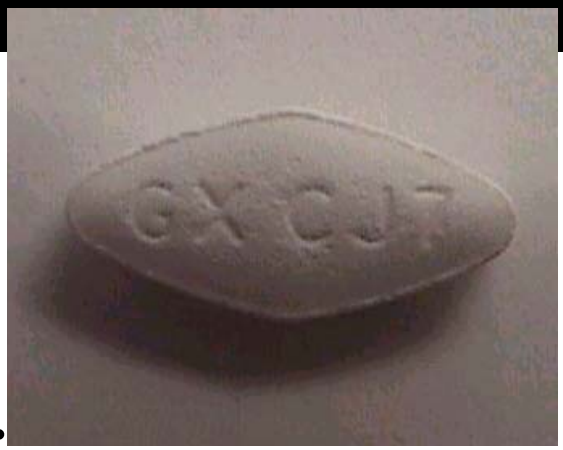
Epivir (lamivudine)



Epivir tablets are film-coated, white, and diamond-shaped with the dosage "150" imprinted on one side and "GX CJ7" on the other side. This drug is also available in a flavored solution.

Also known as: 3TC

Background and description. Epivir received accelerated approval from the US Food and Drug Administration (FDA) in November 1995. The drug is manufactured and distributed by GlaxoSmithKline. Epivir is a nucleoside reverse transcriptase inhibitor (NRTI). In combination with other antiretroviral agents, Epivir can be effective in suppressing viral replication. The drug is also effective in suppressing the Hepatitis B virus (HBV), although in a different formulation ("Zeffix").

Coformulations. Epivir is included in the combination drugs Trizivir (Retrovir, Epivir, and Ziagen) and Combivir (Retrovir and Epivir), both of which are taken twice a day. Epzicom (a fixed-dose, once-daily, co-formulation of Epivir with the HIV drug Ziagen) was approved by the FDA in August 2004. (This is known as "Kivexa" in Europe).

Dose. The recommended Epivir dosing for adults and adolescents (12 to 16 years of age) is 300 mg daily, either as 150 mg twice a day or as 300 mg once a day. For adults with low body weights (less than 110 lb) the recommended dose is 2 mg/kg twice a day. Dosing should be adjusted in patients with kidney problems (based on creatinine clearance).

Food restrictions. Epivir can be taken with or without a meal.

Storage. Tablets should be stored between 36º and 86ºF in a tightly closed container. The solution should also be kept in a tightly closed container and stored between 36º and 77ºF.

Patient assistance. For those who qualify, GlaxoSmithKline offers a patient assistance program. For more information, call 866.728.4368.

Side effects and toxicity. Lactic acidosis and severe hepatomegaly (enlarged liver) with steatosis (fatty liver) are rare, but potentially fatal, and have been associated with NRTI use. Epivir is considered to have minimal toxicity and few side effects. Some reported side effects include headache, fatigue, and nausea.

Patients co-infected with HIV and HBV can have a severe flare-up of HBV when they stop taking Epivir. Liver function should be monitored closely for at least several months in these patients after stopping Epivir.

Drug interactions. There are no known clinically significant drug interactions with Epivir.

Additional info:

Resistance and cross-resistance. Epivir resistance is associated with a mutation at position 184. When used as monotherapy, Epivir results in rapid and uniform resistance, usually within a few weeks. The mutation at position 184 results in 1000-fold resistance to Epivir. Early reports indicated that the 184 mutation could improve susceptibility to Retrovir; other reports have suggested that Epivir resistance confers increased fidelity to the reverse transcriptase enzyme and makes the virus less fit or less pathogenic. The validity of these reports has yet to be proven, but their mere existence and the fact that Epivir has very few side effects and toxicities has led to the widespread use of the drug even in the presence of clear-cut resistance.

A mutation at position 333 confers resistance to both Retrovir and Epivir. A mutation at position 151 is associated with resistance to the entire NRTI class. An insertion at position 69 can also lead to broad NRTI resistance.

Clinical data. Registrational studies for Epivir noted its efficacy when combined with Retrovir, but subsequent data indicate more potent effects when used in combination with other drug classes. Studies of patients failing highly active antiretroviral therapy (HAART) with the combination of Retrovir/Epivir/Crixivan report that virologic rebound is at least initially associated with the mutation at position 184 and resistance to Epivir.

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