

Zalcitabine (ddC, Hivid)

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What is Hivid?

- Hivid is an anti-HIV medication. It is in a category of HIV medications called nucleoside reverse transcriptase inhibitors (NRTIs). Hivid 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.
- Hivid, manufactured by Hoffmann-La Roche, was approved by the U.S. Food and Drug Administration for the treatment of HIV in 1992.
- Hivid must be used in combination with at least two other anti-HIV drugs.

What is known about Hivid?

- The recommended dose of Hivid is one 0.75mg tablet taken every eight hours (three times a day).
- Hivid can be taken either with or without food, although some experts recommend taking Hivid on an empty stomach, as this allows more drug to be absorbed into the bloodstream.
- Hoffmann-La Roche is conducting a clinical trial to determine if Hivid can be taken twice a day, compared

to the approved three-times-daily dosing schedule. If you are interested in taking Hivid twice a day, you should discuss this option with your doctor. The correct dose is one 0.75mg (gray) tablet and one 0.375mg (beige) tablet, taken together twice a day.

- Hivid is not approved for children younger than 13 years. Some researchers have suggested that Hivid can be given to children, based on their body weight. Although the U.S. Food and Drug Administration has not approved it, an experimental liquid formulation of Hivid is available for children through Hoffmann-La Roche (1-800-285-4484).
- Studies have demonstrated that Hivid is effective for the treatment of HIV when combined with other anti-HIV drugs, usually at least one other nucleoside reverse transcriptase inhibitor (NRTI) and either a protease inhibitor or non-nucleoside reverse transcriptase inhibitor (NNRTI). Hivid should not be taken alone (as monotherapy) or with just one other anti-HIV drug.
- The United States Department of Health and Human Services (DHHS) does not recommend Hivid for HIV-positive people starting anti-HIV treatment for the first time. This is because it is not convenient to take (it must

be taken three times a day) and can cause more side effects than other available NRTIs.

- Therapy with Hivid can cause certain changes (mutations) in HIV's structure to occur. Some mutations will prevent Hivid from working against HIV, although these mutations are often slow to develop. Many of these mutations will also prevent Videx® and Videx EC® (ddI) from working against HIV. If your viral load does not go undetectable or becomes detectable (and increases) while you are taking an anti-HIV drug regimen that contains Hivid, your doctor can order a drug-resistance test to determine if your HIV has mutations that are causing resistance to Hivid and to help you figure out which NRTIs your HIV is still sensitive to.

What about drug interactions?

- Hivid should not be combined with Epivir® (3TC). Epivir decreases the amount of Hivid inside T-cells, which reduces the effectiveness of Hivid against HIV.
- Because Hivid can cause peripheral neuropathy, it is probably best to avoid combining Hivid with other drugs that can cause this side effect, including Videx®/Videx EC® (ddI), Zerit® (d4T), isoniazid (used to prevent and treat tuberculosis), and several chemotherapy drugs used to treat cancer.
- Hivid should not be combined with other drugs that can cause pancreatitis, such as Videx®/Videx EC® (ddI) and intravenous pentamidine (used to treat *Pneumocystis pneumonia*).
- Laboratory studies suggest that ribavirin (Rebetol®; Copegus®), a drug used in the treatment of hepatitis C, can decrease the activity of Hivid. However, no clinical trials involving humans have confirmed this. Until information becomes available from clinical trials, it's probably best to avoid taking ribavirin and Hivid at the same time.

What about side effects?

- Lactic acidosis, which can be fatal, and severe liver problems have been reported in people taking nucleoside reverse transcriptase inhibitors (NRTIs), including Hivid. 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.
- A common side effect of Hivid is peripheral neuropathy, which can result in pain, tingling, numbness, or burning in the hands and/or feet. Stopping Hivid 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.
- Fatal and nonfatal pancreatitis (inflammation of the pancreas) has occurred with Hivid. Symptoms of pancreatitis include stomach pain, nausea, or vomiting. If you notice these symptoms, stop taking Hivid, and call your doctor right away.
- Less common side effects include allergic reactions, stomach upset/pain, headache, bone pain (arthralgia), muscle pain (myalgia), nausea, diarrhea, and vomiting. There is also a risk of mouth ulcers and throat ulcers, which are not usually caused by other NRTIs. Decreased white blood cell counts also can occur in people taking Hivid.
- Anti-HIV drug regimens containing NRTIs, including Hivid, 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.

Who should not take Hivid?

- Before taking this medication, tell your doctor if you have: kidney disease; liver disease; a history of pancreatitis; a history of low white blood cells, a history of lactic acidosis or elevated lactate levels; or a history of peripheral neuropathy. You may not be able to take Hivid, or you may require lower doses or special monitoring during treatment, if you have any of these conditions.
- Hivid 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 Hivid passes into breast milk and what effects it may have on a nursing baby. However, to prevent HIV 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 Hivid?

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