

Medication Guide

VIDEX EC (VY-dex Ee-see)
(didanosine, USP)
Delayed-Release Capsules
Enteric-Coated Beadlets

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

VIDEX EC can cause serious side effects, including:

- **Inflammation of your pancreas (pancreatitis)** can happen in people who take VIDEX EC and can lead to death. People who take VIDEX EC in combination with the medicine stavudine may be at an increased risk for pancreatitis. **Do not take VIDEX EC with stavudine.**
Call your healthcare provider right away if you have any of the following symptoms of pancreatitis:
 - severe stomach (abdomen) pain
 - swelling of your stomach
 - nausea and vomiting
 - fever
- **Build-up of an acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take VIDEX EC or similar medicines (nucleoside analogues). Lactic acidosis is a serious medical emergency that can lead to death. There have been deaths reported in pregnant women who get lactic acidosis after taking VIDEX EC and stavudine. Do not take VIDEX EC with stavudine.
Call your healthcare provider right away if you have any of the following symptoms which could be signs of lactic acidosis:
 - 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
 - weight loss
- **Severe liver problems**, including liver failure, can happen in people who take VIDEX EC. Your liver may become large (hepatomegaly), you may develop fat in the liver (steatosis), or you may have 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 EC. Taking VIDEX EC with medicines that contain hydroxyurea or stavudine may increase your risk for liver problems.
You may be more likely to get lactic acidosis or severe liver problems if you are a female, are very overweight (obese), or have been taking nucleoside analogue medicines for a long time.
Call your healthcare provider right away if you have any of the following symptoms of severe liver problems:
 - yellowing of your skin or the white of your eyes (jaundice)
 - dark or “tea-colored” urine
 - light colored stools (bowel movements)
 - loss of appetite
 - nausea
 - pain, aching, or tenderness on the right side of your stomach area

For more information about side effects, see “What are the possible side effects of VIDEX EC?”.

What is VIDEX EC?

VIDEX EC is a prescription medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus (HIV)-1 infection.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

Do not take VIDEX EC if you take:

- allopurinol
- ribavirin
- stavudine

Before you take VIDEX EC, tell your healthcare provider about all of your medical conditions, including if you:

- have or had problems with your pancreas
- have or had kidney problems
- have or had liver problems, including hepatitis
- have or had numbness, tingling, or pain in the hands or feet (peripheral neuropathy)
- are receiving dialysis
- drink alcoholic beverages
- are pregnant or plan to become pregnant. It is not known if VIDEX EC will harm your unborn baby.
Pregnancy Registry: There is a pregnancy registry for women who take antiretroviral medicines, including VIDEX EC during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take VIDEX EC.**

- You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
- It is not known if VIDEX EC can pass into your breast milk and if it could harm your baby.

Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Some medicines interact with VIDEX EC. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with VIDEX EC.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take VIDEX EC with other medicines.

How should I take VIDEX EC?

- Take VIDEX EC exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much VIDEX EC to take and when to take it.
- **Take VIDEX EC on an empty stomach.**
- Take VIDEX EC capsules whole. If you cannot swallow VIDEX EC capsules whole, tell your healthcare provider. You may need a different medicine.
- Your healthcare provider may change your dose. Do not change your dose of VIDEX EC without talking to your healthcare provider.
- Do not miss a dose of VIDEX EC. If you miss a dose of VIDEX EC, take it as soon as possible.
- It is important to take VIDEX EC on a regular schedule. The virus in your blood may increase and the virus may become harder to treat if you miss doses
- Your healthcare provider may lower your dosage of VIDEX EC if your kidneys are not working well.
- If you take too much VIDEX EC, go to the nearest emergency room right away.

What are the possible side effects of VIDEX EC?

VIDEX EC can cause serious side effects, including:

- See **“What is the most important information I should know about VIDEX EC?”**
- **Numbness, tingling, or pain in your hands or feet (peripheral neuropathy). Peripheral neuropathy is common during treatment with VIDEX EC and can be severe.** Peripheral neuropathy happens more often in people who have advanced HIV-1 disease, have a history of peripheral neuropathy, or in people who are being treated with medicines that can cause neurologic problems. Tell your healthcare provider if you get numbness, tingling, or pain in your hands or feet during treatment with VIDEX EC.
- **Vision changes.** Call your healthcare provider if you have changes in vision, such as blurred vision. You should have regular eye exams while taking VIDEX EC.
- **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.
- **Loss of body fat (lipodystrophy)** can happen with VIDEX use. These changes may include less fat in your legs, arms, face, and buttocks.

The most common side effects of VIDEX EC include:

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| • diarrhea | • rash |
| • nausea | • vomiting |
| • headache | |

These are not all the possible side effects of VIDEX EC.

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 EC?

- Store VIDEX EC capsules in a tightly closed container between 59° F to 86° F (15° C to 30° C)

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

General information about the safe and effective use of VIDEX EC.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIDEX EC for a condition for which it was not prescribed. Do not give VIDEX EC to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about VIDEX EC that is written for health professionals.

What are the ingredients in VIDEX EC?

Active Ingredients: didanosine, USP

Inactive Ingredients: carboxymethylcellulose sodium 12, diethyl phthalate, methacrylic acid copolymer, sodium hydroxide, sodium starch glycolate, and talc

Capsule shell: gelatin, and titanium dioxide.

VIDEX® EC is a registered trademark of Bristol-Myers Squibb Company. Distributed by: Bristol-Myers Squibb Company Princeton, NJ 08543 USA
For more information, go to www.bms.com/products/Pages/prescribing.aspx or call 1-800-321-1335.

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