

17.6 FDA-Approved Patient Labeling

VIDEX[®] EC

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

VIDEX[®] EC (didanosine, USP) Delayed-Release Capsules
Enteric-Coated Beadlets

What is VIDEX EC?

VIDEX EC (pronounced *VY dex ee see*) 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 EC belongs to a class of drugs called nucleoside analogues. By reducing the growth of HIV, VIDEX EC helps your body maintain its supply of CD4 cells, which are important for fighting HIV and other infections.

VIDEX EC will not cure your HIV infection. At present there is no cure for HIV infection. Even while taking VIDEX EC, 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 EC 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 antiviral response of long-term use of VIDEX EC.

In VIDEX EC, an enteric coating is used to protect the medicine while it is in your stomach since stomach acids can break it down. The enteric coating dissolves when the medicine reaches your small intestine.

Who should not take VIDEX EC?

Do not take VIDEX EC 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 EC? How should I store it?

VIDEX EC should only be taken once daily. 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 EC or other medicines. Take VIDEX EC **on an empty stomach. Do not take VIDEX EC with food.** Swallow the capsule whole; do not open it. 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.

Store capsules in a tightly closed container at room temperature away from heat and out of the reach of children and pets.

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 EC. Your doctor may also lower your dosage of VIDEX EC.

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

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

What should I avoid while taking VIDEX EC?

Alcohol. Do not drink alcohol while taking VIDEX EC 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 EC 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.**

Pregnancy. It is not known if VIDEX EC can harm a human fetus. Also, pregnant women have experienced serious side effects when taking didanosine (the active ingredient in VIDEX EC) in combination with ZERIT (stavudine), also known as d4T, and other HIV medicines. VIDEX EC 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 EC.**

Nursing. Studies have shown didanosine (the active ingredient in VIDEX EC) 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 EC.

What are the possible side effects of VIDEX EC?

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 EC develop stomach pain, nausea, or vomiting. These can be signs of pancreatitis.*** Before starting VIDEX EC therapy, let your doctor know if you or a child for whom it has been prescribed have 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. If you get pancreatitis, your doctor will tell you to stop taking VIDEX EC.

Lactic acidosis, severe liver enlargement, and liver failure, including deaths, have been reported among patients taking VIDEX EC (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 EC 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 EC. You should be especially careful if you have a history of heavy alcohol use or a liver problem.

Vision changes. VIDEX EC 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 EC have 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 EC therapy, let your doctor know if you or a child for whom it has been prescribed have 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 EC. After stopping VIDEX EC, 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 EC again is right for you. If so, you might be started at a lower dose.

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

Other side effects: The most common side effects in adults taking VIDEX EC in combination with other HIV drugs included diarrhea, nausea, headache, vomiting, and rash. 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 an increased amount of fat in the upper back and neck ("buffalo hump"), 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:

Carboxymethylcellulose sodium 12, diethyl phthalate, methacrylic acid copolymer, sodium hydroxide, sodium starch glycolate, talc, gelatin, and titanium dioxide.

This medicine was prescribed for your particular condition. Do not use VIDEX EC for another condition or give it to others. Keep all medicines out of the reach of children and pets at all times. 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 EC in an unrecognizable closed container in the household trash.

This summary does not include everything there is to know about VIDEX EC. 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 EC, 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.

Bristol-Myers Squibb Company
Princeton, NJ 08543 USA

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

XXXXXXX

Rev September 2008