

Lamivudine (3TC, Epivir)

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What is Epivir?

- Epivir is an anti-HIV medication. It is in a category of HIV medications called nucleoside reverse transcriptase inhibitors (NRTIs). Epivir prevents HIV from altering the genetic material of healthy T-cells. This prevents the cells from producing new virus and decreases the amount of virus in the body.
- Epivir, manufactured by GlaxoSmithKline, was approved for the treatment of HIV by the U.S. Food and Drug Administration (FDA) in 1995.
- Epivir is available in pharmacies as a single drug, which is always combined with other anti-HIV drugs, or in three combination tablets: Combivir® (Retrovir and Epivir) or Trizivir® (Retrovir, Ziagen, and Epivir), or Epzicom™ (Ziagen and Epivir).
- Epivir is also approved for the treatment of chronic hepatitis B infection (Epivir HBV). The Epivir dose normally used to treat hepatitis B is one 100mg tablet once a day. The dose used to treat HIV is one 300mg tablet once a day, or one 150mg tablet every 12 hours. If you are infected with both HIV and hepatitis B, it is important that you take the dose used to treat HIV.
- Epivir must be used in combination with at least two other anti-HIV drugs.

What is known about Epivir?

- The recommended dose for Epivir is one 300mg tablet once a day, or one 150mg tablet every 12 hours. Combivir®, which contains Retrovir® (AZT) and Epivir, and Trizivir®, which contains Ziagen® (abacavir), Retrovir, and Epivir, must be taken twice a day: one tablet in the morning and one tablet in the evening. Epzicom™, which contains Ziagen and Epvir, only needs to be taken once a day.
- For children, a liquid formula of Epivir is available. The correct dose depends on the child's body weight and will change as the child gets older.
- The chemical structure of Epivir looks very much like that of Emtriva® (FTC).
- Epivir won't likely be effective for people who have already taken and become resistant to Emtriva. This is because one of the key changes, or mutations, in HIV's genetic structure that occurs as a result of Emtriva therapy also causes resistance to Epivir.
- Epivir (Combivir, Trizivir, and Epzicom) can be taken with food or on an empty stomach. Many patients report less stomach discomfort if Combivir, Trizivir, and Epzicom are taken with food.
- Numerous studies have demonstrated that Epivir is effective for the treatment of HIV when combined with

other anti-HIV drugs, most notably Retrovir® (AZT) or Zerit® (d4T) and at least one protease inhibitor or non-nucleoside reverse transcriptase inhibitor (NNRTI).

- The United States Department of Health and Human Services (DHHS) lists Epivir as a “preferred” NRTI for HIV-positive people starting anti-HIV treatment for the first time. For best results, the DHHS recommends combining Epivir with the NRTIs Retrovir® (AZT), Zerit® (d4T), or Viread® (tenofovir), plus either the NNRTI Sustiva® (efavirenz) or the protease inhibitor Kaletra® (lopinavir/ritonavir). Alternative combinations have also been shown to be safe and effective.
- Therapy with Epivir can cause certain changes (mutations) in HIV’s structure to occur. Some mutations will prevent Epivir from working against HIV. The key mutation that causes resistance to Epivir (the M184V mutation in HIV’s reverse transcriptase gene) can cause the virus to be at least partially resistant to other NRTIs, including Ziagen® (abacavir) and Hivid® (ddC) and will likely prevent the NRTI Emtriva® (FTC) from working at all against the virus. However, Epivir resistance might make the virus even more sensitive to other NRTIs, most notably Retrovir (even if HIV has mutations in its structure that would normally cause it to be resistant to Retrovir) and Viread.

What about Epivir for hepatitis B?

- Epivir is sold as “Epivir HBV” for the treatment of chronic hepatitis B infection in people who are not also infected with HIV.
- The dose of Epivir HBV used to treat chronic hepatitis B is one 100mg every day. However, this dose is much lower than the one used to treat HIV. Thus, if you have both HIV and chronic hepatitis B, your doctor should prescribe the dose used to treat HIV (300mg once a day). This dose is high enough to help treat both infections.
- The hepatitis B virus (HBV) does not become resistant to Epivir as quickly as HIV. In turn, even if your HIV is resistant to Epivir, it might still be

useful to continue taking this drug if you are also trying to treat hepatitis B.

