

Medication Guide

VIDEX[®] (VY-dex)

(didanosine, also known as ddi)

Pediatric Powder for Oral Solution

Read this Medication Guide before you start taking VIDEX and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. You and your healthcare provider should talk about your treatment with VIDEX before you start taking it and at regular check-ups. You should stay under your healthcare provider's care when taking VIDEX.

What is the most important information I should know about VIDEX?

VIDEX may cause serious side effects, including:

1. Swelling of your pancreas (pancreatitis) that may cause death. Pancreatitis can happen at any time during your treatment with VIDEX. Before you start taking VIDEX, tell your healthcare provider if you:

- have had pancreatitis
- have advanced HIV (human immunodeficiency virus) infection
- have kidney problems
- drink alcoholic beverages
- take a medicine called ZERIT[®] (stavudine)

It is important to call your healthcare provider right away if you have:

- stomach pain
- swelling of your stomach
- nausea and vomiting
- fever

2. Build-up of acid in your blood (lactic acidosis). Lactic acidosis must be treated in the hospital as it may cause death. The risk for lactic acidosis may be higher if you:

- have liver problems
- are pregnant. There have been deaths reported in pregnant women who get lactic acidosis after taking VIDEX and ZERIT (stavudine).
- are overweight
- have been treated for a long time with other medicines to treat HIV

It is important to call your healthcare provider right away if you:

- feel weak or tired
- have unusual (not normal) muscle pain

- have trouble breathing
- have stomach pain with nausea and vomiting
- feel cold, especially in your arms and legs
- feel dizzy or light-headed
- have a fast or irregular heartbeat

3. **Liver problems.** Some people (including pregnant women) who have taken VIDEX have had serious liver problems. These problems include liver enlargement (hepatomegaly), fat in the liver (steatosis), liver failure, and high blood pressure in the large vein of the liver (portal hypertension). Severe liver problems can lead to liver transplantation or death in some people taking VIDEX. Your healthcare provider should check your liver function while you are taking VIDEX. You should be especially careful if you have a history of heavy alcohol use or liver problems.

It is important to call your healthcare provider right away if you have:

- yellowing of your skin or the white of your eyes (jaundice)
- dark urine
- pain on the right side of your stomach
- swelling of your stomach
- easy bruising or bleeding
- loss of appetite
- nausea or vomiting
- vomiting blood or dark colored stools (bowel movements)

What is VIDEX?

VIDEX is a prescription medicine used with other antiretroviral medicines to treat human immunodeficiency virus (HIV) infection in children and adults. VIDEX belongs to a class of drugs called nucleoside analogues.

VIDEX will not cure your HIV infection. At present there is no cure for HIV infection. Even while taking VIDEX, you may continue to have HIV-related illnesses, including infections with other disease-producing organisms. Continue to see your healthcare provider regularly and report any medical problems that occur.

Who should not take VIDEX?

Do not take VIDEX if you take:

- ZYLOPRIM[®], LOPURIN[®], ALOPRIM[®] (allopurinol)
- COPEGUS[®], REBETOL[®], RIBASPHERE[®], RIBAVIRIN[®], VIRAZOLE[®] (ribavirin)

What should I tell my healthcare provider before taking VIDEX?

Before you take VIDEX, tell your healthcare provider if you:

- have or had kidney problems
- have or had liver problems (such as hepatitis)
- have or had persistent numbness, tingling, or pain in the hands or feet (neuropathy)
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if VIDEX will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking VIDEX. You and your healthcare provider will decide if you should take VIDEX while you are pregnant.

Pregnancy Registry: There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.

- are breast-feeding or plan to breast-feed. **Do not breast-feed while you take VIDEX.** It is not known if VIDEX passes into your breast milk. The Centers for Disease Control and Prevention (CDC) recommends that HIV-infected mothers **not** breast-feed to avoid the risk of passing HIV infection to your baby.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. VIDEX may affect the way other medicines work, and other medicines may affect how VIDEX works.

