

Didanosine (*Videx*)

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Drug Summary

Didanosine, an early nucleoside reverse transcriptase inhibitor (NRTI), has become obsolete and replaced by better-tolerated and safer options. Didanosine poses risk of serious toxicity, including peripheral neuropathy (which can be permanent), pancreatitis, lipodystrophy, and lactic acidosis. Fatal and nonfatal cases of pancreatitis and lactic acidosis have been reported, especially when didanosine was combined with stavudine. A history of didanosine use has also been associated with non-cirrhotic portal hypertension. In the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, didanosine is no longer recommended for the treatment of HIV infection in persons in the United States due to potentially severe toxicity. Further, all patients taking didanosine should be strongly encouraged to promptly switch to a currently recommended medication to reduce the risk of toxicity. The sale and distribution of all strengths of didanosine will be completely discontinued and removed from the market in the United States in 2020.

Guidelines for use in Antiretroviral-Naïve Patients

In the July 14, 2016 version of the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, for treatment-naïve patients, **didanosine** is NOT included in the recommended or alternative regimen options.

Key Clinical Trials

At the time didanosine was initially FDA-approved, the use of antiretroviral therapy typically consisted of mono- or dual NRTI antiretroviral therapy. An early A trial that compared didanosine to zidovudine monotherapy and assessed an endpoint of AIDS-defining event or death found zidovudine to be superior for individuals with no history of prior antiretroviral treatment and didanosine to be superior for individuals with a history of 8 to 16 weeks of zidovudine treatment [[ACTG 116](#)].

Similarly, another trial compared continued zidovudine monotherapy to switching to didanosine monotherapy and found the switch to be superior in terms of preventing AIDS events or death [[ACTG 116B/117](#)]. Subsequently, didanosine was studied as part of dual NRTI therapy, in combination with zidovudine, stavudine, or zalcitabine; these dual therapy combinations increased CD4 counts and delayed disease progression more than NRTI monotherapy [[CPCRA007](#)]. Studies of triple therapy with didanosine demonstrated good virologic efficacy, though toxicity from didanosine was often limiting. For example, a trial that compared didanosine plus lamivudine plus efavirenz to zidovudine-lamivudine plus efavirenz found equivalent rates of virologic suppression at 48 weeks but more treatment discontinuations due to toxicity in the didanosine arm [[GESIDA 3903](#)].

Adverse Effects

Didanosine may cause serious adverse events and there is an FDA black box warning for lactic acidosis, hepatomegaly with steatosis, and pancreatitis. All of these reactions can be fatal and are more likely to occur if didanosine is combined with stavudine, but can occur with didanosine alone. Didanosine can also cause nausea, vomiting, diarrhea, rash, lipodatrophy, and a debilitating peripheral neuropathy that often does not resolve with cessation of the drug. Long-term use of didanosine has also been associated with development of non-cirrhotic portal hypertension.

Use In Pregnancy

In the October 26, 2016 version of the HHS Perinatal Treatment Guidelines for Initial Combination Regimens for Antiretroviral-Naïve Pregnant Women, didanosine is listed as not recommended (due to toxicity) in antiretroviral naïve pregnant women.

- For additional information regarding the safety and toxicity of didanosine in pregnancy see the HHS Perinatal Guidelines summary on [Didanosine](#).

Resistance

For a listing of the most common clinically significant mutations associated with didanosine (ddl) resistance, see the [NRTI Resistance Notes on the Stanford University HIV Drug Resistance Database](#).

Key Drug Interactions

For complete information on didanosine-related drug interactions, see the [Drug Interactions section in the Didanosine \(Videx\) Prescribing Information](#).

No Clinical Trials Available

We do not currently have any clinical trials on file for this drug.