- If you have hepatitis B and HIV and plan to stop taking Epivir, your doctor might want to frequently check your liver enzymes after stopping treatment. This is because HBV can “flare” after Epivir treatment is stopped, which can cause damage to the liver.

What about drug interactions?

- TMP/SMX (Bactrim®; Septra®), a treatment used to prevent Pneumocystis pneumonia (PCP), can increase the amount of Epivir in the body. However, it is not necessary to change the doses of either TMP/SMX or Epivir.
- Epivir should not be taken at the same time as Emtriva® or Truvada™ (containing Viread® and Emtriva®). This is because Epivir and Emtriva are very similar and it is not believed that combining these two anti-HIV drugs will make a regimen any more effective against the virus.
- Other drug interactions might be possible. However, it is believed that Epivir can be safely taken at the same time as most drugs used to treat HIV and AIDS-related complications.

What about side effects?

- Lactic acidosis, which can be fatal, and severe liver problems (fatty liver) have been reported in people taking nucleoside reverse transcriptase inhibitors (NRTIs). These problems are more likely to occur in HIV-positive people taking drug regimens that contain Zerit® (d4T) or Zerit and Videx® (ddI). It is possible that Ziagen® (abacavir) can also cause these side effects. Contact your doctor immediately if you experience nausea, vomiting, or unusual or unexpected stomach discomfort; weakness and tiredness; shortness of breath; weakness in the arms and legs; yellowing of the skin or eyes; or pain in the upper stomach area. These may be early symptoms of lactic acidosis or liver problems.
- Rarely, Epivir can cause inflammation of the pancreas (pancreatitis). Pancreatitis is a rare but serious side effect that can be life-threatening in

some cases. Notify your doctor immediately if you develop symptoms of pancreatitis, including nausea, vomiting, diarrhea, and abdominal pain.

- Another rare side effect of Epivir is peripheral neuropathy, which can result in pain, tingling, numbness, or burning in the hands and/or feet. Stopping Epivir and starting another NRTI that does not usually cause peripheral neuropathy—for example, Retrovir® (AZT) or Ziagen® (abacavir)—is often the best way to stop peripheral neuropathy.
- Other, less serious side effects may occur. Continue taking Epivir and talk to your doctor if you experience a cough, dizziness, fatigue, stomach discomfort, headache, and trouble sleeping. Epivir has also been known to cause anemia (decreased red blood cell function), hair loss, rash, and neutropenia (decreased neutrophils, a type of white blood cell)
- Anti-HIV drug regimens containing NRTIs, including Epivir, can cause increased fat levels (cholesterol and triglycerides) in the blood, abnormal body-shape changes (lipodystrophy; including increased fat around the abdomen, breasts, and back of the neck, as well as decreased fat in the face, arms, and legs), and diabetes.
- Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

Who should not take Epivir?

- Before taking this medication, tell your doctor if you have: kidney disease; liver disease; a history of pancreatitis; low red blood cells or neutrophils. You may not be able to take Epivir, or you may require lower doses or special monitoring during treatment, if you have any of these conditions.
- Be sure to tell your doctor if you have allergies to medications, including Epivir.
- Epivir is classified by the FDA as a pregnancy category C drug. All the FDA-approved anti-HIV drugs are classified as either category B or C. Pregnancy category B means that animal studies have failed to demonstrate a risk to the fetus, but there are no adequate and well-controlled studies in

pregnant women. Pregnancy category C means that animal studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. HIV-positive women who become pregnant should discuss the benefits and possible side effects of anti-HIV treatment to help protect their babies from HIV.

- It is not known whether Epivir passes into breast milk and what effect it may have on a nursing baby. To prevent transmission of the virus to uninfected babies, it is recommended that HIV-positive mothers not breast-feed.

Where can I learn more about clinical trials that are using Epivir?

- If you would like to find out if you are eligible for any clinical trials that include Epivir, there is an interactive web site run by amfAR, the American Foundation for AIDS Research.
- Another useful service for finding clinical trials is *AIDSinfo.nih.gov*, a site run by the U.S. National Institutes of Health. They have “health information specialists” you can talk to at their toll-free number at 1-800-HIV-0440 (1-800-448-0440).

a note about this publication

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