Especially tell your healthcare provider if you take:

- VIREAD[®] (tenofovir disoproxil fumarate)
- DROXIA[®], HYDREA[®] (hydroxyurea)
- RESCRIPTOR[®] (delavirdine mesylate)
- CYTOVENE[®], VALCYTE[®] (ganciclovir)
- CRIXIVAN[®] (indinavir)
- DOLOPHINE[®] HYDROCHLORIDE, METHADOSE[®] (methadone)
- VIRACEPT[®] (nelfinavir)
- antacids
- antifungal medicines such as NIZORAL[®] (ketoconazole) or SPORANOX[®] (itraconazole)
- quinolone antibiotics such as CIPRO[®], PROQUIN[®] XR (ciprofloxacin)
- tetracycline antibiotics such as BRISTACYCLINE[®], SUMYCIN[®] (tetracycline)
- alcoholic beverages

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

Ask your healthcare provider if you are not sure if you take one of the medicines listed above.

How should I take VIDEX?

- Take VIDEX exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much VIDEX to take and when to take it.
- Your healthcare provider may change your dose. Do not change your dose of VIDEX without talking to your healthcare provider.
- **Do not take VIDEX with food.** Take VIDEX on an empty stomach at least 30 minutes before or 2 hours after you eat.
- Try not to miss a dose, but if you do, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
- **Some medicines should not be taken at the same time of day that you take VIDEX.** Check with your healthcare provider.
- If your kidneys are not working well, your healthcare provider will need to do regular blood and urine tests to check how they are working while you take VIDEX. Your healthcare provider may also lower your dosage of VIDEX if your kidneys are not working well.
- **If you take too much VIDEX,** contact a poison control center or emergency room right away.

What should I avoid while taking VIDEX?

- **Alcohol.** Do not drink alcohol while you take VIDEX. Alcohol may increase your risk of getting pain and swelling of your pancreas (pancreatitis) or may damage your liver.

What are the possible side effects of VIDEX?

VIDEX can cause pancreatitis, lactic acidosis, and liver problems. See “**What is the most important information I should know about VIDEX?**” at the beginning of this Medication Guide.

- **Vision changes.** You should have regular eye exams while you take VIDEX.
- **Peripheral neuropathy. Symptoms include:** numbness, tingling, or pain in your hands or feet. This condition is more likely to happen in people who have had it before, in patients taking medicines that affect the nerves, and in people with advanced HIV disease. A child may not notice these symptoms. Ask your child’s healthcare provider for the signs and symptoms of peripheral neuropathy in children.
- **Changes in your immune system (immune reconstitution syndrome).** Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider if you start having new or worse symptoms of infection after you start taking HIV medicine.

- **Changes in body fat (fat redistribution).** Changes in body fat have been seen in people who take antiretroviral medicines. These changes may include:
 - more fat in or around your
 - upper back and neck (buffalo hump)
 - breasts or chest
 - trunk
 - less fat in your
 - legs
 - arms
 - face

Tell your healthcare provider if you have any of the symptoms listed above.

The most common side effects of VIDEX include:

- diarrhea
- stomach pain
- nausea
- vomiting
- headache
- rash

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of VIDEX. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VIDEX?

Store the VIDEX liquid mixture in a tightly closed container in the refrigerator between 36° F to 46° F (2° C to 8° C) for up to 30 days.

- Safely throw away any unused VIDEX after 30 days.

Keep VIDEX and all medicines out of the reach of children and pets.

General Information about the safe and effective use of VIDEX.

VIDEX has not been shown to prevent a patient infected with HIV from passing the virus to other people. To protect others, you must continue to practice safer sex and take precautions to prevent others from coming in contact with your blood and other body fluids.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIDEX for a condition for which it was not prescribed. Do not give VIDEX to other people, even if they have the same symptoms as you have. It may harm them. Do not keep medicine that is out of date or that you no longer need. Dispose of unused medicines through community take-back disposal programs when available or place VIDEX in an unrecognizable closed container in the household trash.

This Medication Guide summarizes the most important information about VIDEX. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about VIDEX that is written for health professionals. For more information, go to http://packageinserts.bms.com/pi/pi_videx.pdf or call 1-800-321-1335.

What are the ingredients in VIDEX?

Active Ingredients: didanosine

Inactive Ingredients:

Pediatric Oral Solution: Maximum Strength Mylanta[®] Liquid.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.