

Combivir (AZT+3TC)

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What is Combivir?

- Combivir is an anti-HIV medication. It is in a category of HIV medicines called nucleoside reverse transcriptase inhibitors (NRTIs). Combivir 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.
- Combivir is marketed by GlaxoSmithKline. It was approved by the U.S. Food and Drug Administration (FDA) for use by people living with HIV in 1997.
- Combivir is a combination of two drugs: 300mg of Retrovir® (AZT) and 150mg of Epivir® (3TC). Combivir should be prescribed by a healthcare provider for patients who need both of these drugs. Both of these drugs can still be purchased individually for use in combination with other anti-HIV drugs.
- Combivir must be combined with at least one other anti-HIV drug, usually a protease inhibitor (PI) or a non-nucleoside reverse transcriptase inhibitor (NNRTI).

What is known about Combivir?

- Combivir is taken twice daily, one tablet in the morning and one tablet in the evening, with or without food.
- Combivir should not be any more or less effective than Retrovir and Epivir taken as separate pills together. However, it is considered to be a much more convenient way of taking these two anti-HIV drugs.

- See the “What is known about ...” sections of Retrovir and Epivir for information about possible drug resistance.

What about drug interactions?

- Combivir should not be taken at the same time as Emtriva® or Truvada™ (containing Viread and Emtriva). This is because the Epivir in Combivir is very similar to Emtriva, and it is not believed that combining these two anti-HIV drugs will make a regimen any more effective against the virus.
- See the “What about drug interactions?” sections of Retrovir and Epivir.

What about side effects?

- Bone marrow problems, such as decreased production of red blood cells and/or white blood cells, can occur in people taking Retrovir® (AZT), one of the two active drugs in Combivir. Contact your doctor immediately if you develop unusual fatigue, pale skin, sore throat, fever, or chills, which may be signs of bone marrow problems.
- A rare but potentially serious side effect of Retrovir, one of the two drugs in Combivir, is myopathy (damage to the muscles, including the heart). People who use Retrovir for a long period of time, meaning several years, are at the greatest risk for myopathy. General symptoms of myopathy include weakness of limbs, usually proximal (located close to the center of the body).

- Lactic acidosis, which can be fatal, and severe liver problems have been reported in people taking nucleoside reverse transcriptase inhibitors (NRTIs), including Retrovir and Epvir, the two active drugs in Combivir. 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.
- Anti-HIV drug regimens containing nucleoside reverse transcriptase inhibitors (NRTIs), including Combivir, 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.
- If you have hepatitis B and HIV and plan to stop taking Combivir, your doctor might want to frequently check your liver enzymes after stopping treatment. This is because the Epivir in Combivir is also active against the hepatitis B virus (HBV). If Epivir is stopped abruptly, it can cause liver disease to “flare” and damage the liver.
- See the “What about side effects?” sections of Retrovir and Epivir for additional possible side effects.

Who should not take Combivir?

- Before taking this medication, tell your doctor if you have: kidney disease; liver disease; a history of pancreatitis; decreased activity of your bone marrow (low red blood cells [anemia] or low white blood cells). You may not be able to take Combivir, or you may require a lower dose or special monitoring during treatment if you have any of these conditions.
- Combivir 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 Combivir 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 involving Combivir?

- If you would like to find out if you are eligible for any clinical trials that include Combivir, 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 US 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

This publication is reprinted here from another source (www.aidsmeds.com). We do not always have the resources at Project Inform to produce our own treatment information on every treatment topic. In these cases, we try to provide reliable information from other sources but cannot confirm that every fact in these publications is accurate. References to other materials have been pulled. This information is designed to support, not replace, the relationship that exists between you and your doctor or medical provider.

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