



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use lamivudine tablets (HBV) safely and effectively. See full prescribing information for lamivudine tablets (HBV).

LAMIVUDINE Tablets (HBV) for oral use
Initial U.S. Approval: 1995

WARNING: RISK OF LACTIC ACIDOSIS, EXACERBATIONS OF HEPATITIS B UPON DISCONTINUATION OF LAMIVUDINE TABLETS (HBV), AND RISK OF HIV-1 RESISTANCE IF LAMIVUDINE TABLETS (HBV) IS USED IN PATIENTS WITH UNRECOGNIZED OR UNTREATED HIV-1 INFECTION

- See full prescribing information for complete boxed warning
Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues. Suspend treatment if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity occur. (5.1)
Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued anti-hepatitis B therapy (including lamivudine tablets (HBV)). Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment. (5.2)
Lamivudine tablets (HBV) contain a lower dose of the same active ingredient (lamivudine) as EPVIR tablets and oral solution used to treat HIV-1 infection. HIV-1 resistance may emerge in chronic hepatitis B patients with unrecognized or untreated HIV-1 infection because the lamivudine dosage in lamivudine tablets (HBV) is subtherapeutic and monotherapy is inappropriate for the treatment of HIV-1 infection. HIV counseling and testing should be offered to all patients before beginning treatment with lamivudine tablets (HBV) and periodically during treatment. (5.3)

INDICATIONS AND USAGE

- Lamivudine tablets (HBV) are a nucleoside analogue reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B virus infection associated with evidence of hepatitis B viral replication and active liver inflammation. (1)

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: RISK OF LACTIC ACIDOSIS, EXACERBATIONS OF HEPATITIS B UPON DISCONTINUATION OF LAMIVUDINE TABLETS (HBV), AND RISK OF HIV-1 RESISTANCE IF LAMIVUDINE TABLETS (HBV) IS USED IN PATIENTS WITH UNRECOGNIZED OR UNTREATED HIV-1

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FULL PRESCRIBING INFORMATION

WARNING: RISK OF LACTIC ACIDOSIS, EXACERBATIONS OF HEPATITIS B UPON DISCONTINUATION OF LAMIVUDINE TABLETS (HBV), AND RISK OF HIV-1 RESISTANCE IF LAMIVUDINE TABLETS (HBV) IS USED IN PATIENTS WITH UNRECOGNIZED OR UNTREATED HIV-1

Lactic Acidosis and Severe Hepatomegaly

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination, including lamivudine tablets (HBV). Suspend treatment if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity occur [see Warnings and Precautions (5.1)].

Exacerbations of Hepatitis B Upon Discontinuation of Lamivudine Tablets (HBV)

Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued anti-hepatitis B therapy (including lamivudine tablets (HBV)). Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy. If appropriate, initiation of anti-hepatitis B therapy may be warranted [see Warnings and Precautions (5.2)].

Risk of HIV-1 Resistance if Lamivudine Tablets (HBV) Is Used in Patients With Unrecognized or Untreated HIV-1 Infection

Lamivudine tablets (HBV) are not approved for the treatment of HIV-1 infection because the lamivudine dosage in lamivudine tablets (HBV) is subtherapeutic and monotherapy is inappropriate for the treatment of HIV-1 infection. HIV-1 resistance may emerge in chronic hepatitis B-infected patients with unrecognized or untreated HIV-1 infection. Counseling and testing should be offered to all patients before beginning treatment with lamivudine tablets (HBV) and periodically during treatment [see Warnings and Precautions (5.3)].

1 INDICATIONS AND USAGE

Lamivudine tablets (HBV) are indicated for the treatment of chronic hepatitis B virus (HBV) infection associated with evidence of hepatitis B viral replication and active liver inflammation [see Clinical Studies (14.1, 14.2)].

The following points should be considered when initiating therapy with lamivudine tablets (HBV):

- Due to high rates of resistance development in treated patients, initiation of treatment with lamivudine tablets (HBV) should only be considered when the use of an alternative antiviral agent with a higher genetic barrier to resistance is not available or appropriate.
Lamivudine tablets (HBV) have not been evaluated in patients co-infected with HIV, hepatitis C virus (HCV), or hepatitis delta virus.
Lamivudine tablets (HBV) have not been evaluated in liver transplant recipients or in patients with chronic hepatitis B virus infection with decompensated liver disease.
Lamivudine tablets (HBV) have not been evaluated in pediatric patients younger than 2 years of age with chronic HBV infection.

