

# Retrovir (zidovudine)



*Zidovudine is supplied most commonly in film-coated tablets (300 mg, biconvex, round and white) with “GXCW3” on one side and “300” on the other. The drug also comes in capsules (100 mg), flavored syrup, and an intravenous infusion. Dosing may vary.*



**Also known as:** azidothymidine, AZT

**Background and description.** Retrovir was approved by the US Food and Drug Administration (FDA) in March 1987 as the first antiretroviral to treat HIV disease. The drug is manufactured and distributed by GlaxoSmithKline. Retrovir is a nucleoside reverse transcriptase inhibitor (NRTI). In September 2005, the FDA approved a generic version of zidovudine.

**Coformulations.** Retrovir is included in the combination drugs Trizivir (Retrovir, Efavirenz, and Ziagen) and Combivir (Retrovir and Efavirenz), both of which are taken twice daily.

**Dose.** The recommended dose for Retrovir in adults is 300 mg twice a day.

**Food restrictions.** Retrovir can be taken with or without food.

**Storage.** Tablets and capsules should be stored at a temperature of 59° to 77°F. Capsules should be protected from moisture.

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

**Side effects and toxicity.** Retrovir can suppress bone marrow production of blood cells, resulting in anemia or neutropenia. In patients with low neutrophil counts (less than 1000) or hemoglobin levels (less than 9.5) Retrovir should be used with caution. Special care should be taken when administering the drug to patients with advanced HIV disease or other conditions characterized by anemia or neutropenia. Lactic acidosis and severe hepatomegaly (enlarged liver) with steatosis (fatty liver) is rare, but potentially fatal, and has been associated with NRTI use. Additionally, some complaints of gastrointestinal intolerance (pain, nausea and diarrhea), headache, insomnia, and asthenia (weakness) have been documented. Myopathy (muscle wasting) and myositis (muscle inflammation), similar to that produced by HIV itself, have been associated with prolonged use of Retrovir. As a class, NRTIs have been implicated in damage to mitochondrial DNA and may therefore play a role in the development of lipodystrophy (fat accumulation and fat atrophy).

**Drug interactions.** Because of blood cell (hematologic) toxicity, caution should be used when co-administering Retrovir with bone marrow suppressive agents or interferon alpha. Dose reduction or interruption of one or more agents may be necessary; frequent hematologic monitoring is recommended. Ribavirin should be avoided in combination with Retrovir, since it inhibits processing of Retrovir during metabolism.

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## Additional info:

**Resistance and cross-resistance.** Retrovir resistance is associated with mutations at positions 41, 67, 70, 215, and 219. In general, a greater number of mutations confers greater resistance, with the 215 mutation being most significant. Cross-resistance can occur with other NRTIs. 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.** Early use of zidovudine showed some effect on viral replication resulting in approximately a 0.6 log drop in viral load. This effect was short-lived when zidovudine was used as monotherapy. Other studies show the efficacy of Retrovir in combination with another NRTI, such as Epivir, and a protease inhibitor.

The START 1 study looked at Zerit/Epivir/Crixivan compared to Retrovir/Epivir/Crixivan in antiretroviral-naive subjects. Out to 24 weeks, both arms performed equally well in decreasing viral load to less than 500 copies/mL. The START 2 study compared regimens of Zerit/Videx/Crixivan versus Retrovir/Epivir/Crixivan in antiretroviral treatment-naive subjects. The percentages of subjects in each arm with viral loads less than 500 copies/mL at 24 weeks were 68% and 77% respectively.

Retrovir therapy is the current standard in preventing vertical transmission (mother to child) of HIV. In a study of pregnant women, ACTG 076, the estimated risk of mother-to-child transmission of HIV was less than 8% in Retrovir-treated infants (antenatal, perinatal, and neonatal drug administration) versus almost 25% in the placebo group.



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