

# Videx (didanosine)



*Videx tablets (left) are round and off-white to pale yellow-orange, with "Videx" on one side and the tablet strength on the other side. Videx EC (right) is an enteric-coated, white capsule labeled with "BMS 400 mg" and "6674" in red. The EC formulation protects the drug from stomach acid, which is why the older formulation contains so much powdery buffer. Videx is also available in a powder form for oral solution. Dosing may vary.*



Also known as: ddi

**Background and description.** Videx was approved by the US Food and Drug Administration (FDA) in October 1991. The drug is a nucleoside reverse transcriptase inhibitor (NRTI), manufactured and distributed by Bristol-Myers Squibb. In December 2004, the FDA approved a generic version of didanosine.

**Dose.** Videx was initially approved for twice daily dosing, but since October 1999 once daily dosing is available. Tablets are chewable or dispersible in water and dosing is weight-dependent. For patients weighing greater than or equal to 132 lb, a dose of 400 mg once a day or 200 mg twice a day of Videx is recommended (200-mg tablets are only to be used in once-daily dosing; 2 tablets equaling a full dose should be ingested each time to ensure adequate buffer intake). For patients in this weight group, a dose of 250 mg twice a day of Videx powder can be used as well. For patients weighing less than 132 lb, a dose of 250 mg once a day or 125 mg twice a day is recommended (at least 2 tablets at each dose); 167 mg twice a day of Videx powder can also be used. Special dosing adjustments are necessary in patients with renal impairment. Patients with peripheral neuropathy may require lower doses. *In 2001, a new "enteric-coated" formulation, Videx EC, was released that reduced pill burden to one 400-mg capsule once a day.*

**Food restrictions.** Videx should be taken on an empty stomach (either 30 minutes before or 1 to 2 hours after a meal).

**Storage.** Tablets should be kept in tightly closed containers and stored at 59° to 86°F. If tablets are dispersed in water, the mixture may be kept for 1 hour at room temperature. When dissolving the powder for oral solution, the mixture can be kept at room temperature for 4 hours.

**Patient assistance.** For those who qualify, Bristol-Myers Squibb offers a patient assistance program. For more information, call 800.272.4878.

**Side effects and toxicity.** Videx is associated with pancreatitis, peripheral neuropathy, vision changes (retinal depigmentation or optic neuritis), nau-

sea, and diarrhea. As a class, NRTIs have been implicated in damage to mitochondrial DNA and may play a role in the development of metabolic and morphologic abnormalities. Lactic acidosis and severe hepatomegaly (enlarged liver) with steatosis (fatty liver) are rare, but potentially fatal, and have been associated with NRTI use. In particular, Zerit and Videx are not recommended for use in pregnant women because of increased risk of lactic acidosis and liver damage.

**Drug interactions.** Drugs known to cause or contribute to pancreatitis, including alcohol, should be used with caution when administering Videx. Antacids containing magnesium or aluminum may cause adverse side effects if given with Videx tablets. Drugs affected by stomach acidity like Nizoral (ketoconazole) or Sporanox (itraconazole) should be taken at least 2 hours before Videx. Videx should be taken 2 hours after or 6 hours before Cipro (ciprofloxacin); caution should be taken with other quinolone antibiotics as well. Methadone can decrease Videx levels up to 41% (however, methadone levels remain unchanged), so increased dosing of Videx should be considered. Ribavirin taken with Videx should be done with caution, and patients should be monitored closely for Videx-related toxicities. Videx should be suspended if signs or symptoms of pancreatitis, elevated lactate levels, or lactic acidosis develop.

Viread significantly increases the levels of Videx in your blood, possibly causing an increase in Videx side effects, including T-cell toxicity (reduced counts of T cells). A dose reduction to 250 mg of Videx EC when taken with Viread is recommended. **The combination of Viread and Videx may not be ideal for patients with other options; this combination should definitely not be used with Sustiva or Viramune because a greater chance of regimen failure is possible.**

Rescriptor and Crixivan should be given 1 hour before Videx. Viracept can be administered with a light meal 1 hour after Videx. Videx is not recommended for use with Hivid and is generally *not recommended with Zerit.*

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## Additional info:

**Resistance and cross-resistance.** Videx resistance is associated with mutations at positions 65 and 74. The mutation at 74 is more common. 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.** Although clinical studies showing marginal efficacy of Videx monotherapy were used to get approval for the drug's registration, monotherapy is no longer considered optimal use of this or any antiretroviral drug. Studies A1454-148 and START 2, using combination therapy with dual NRTIs and a protease inhibitor, have shown that Videx performs well in combination with other antiretroviral drugs in lowering viral load below 400 copies/mL and increasing CD4 T cell counts.

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