2 DOSAGE AND ADMINISTRATION

2.1 HIV Counseling and Testing

HIV counseling and testing should be offered to all patients before beginning treatment with lamivudine tablets (HBV) and periodically during treatment because of the risk of emergence of resistant-HIV-1 and limitation of treatment options if lamivudine tablets (HBV) is prescribed to treat chronic hepatitis B infection in a patient who has unrecognized HIV-1 infection or acquires HIV-1 infection during treatment [see Warnings and Precautions (5.3)].

2.2 Dosage in Adult Patients

The recommended oral dosage of lamivudine tablets (HBV) is 100 mg once daily.

2.3 Dosage in Pediatric Patients

The recommended oral dosage of lamivudine tablets (HBV) for pediatric patients aged 2 to 17 years is 3 mg per kg once daily up to a maximum daily dosage of 100 mg. The oral solution formulation should be prescribed for patients requiring a dosage less than 100 mg or if unable to swallow tablets.

2.4 Dosage Adjustment in Adult Patients With Renal Impairment

Dosage recommendations for adult patients with reduced renal function are provided in Table 1 [see Clinical Pharmacology (12.3)].

Table 1. Dosage of Lamivudine Tablets (HBV) in Adult Patients With Renal Impairment

Table with 2 columns: Creatinine Clearance (mL/min) and Recommended Dosage of Lamivudine Tablets (HBV). Rows include >=50, 30-49, 15-29, 5-14, and <5 mL/min.

Following correction of the dosage for renal impairment, no additional dosage modification of lamivudine tablets (HBV) is required after routine (4-hour) hemodialysis or peritoneal dialysis [see Clinical Pharmacology (12.3)].

There are insufficient data to recommend a specific dosage of lamivudine tablets (HBV) in pediatric patients with renal impairment.

2.5 Important Administration Instructions

- Lamivudine tablets (HBV) may be administered with or without food.
The tablets may be used interchangeably [see Clinical Pharmacology (12.3)].
The oral solution should be used for doses less than 100 mg.
Lamivudine tablets (HBV) should not be used with other medications that contain lamivudine or medications that contain emtricitabine [see Warnings and Precautions (5.4)].

2.6 Assessing Patients During Treatment

Patients should be monitored regularly during treatment by a physician experienced in the management of chronic hepatitis B. During treatment, combinations of such events such as return of persistently elevated ALT, increasing levels of HBV DNA over time after an initial decline below assay limit, progression of clinical signs or symptoms of hepatic disease, and/or worsening of hepatic necroinflammatory findings may be considered as potentially reflecting loss of therapeutic response. Such observations should be taken into consideration when determining the advisability of continuing therapy with lamivudine tablets (HBV).

DOSAGE AND ADMINISTRATION

- Adult patients: 100 mg, once daily. (2.2)
Pediatric patients aged 2 to 17 years: 3 mg per kg once daily up to 100 mg once daily. Prescribe oral solution for pediatric patients requiring less than 100 mg daily. (2.3)
Patients with renal impairment: Doses of lamivudine tablets (HBV) must be adjusted in accordance with renal function. (2.4)
Lamivudine tablets (HBV) should not be used with other medications that contain lamivudine or emtricitabine. (2.5)

DOSAGE FORMS AND STRENGTHS

- Tablets: 100 mg (3)

CONTRAINDICATIONS

Patients with previously demonstrated clinically significant hypersensitivity (e.g., anaphylaxis) to any of the components of the products. (4)

WARNINGS AND PRECAUTIONS

- Lamivudine tablets (HBV) should not be used with other medications that contain lamivudine or with medications that contain emtricitabine. (5.4)
Emergence of Resistance-Associated HBV Substitutions: Monitor ALT and HBV DNA levels during lamivudine treatment to aid in treatment decisions if emergence of viral mutants or loss of therapeutic response is suspected. (2.6, 5.5)

ADVERSE REACTIONS

- The most common reported adverse reactions in those receiving lamivudine tablets (HBV) (incidence greater than or equal to 10% and reported at a rate greater than placebo) were ear, nose and throat infections, sore throat, and diarrhea. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Hetero Labs Limited at 866-495-1995 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

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*Sections or subsections omitted from the full prescribing information are not listed.

The optimal duration of treatment, the durability of HBeAg seroconversions occurring during treatment, and the relationship between treatment response and long-term outcomes such as hepatocellular carcinoma or decompensated cirrhosis are not known.

3 DOSAGE FORMS AND STRENGTHS

- Lamivudine tablets (HBV): 100 mg are pink colored, capsule shaped, biconvex, film coated tablets, debossed with '37' on one side and '1' on the other side.

