

Mfg. Lic. No.: 50/MN/AP/2009/F/G

Manufactured by:
HETERO™
HETERO LABS LIMITED
Unit V, Polepally, Jadcherla,
Mahaboob Nagar 509 301, India.
2023406

Reference ID: 3429747
Lamivudine Tablets (HBV) 100 mg

Each film coated tablet contains 100 mg of lamivudine USP.

USUAL DOSAGE: See prescribing information for Dosage and Administration.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

US Contact Number: 866-495-1995

Manufactured by:
HETERO LABS LIMITED
Unit V, Polepally, Jadacherla,
Mahaboob Nager - 509 301, India.

Rx only
100 (10 x 10) Unit Dose Tablets

PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.

NDC 68554-5052-4

Reference ID: 3429747
PATIENT INFORMATION
Lamivudine Tablets (HBV)

Read this Patient Information before you start taking lamivudine tablets (HBV) and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

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

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

- Build-up of an acid in your blood (lactic acidosis). Lactic acidosis can happen in some people who take lamivudine tablets (HBV) or similar (nucleoside analogs) medicines. Lactic acidosis is a serious medical emergency that can lead to death.

Lactic acidosis can be hard to identify early because the symptoms could seem like symptoms of other health problems. 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

Severe liver problems. Severe liver problems can happen in people who take lamivudine tablets (HBV) or similar medicines. In some cases these 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 of liver problems:

- your skin or the white part of your eyes turns yellow (jaundice)
- dark “tea-colored” urine
- light-colored bowel movements (stools)
- loss of appetite for several days or longer
- nausea
- stomach pain

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight, or have been taking nucleoside analogue medicines for a long time.

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 that is not being treated with medicines while taking lamivudine tablets (HBV), the HIV virus may develop resistance to certain HIV 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. See “What should I tell my healthcare provider?” for a list of medicines you should not take with lamivudine tablets (HBV).

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.

What are lamivudine tablets (HBV)?

Lamivudine tablet (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).

- Lamivudine tablets (HBV) will not cure HBV.
- Lamivudine tablets (HBV) may lower the amount of HBV in your body.
- Lamivudine tablets (HBV) may lower the ability of HBV to multiply and infect new liver cells.
- Lamivudine tablets (HBV) may improve the condition of your liver.
- The long-term benefits of taking lamivudine tablets (HBV) for treatment of chronic hepatitis B infection are not known.

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 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 share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

A vaccine is available to protect people at risk for becoming infected with HBV. You can ask your healthcare provider for information about this vaccine.

Who should not take lamivudine tablets (HBV)?

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 leaflet for a complete list of ingredients in lamivudine tablets (HBV).
What should I tell my healthcare provider before taking lamivudine tablets (HBV)?

Before you take lamivudine tablets (HBV), tell your healthcare provider if you:

- have HIV-1 infection
- have kidney problems
- have any other medical condition
- 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.

Do not take lamivudine tablets (HBV) if you also take:

- other medicines that contain lamivudine (COMBIVIR®, EPIVIR®, EPZICOM®, TRIZIVIR®)
- medicines that contain emtricitabine (ATRIPLA®, COMPLERA®, EMTRIVA®, STRIBILD®, TRUVADA®)

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.
- Lamivudine tablet (HBV) is taken 1 time each day.
- 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 the right dose of lamivudine tablets (HBV) based on your child’s body weight.
- Take lamivudine tablets (HBV) by mouth, with or without food.
- Tell your healthcare provider if you have 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.
- It is important to stay under your healthcare provider’s care while taking lamivudine tablets (HBV). Tell your healthcare provider about any new symptoms that you have.

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)?”

The most common side effects of lamivudine tablets (HBV) include:

- ear, nose, and throat infections
- sore throat
- 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). For more information, ask your healthcare provider or pharmacist.

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.

If you would like more information, talk with your healthcare provider. You can as 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, USP

Inactive ingredients:

Lamivudine tablets (HBV): crosopovidone, isomalt, isopropyl alcohol, magnesium stearate and methylene chloride. The tablets are coated with Opadry Pink containing hypromellose, iron oxide red, polyethylene glycol, polysorbate 80, titanium dioxide and yellow iron oxide.

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Revised: December 2013