



GlaxoSmithKline
Research Triangle Park, NC 27709

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Date of Issue

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PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

PATIENT INFORMATION

EPIVIR -HBV[®] (lamivudine) Tablets **EPIVIR-HBV[®] (lamivudine) Oral Solution**

Please read this information before you start taking EPIVIR-HBV (pronounced EP-i-veer h-b-v). Re-read it each time you get your prescription, in case some information has changed. **This information does not take the place of careful discussions with your doctor when you start this medication and at checkups. Stay under a doctor's care when you take EPIVIR-HBV and do not change or stop treatment without first talking with your doctor.**

What is EPIVIR-HBV?

EPIVIR-HBV is the brand name of a product that contains lamivudine, a drug used to treat chronic hepatitis B in patients with actively growing virus and liver inflammation. Hepatitis B can cause damage to cells in the liver. Eventually, this can scar the liver.

The lamivudine in EPIVIR-HBV can reduce the ability of the hepatitis B virus to multiply and infect new liver cells. It may help to lower the amount of hepatitis B virus in your body. EPIVIR-HBV contains a lower dose of lamivudine than the dose in EPIVIR[®], COMBIVIR[®], EPZICOM[®], and TRIZIVIR[®].

Why should I consider HIV testing before starting treatment with EPIVIR-HBV?

Your doctor or healthcare provider should offer you counseling and testing for HIV infection (sometimes called the AIDS virus) before treatment for hepatitis B is started with EPIVIR-HBV, and periodically during treatment. EPIVIR-HBV Tablets and EPIVIR-HBV Oral Solution contain a lower dose of the medicine than other lamivudine-containing drugs, such as EPIVIR, COMBIVIR, EPZICOM, and TRIZIVIR which are used to treat HIV. Treatment with EPIVIR-HBV in HIV-infected patients may cause the HIV virus to be less treatable with lamivudine and some other drugs.

If I am HIV-positive, can I take EPIVIR-HBV?

People who have both chronic hepatitis B and HIV should not take EPIVIR-HBV. EPIVIR-HBV Tablets and EPIVIR-HBV Oral Solution contain a lower dose of the same drug (lamivudine) as EPIVIR Tablets, EPIVIR Oral Solution, COMBIVIR Tablets, EPZICOM Tablets, and TRIZIVIR Tablets. If you have both hepatitis B and HIV, make sure that your doctor or healthcare provider is aware that you have both infections. If you are prescribed lamivudine as part of your combination treatment for HIV, you should use only the products and doses that are intended for treatment of HIV infection, because the lower dose of lamivudine in EPIVIR-HBV could cause the HIV virus to be less responsive to treatment. If you are planning to change your HIV treatment to a regimen that does not include EPIVIR, COMBIVIR, EPZICOM, or TRIZIVIR, you should first discuss this change with your doctor or healthcare provider.

Does EPIVIR-HBV cure hepatitis B infection?

EPIVIR-HBV is not a cure for hepatitis B. In studies comparing EPIVIR-HBV with placebo (an inactive sugar pill) for 1 year, more people treated with EPIVIR-HBV had reductions in liver inflammation. It is not known whether EPIVIR-HBV will reduce the risk of getting liver cancer or cirrhosis that may be caused by the hepatitis B virus.

In studies, some patients developed hepatitis B viruses that are resistant to EPIVIR-HBV. These patients generally had less benefit from treatment with EPIVIR-HBV. Some patients have had worsening of hepatitis after resistant virus appears. The long-term importance of a resistant virus is not known.

What happens if I stop taking EPIVIR-HBV?

After stopping treatment with EPIVIR-HBV, some patients have had symptoms or blood tests showing that their hepatitis has gotten worse. Therefore, your doctor should check your health, which may include blood tests, for at least several months after stopping treatment with EPIVIR-HBV. Tell your doctor right away about any new or unusual symptoms that you notice after stopping treatment.

Who should not take EPIVIR-HBV?

You should not take EPIVIR-HBV if you have or may have HIV infection (sometimes called the AIDS virus). EPIVIR-HBV does not contain an appropriate dose of lamivudine for treatment of HIV infection, and using EPIVIR-HBV could cause the HIV virus to become less treatable with lamivudine and some other drugs.

You should not take EPIVIR-HBV if you are also taking EPIVIR, COMBIVIR, EPZICOM, or TRIZIVIR. These drugs all contain lamivudine.

You should not take EPIVIR-HBV if you have had an allergic reaction to lamivudine.

EPIVIR-HBV has not been studied in children less than 2 years old.

Can pregnant women and nursing mothers take EPIVIR-HBV?