4 CONTRAINDICATIONS

Lamivudine tablets (HBV) are contraindicated in patients who have experienced a previous hypersensitivity reaction (e.g., anaphylaxis) to lamivudine or to any component of the tablets.

5 WARNINGS AND PRECAUTIONS

5.1 Lactic Acidosis and Severe Hepatomegaly With Steatosis

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination, including lamivudine tablets (HBV) and other antiretrovirals. A majority of these cases have been in women. Obesity and prolonged nucleoside exposure may be risk factors. Most of these reports have described patients receiving nucleoside analogues for treatment of HIV infection, but there have been reports of lactic acidosis in patients receiving lamivudine for hepatitis B. Particular caution should be exercised when administering lamivudine tablets (HBV) to any patient with known risk factors for liver disease; however, cases have also been reported in patients with no known risk factors. Treatment with lamivudine tablets (HBV) should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations).

5.2 Exacerbation of Hepatitis After Discontinuation of Treatment

Clinical and laboratory evidence of exacerbations of hepatitis have occurred after discontinuation of lamivudine tablets (HBV) (these have been primarily detected by serum ALT elevations, in addition to the re-emergence of HBV DNA commonly observed after stopping treatment; see Table 4 for more information regarding frequency of posttreatment ALT elevations) [see Adverse Reactions (6.1)]. Although most events appear to have been self-limited, fatalities have been reported in some cases. The causal relationship of hepatitis exacerbation after discontinuation of lamivudine tablets (HBV) has not been clearly established. Patients should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment with lamivudine tablets (HBV). There is insufficient evidence to determine whether re-initiation of lamivudine tablets (HBV) alters the course of posttreatment exacerbations of hepatitis.

5.3 Risk of HIV-1 Resistance if Lamivudine Tablets (HBV) Is Used in Patients With Unrecognized or Untreated HIV-1 Infection

Lamivudine tablets (HBV) contain a lower lamivudine dose than the lamivudine dose in the following drugs used to treat HIV-1 infection:

- EPVIR® tablets and oral solution,
COMBIVIR® (lamivudine/zidovudine) tablets,
EPZICOM® (abacavir sulfate and lamivudine) tablets, and
TRIZIVIR® (abacavir, lamivudine, and zidovudine) tablets.

The formulation and dosage of lamivudine in lamivudine tablets (HBV) are not approved for patients co-infected with HBV and HIV. If a decision is made to administer lamivudine to such patients, the higher dosage indicated for HIV therapy should be used as part of an appropriate combination regimen, and the prescribing information for EPVIR, COMBIVIR, EPZICOM, or TRIZIVIR, as well as for lamivudine tablets (HBV), should be consulted. HIV counseling and testing should be offered to all patients before beginning lamivudine tablets (HBV) and periodically during treatment because of the risk of rapid emergence of resistant HIV and limitation of treatment options if lamivudine tablets (HBV) is prescribed to treat chronic hepatitis B in a patient who has unrecognized or untreated HIV-1 infection or acquires HIV-1 infection during treatment.

5.4 Coadministration With Other Medications Containing Lamivudine or Emtricitabine

Do not coadminister lamivudine tablets (HBV) with other lamivudine-containing products including EPVIR (lamivudine), COMBIVIR (lamivudine/zidovudine), EPZICOM (abacavir/lamivudine), or TRIZIVIR (abacavir/lamivudine/zidovudine).

Do not coadminister lamivudine tablets (HBV) with emtricitabine-containing products including ATRIPLA® (efavirenz/emtricitabine/tenofovir disoproxil fumarate), COMPLERA® (rilpivirine/emtricitabine/tenofovir disoproxil fumarate), EMTRIVA® (emtricitabine), STRIBILD® (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate), or TRUVADA® (emtricitabine/tenofovir disoproxil fumarate).

5.5 Emergence of Resistance-Associated HBV Substitutions

In controlled clinical trials, YMDD-mutant HBV was detected in subjects with on-lamivudine tablets (HBV) re-emergence of HBV DNA after an initial decline below the solution-hybridization assay limit [see Microbiology (12.4)]. Subjects treated with lamivudine tablets (HBV) (adults and children) with YMDD-mutant HBV at 52 weeks showed diminished treatment responses in comparison with subjects treated with lamivudine tablets (HBV) without evidence of YMDD substitutions, including the following: lower rates of HBeAg seroconversion and HBeAg loss (no greater than placebo recipients), more frequent return of positive HBV DNA, and more frequent ALT elevations. In the controlled trials, when subjects developed YMDD-mutant HBV, they had a rise in HBV DNA and ALT from their own previous on-treatment levels. Progression of hepatitis B, including death, has been reported in some subjects with YMDD-mutant HBV, including subjects from the liver transplant setting and from other clinical trials. In clinical practice, monitoring of ALT and HBV DNA levels during treatment with lamivudine tablets (HBV) may aid in treatment decisions if emergence of viral mutants is suspected.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Lactic acidosis and severe hepatomegaly with steatosis [see Warnings and Precautions (5.1)].
Exacerbation of hepatitis B after discontinuation of treatment [see Warnings and Precautions (5.2)].
Risk of emergence of resistant HIV-1 infection [see Warnings and Precautions (5.3)].
Risk of emergence of resistant HBV infection [see Warnings and Precautions (5.4)].

