

Patient Information

Rx only

VIDEX[®]

(generic name = **didanosine** also known as **ddl**)

VIDEX[®] (didanosine) Pediatric Powder for Oral Solution

What is VIDEX?

VIDEX (pronounced VY dex) is a prescription medicine used in combination with other drugs to treat children and adults who are infected with HIV (the human immunodeficiency virus, the virus that causes AIDS). VIDEX belongs to a class of drugs called nucleoside analogues. By reducing the growth of HIV, VIDEX helps your body maintain its supply of CD4 cells, which are important for fighting HIV and other infections.

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 doctor regularly and report any medical problems that occur.

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

There is limited information on the effects of long-term use of VIDEX.

Who should not take VIDEX?

Do not take VIDEX if you are allergic to any of its ingredients, including its active ingredient, didanosine and the inactive ingredients. (See **Inactive Ingredients** at the end of this leaflet.) Tell your doctor if you think you have had an allergic reaction to any of these ingredients.

How should I take VIDEX? How should I store it?

Your doctor will determine your dose based on your body weight, kidney and liver function, other medicines you are taking, and any side effects that you may have had with VIDEX or other medicines. Take VIDEX **on an empty stomach - that means at least 30 minutes before or 2 hours after eating. Do not take VIDEX with food.** 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.

Your pharmacist will prepare the oral solution. Shake the solution well before each use. Store in the refrigerator. Throw away any unused portion after 30 days.

If you have kidney disease: If your kidneys are not working properly, your doctor will need to do regular tests to check how they are working while you take VIDEX. Your doctor may also lower your dosage of VIDEX.

What should I do if someone takes an overdose of VIDEX?

If someone may have taken an overdose of VIDEX, get medical help right away. Contact their doctor or a poison control center.

What should I avoid while taking VIDEX?

Alcohol. Do not drink alcohol while taking VIDEX since alcohol may increase your risk of pancreatitis (pain and inflammation of the pancreas) or liver damage.

Other medicines. Other medicines, including those you can buy without a prescription, may interfere with the actions of VIDEX or may increase the possibility or severity of side effects. **Do not take any medicine, vitamin supplement, or other health preparation without first checking with your doctor.**

Antacids. Since VIDEX is mixed with an antacid, any side effects related to VIDEX's ingredients may get worse if you also take an antacid.

Medicines at the same time you take your VIDEX dose. Some medicines should not be taken at the same time of day that you take VIDEX. Check with your doctor.

Pregnancy. It is not known if VIDEX can harm a human fetus. Also, pregnant women have experienced serious side effects when taking VIDEX in combination with ZERIT (stavudine), also known as d4T, and other HIV medicines. VIDEX should be used during pregnancy only after discussion with your doctor. **Tell your doctor if you become pregnant or plan to become pregnant while taking VIDEX.**

Nursing. Studies have shown VIDEX is in the breast milk of animals getting the drug. It may also be in human breast milk. The Centers for Disease Control and Prevention (CDC) recommends that HIV-infected mothers **not** breast-feed. This should reduce the risk of passing HIV infection to their babies and the potential for serious adverse reactions in nursing infants. Therefore, do not nurse a baby while taking VIDEX.

What are the possible side effects of VIDEX?

Pancreatitis. Pancreatitis is a dangerous inflammation of the pancreas that may cause death. *Tell your doctor right away if you or a child taking VIDEX develops stomach pain, nausea, or vomiting. These can be signs of pancreatitis.* Before starting VIDEX therapy, let your doctor know if you or a child for whom it has been prescribed has ever had pancreatitis. This condition is more likely to happen in people who have had it before. It is also more likely in people with advanced HIV disease. However, it can occur at any stage of HIV disease. It may be more common in patients with kidney problems, those who drink alcohol, and those who are also treated with stavudine or hydroxyurea. If you get pancreatitis, your doctor will tell you to stop taking VIDEX.

Lactic acidosis, severe liver enlargement, and liver failure, including deaths, have been reported among patients taking VIDEX (including pregnant women). Symptoms that may indicate a liver problem are:

- feeling very weak, tired, or uncomfortable,
- unusual or unexpected stomach discomfort,
- feeling cold,
- feeling dizzy or lightheaded,
- suddenly developing a slow or irregular heartbeat.

Lactic acidosis is a medical emergency that must be treated in a hospital.

If you notice any of these symptoms or if your medical condition changes, stop taking VIDEX and **call your doctor right away.** Women, overweight patients, and those who have

been treated for a long time with other medicines used to treat HIV infection are more likely to develop lactic acidosis. Your doctor should check your liver function periodically while you are taking VIDEX. You should be especially careful if you have a history of heavy alcohol use or a liver problem.

Vision changes. VIDEX may affect the nerves in your eyes. Because of this, you should have regular eye examinations. You should also report any changes in vision to your doctor right away. This includes, for example, seeing colors abnormally or blurred vision.

Peripheral neuropathy. This is a problem with the nerves in your hands or feet. The nerve problem may be serious. *Tell your doctor right away if you or a child taking VIDEX has continuing numbness, tingling, or pain in the feet or hands.* A child may not recognize these symptoms or know to tell you that his or her feet or hands are numb, burning, tingling, or painful. Ask your child's doctor how to find out if your child is developing peripheral neuropathy.

Before starting VIDEX therapy, let your doctor know if you or a child for whom it has been prescribed has ever had peripheral neuropathy. This condition is more likely to happen in people who have had it before. It is also more likely in patients taking medicines that affect the nerves and in people with advanced HIV disease. However, it can occur at any stage of HIV disease. If you get peripheral neuropathy, your doctor will tell you to stop taking VIDEX. After stopping VIDEX, the symptoms may get worse for a short time and then get better. Once symptoms of peripheral neuropathy go away completely, you and your doctor should decide if starting VIDEX is right for you. If so, you might be started at a lower dose.

Special note about other medicines. If you take VIDEX along with other medicines with similar side effects, you may increase the chance of having these side effects. For example, using VIDEX in combination with other medicines that may cause pancreatitis, peripheral neuropathy, or liver problems (including stavudine and hydroxyurea) may increase your chance of having these side effects.

Other side effects: The most common side effects in adults taking VIDEX are diarrhea, neuropathy (nerve disorders), chills or fever, rash, abdominal pain, weakness, headache, and nausea and vomiting. Children may have similar side effects as adults.

Changes in body fat have been seen in some patients taking antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"),

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breast, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known at this time.

Inactive Ingredients:

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

This medicine was prescribed for your particular condition. Do not use VIDEX for another condition or give it to others. Keep VIDEX and all medicines out of the reach of children. Throw away VIDEX when it is outdated or no longer needed by flushing it down the toilet or pouring it down the sink.

This summary does not include everything there is to know about VIDEX. Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. If you have questions or concerns, or want more information about VIDEX, your physician and pharmacist have the complete prescribing information upon which this leaflet is based. You may want to read it and discuss it with your doctor or other healthcare professional. Remember, no written summary can replace careful discussion with your doctor.

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This Patient Information Leaflet has been approved by the U.S. Food and Drug Administration.

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