There are no studies of EPIVIR-HBV in pregnant women. If you are pregnant or if you become pregnant while taking EPIVIR-HBV, notify your doctor or healthcare provider immediately.

EPIVIR-HBV has not been shown to prevent the spread of the hepatitis B virus from mother to infant.

It is not known whether lamivudine is passed to the infant in breast milk. If there is lamivudine in the breast milk, this could cause side effects in nursing infants. Mothers should not breastfeed while taking EPIVIR-HBV or other forms of lamivudine.

How should I take EPIVIR-HBV?

Your doctor will tell you how much EPIVIR-HBV to take. The usual dose is 1 EPIVIR-HBV Tablet orally (by mouth) once a day. Your doctor may prescribe a lower dose if you have problems with your kidneys. EPIVIR-HBV may be taken with food or on an empty stomach. To help you remember to take your EPIVIR-HBV as prescribed, you should try to take EPIVIR-HBV at the same time each day. You must not skip doses or stop treatment without first talking with your doctor or healthcare provider. A strawberry-banana-flavored liquid of EPIVIR-HBV is available for patients who need a liquid.

If you miss your regular time for taking your dose, but then remember it during that same day, take your missed dose immediately. Then, take your next dose at the regularly scheduled time the following day. Do **not** take 2 doses of EPIVIR-HBV at once to make up for missing a dose. If you are not sure what to do if you miss taking your medication, check with your doctor or healthcare provider for further instructions.

EPIVIR-HBV can usually be taken with many other medications; however, be sure to tell your doctor or healthcare provider about all medications (including over-the-counter and prescription drugs) that you are taking. EPIVIR-HBV Tablets and EPIVIR-HBV Oral Solution contain a lower dose of the same drug (lamivudine) as EPIVIR Tablets, EPIVIR Oral Solution, COMBIVIR Tablets, **EPZICOM Tablets**, and TRIZIVIR Tablets; therefore, EPIVIR-HBV should not be taken together with EPIVIR, COMBIVIR, **EPZICOM**, or TRIZIVIR.

You should talk to your doctor about any changes in your treatment.

What are the possible side effects of EPIVIR-HBV?

You should stay under the care of a doctor during treatment so you can be checked for possible serious side effects. Serious side effects such as inflammation of the pancreas can occur with EPIVIR-HBV. Lactic acid buildup in the body and an enlarged liver have been reported with EPIVIR-HBV; this is not common but can result in death.

Hepatitis B virus sometimes becomes resistant to EPIVIR-HBV during treatment, and some people have had tests showing that their hepatitis was getting worse around the time the virus became resistant. Some people also have worsening of hepatitis after stopping EPIVIR-HBV. You should discuss any change in treatment with your doctor.

In studies, the most common side effects seen during treatment with EPIVIR-HBV were ear, nose, and throat infections; malaise and fatigue (feeling tired and run down); headache; abdominal discomfort and pain; nausea and vomiting; diarrhea; muscle pain; sore throat; joint pain; fever or chills; and skin rash.

This list of possible side effects is not complete. Your doctor or pharmacist can discuss with you a more complete list of possible side effects with EPIVIR-HBV. Talk to your doctor right away about any side effects or other unusual symptoms that occur when taking EPIVIR-HBV.

Does EPIVIR-HBV reduce the risk of passing hepatitis B to others?

No, EPIVIR-HBV has not been shown to reduce the risk of passing hepatitis B to others through sexual contact or exposure to infected blood. EPIVIR-HBV also has not been shown to reduce the risk of a mother passing hepatitis B to her baby.

What previous or current medical problems or conditions should I discuss with my doctor or healthcare provider?

Talk to your doctor or healthcare provider if:

- You have HIV infection.
- You are pregnant or if you become pregnant while taking EPIVIR-HBV.
- You are breastfeeding.
- You have diabetes. Each 20-mL dose (100 mg) of EPIVIR-HBV Oral Solution contains 4 grams of sucrose.

Also talk to your doctor or healthcare provider about:

- Problems with your blood counts.
- Problems with your muscles.
- Problems with your kidneys.
- Problems with your pancreas.
- Any side effects or unusual symptoms during treatment.

How should I store EPIVIR-HBV Tablets and Oral Solution?

EPIVIR-HBV Tablets and Oral Solution should be stored at room temperature. They do not require refrigeration. **Keep EPIVIR-HBV and all medicines out of the reach of children.**

Other Information

This medication is prescribed for a particular condition. Do not use it for any other condition or give it to anybody else.

For more complete information about EPIVIR-HBV ask your doctor or pharmacist. You can also ask to read the longer information leaflet that is written for health professionals.

Keep EPIVIR-HBV and all medicines out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.



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