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse Reactions in Clinical Trials of Adults With Chronic Hepatitis B Virus Infection: Clinical adverse reactions (regardless of investigator's causality assessment) reported in greater or equal to 10% of subjects who received lamivudine tablets (HBV) and reported at a rate greater than placebo are listed in Table 2.

Table 2. Clinical Adverse Reactions* Reported in >=10% of Subjects who Received Lamivudine Tablets (HBV) for 52 to 68 Weeks and at an Incidence Greater than Placebo (Trials 1 to 3)

Table with 3 columns: Adverse Event, Lamivudine Tablets (HBV) (n = 332), and Placebo (n = 200). Rows include Ear, Nose, and Throat; Gastrointestinal; and Diarrhea.

* Includes adverse events regardless of severity and causality assessment.

Specified laboratory abnormalities reported in subjects who received lamivudine tablets (HBV) and reported at a rate greater than in subjects who received placebo are listed in Table 3.

Table 3. Frequencies of Specified Laboratory Abnormalities Reported During Treatment at a Greater Frequency in Subjects Treated with Lamivudine Tablets (HBV) Than With Placebo (Trials 1 to 3)†

Table with 3 columns: Test (Abnormal Level), Lamivudine Tablets (HBV), and Placebo. Rows include Serum Lipase >=2.5 x ULN, CPK >=7 x baseline, and Platelets <50,000/mm³.

† Includes subjects treated for 52 to 68 weeks.

‡ Includes observations during and after treatment in the 2 placebo-controlled trials that collected this information.

ULN = Upper limit of normal.

In subjects followed for up to 16 weeks after discontinuation of treatment, posttreatment ALT elevations were observed more frequently in subjects who had received lamivudine tablets (HBV) than in subjects who had received placebo. A comparison of ALT elevations between Weeks 52 and 68 in subjects who discontinued lamivudine tablets (HBV) at Week 52 and subjects in the same trials who received placebo throughout the treatment course is shown in Table 4.

Table 4. Posttreatment ALT Elevations With No Active-Treatment Follow-up (Trials 1 and 3)

Table with 3 columns: Abnormal Value, Lamivudine Tablets (HBV)†, and Placebo†. Rows include ALT >=2 x baseline value, ALT >=3 x baseline value, ALT >=2 x baseline value and absolute ALT >500 IU/L, and ALT >=2 x baseline value; and bilirubin >2 x ULN and >=2 x baseline value.

† Each subject may be represented in one or more category.

‡ During treatment phase.

§ Comparable to a Grade 3 toxicity in accordance with modified WHO criteria.

ULN = Upper limit of normal.

Adverse Reactions in Clinical Trials of Pediatric Subjects With Chronic Hepatitis B Virus Infection: Most commonly observed adverse reactions in the pediatric trials were similar to those in adult trials. Posttreatment transaminase elevations were observed in some subjects followed after cessation of lamivudine tablets (HBV).

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been reported during postmarketing use of lamivudine tablets (HBV). Because these reactions are reported voluntarily from a population of unknown size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure. These reactions have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to lamivudine.

Blood and Lymphatic System Disorders: Thrombocytopenia.

Digestive: Stomatitis.

Endocrine and Metabolic: Hypoglycemia.

General: Weakness.

Blood and Lymphatic: Anemia (including pure red cell aplasia and severe anemias progressing on therapy), lymphadenopathy, splenomegaly.

Hepatic and Pancreatic: Lactic acidosis and steatosis, posttreatment exacerbation of hepatitis [see Boxed Warning], pancreatitis.

Hypersensitivity: Anaphylaxis, urticaria.

Musculoskeletal: Cramps, rhabdomyolysis.

Nervous: Paresthesia, peripheral neuropathy.

Respiratory: Abnormal breath sounds/wheezing.

Skin: Alopecia, pruritus, rash.

7 DRUG INTERACTIONS

Lamivudine is predominantly eliminated in the urine by active organic cationic secretion. The possibility of interactions with other drugs administered concurrently should be considered, particularly when their main route of elimination is active renal secretion via the organic cationic transport system (e.g., trimethoprim). No data are available regarding interactions with other drugs that have renal clearance mechanisms similar to that of lamivudine.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy: Teratogenic Effects:

Pregnancy Category C.

There are no adequate and well-controlled trials of lamivudine tablets (HBV) in pregnant women. Because animal reproduction studies are not always predictive of human response, lamivudine tablets (HBV) should be used during pregnancy only if the potential benefits outweigh the potential risks to the fetus.

Antiretroviral Pregnancy Registry: To monitor maternal-fetal outcomes of pregnant women exposed to lamivudine, a Pregnancy Registry has been established. Healthcare providers are encouraged to register patients by calling 1-800-256-4263.

Animal Data: Animal reproduction studies in rats and rabbits revealed no evidence of teratogenicity. Reproductive studies have been performed in rats and rabbits at orally administered doses up to 4,000 mg/kg/day and 1,000 mg/kg/day, respectively, producing plasma levels up to approximately 60 times that for the adult HBV dose. Evidence of early embryolethality was seen in the rabbit at exposure levels similar to those observed in humans, but there was no indication of this effect in the rat at exposure levels up to 60 times those in humans.

Studies in pregnant rats and rabbits showed that lamivudine is transferred to the fetus through the placenta.

8.3 Nursing Mothers

Lamivudine is excreted in human milk. Samples of breast milk obtained from 20 mothers receiving lamivudine monotherapy (300 mg twice daily, 6 times the recommended dosage for hepatitis B infection) or combination therapy (150 mg lamivudine twice daily [3 times the recommended dosage for hepatitis B infection] and 300 mg zidovudine twice daily) had measurable concentrations of lamivudine.

Because of the potential for serious adverse reactions in nursing infants, a decision should be made to discontinue lamivudine tablets (HBV) taking into consideration the importance of continued hepatitis B therapy to the mother and the known benefits of breastfeeding.

8.4 Pediatric Use

Lamivudine tablets (HBV) is indicated for the treatment of chronic hepatitis B virus infection in pediatric patients aged 2 to 17 years [see Indications and Usage (1), Clinical Pharmacology (12.3), Clinical Studies (14.2)]. The safety and efficacy of lamivudine tablets (HBV) in pediatric patients younger than 2 years have not been established.

8.5 Geriatric Use

Clinical trials of lamivudine tablets (HBV) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. In particular, because lamivudine is substantially excreted by the kidney and elderly patients are more likely to have decreased renal function, renal function should be monitored and dosage adjustments should be made accordingly [see Dosage and Administration (2.4), Clinical Pharmacology (12.3)].

8.6 Patients With Impaired Renal Function

Reduction of the dosage of lamivudine tablets (HBV) is recommended for patients with impaired renal function [see Dosage and Administration (2.4), Clinical Pharmacology (12.3)].

8.7 Patients With Impaired Liver Function

No dose adjustment for lamivudine is required for patients with impaired hepatic function.

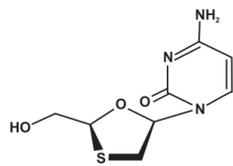
10 OVERDOSAGE

There is no known antidote for lamivudine tablets (HBV). If overdose occurs, the patient should be monitored, and standard supportive treatment utilized, as required.

Because a negligible amount of lamivudine was removed via (4-hour) hemodialysis, continuous ambulatory peritoneal dialysis, and automated peritoneal dialysis, it is not known if continuous hemodialysis would provide clinical benefit in a lamivudine overdose event.

11 DESCRIPTION

Lamivudine tablets (HBV) is a synthetic nucleoside analogue with activity against HBV. The chemical name of lamivudine, USP is 2(1H)-Pyrimidinoine, 4-amino-1-[2-(hydroxymethyl)-1,3-oxathio-lan-5-yl], (2R-cis)-. It has a molecular formula of C8H11N5O3S and a molecular weight of 229.26. It has the following structural formula:



PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

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 analog) 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 be signs of lactic acidosis:
feeling very weak or tired
feeling very weak or tired
unusual (not normal) muscle pain
trouble breathing
stomach pain with nausea and vomiting
feeling cold, especially in your arms and legs
feeling dizzy or light-headed
having a fast or irregular heartbeat
Severe liver problems. Severe liver problems can happen in people who have discontinued anti-hepatitis B therapy (including lamivudine tablets (HBV)). 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 lamivud

