

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PART III: PATIENT MEDICATION INFORMATION

PrVIDEX EC®

(Didanosine [ddI])

Read this carefully before you start taking VIDEX EC and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about VIDEX EC.

Serious Warnings and Precautions

The following have occurred with the use of didanosine or didanosine and other medications:

- pancreatitis (inflamed pancreas).
- lactic acidosis (too much lactic acid in the blood).
- swollen liver (hepatomegaly).
- fatty liver (steatosis).

These conditions have sometimes led to death. See “What are the possible side effects” section.

What is VIDEX EC used for?

VIDEX EC (pronounced VYE-dex) is a medicine to treat adults who are infected with the virus that causes AIDS.

How does VIDEX EC work?.

VIDEX EC stops the virus from multiplying in the cell. VIDEX EC helps your body maintain its supply of CD4 cells. These cells are important for fighting HIV and other infections.

VIDEX EC contain a coating that stops it from dissolving in the stomach. It dissolves in the intestine where it is absorbed into the body

What are the ingredients in VIDEX EC

Medicinal ingredient: didanosine

Non-Medicinal ingredients in the beadlets are: carboxy methyl cellulose sodium, diethyl phthalate, methacrylic acid copolymer, sodium hydroxide, sodium starch glycolate and talc.

Non-Medicinal ingredients in the capsule shell are: gelatin, sodium lauryl sulfate, and titanium dioxide. Capsules are imprinted with edible ink.

VIDEX EC comes in the following dosage forms

Capsules, in 125, 200, 250 and 400 mg.

Do not use VIDEX EC if

- you take allopurinol, stavudine or ribavirin. Fatal liver failure, pancreatitis, lactic acidosis and other serious reactions have occurred in patients taking VIDEX EC with these drugs.
- you are allergic to **any** of the ingredients in VIDEX EC (See “What are the ingredients in VIDEX EC”). Tell your doctor if you think you have had an allergic reaction to any of the ingredients in this product.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VIDEX EC. Talk about any health conditions or problems you may have, including if you experience:

- **pancreatitis (inflammation of the pancreas)**, which can be fatal with symptoms such as:
 - stomach pain, feeling sick to your stomach, or vomiting.
- **peripheral neuropathy (nerve disorder)** with symptoms such as:
 - feeling ‘pins and needles’, having a burning feeling or having pain or feeling numbness in your hands or feet.
- **lactic acidosis (too much lactic acid in the blood)** with symptoms such as:
 - losing weight, feeling tired, being short of breath, feeling discomfort, , stomach pain , and a fast heart beat.
- **liver problems** including swollen liver (hepatomegaly) with fats collecting in the liver (steatosis) with symptoms such as:
 - stomach pain, feeling sick to your stomach, vomiting, and the skin and eyes turning yellow.
- **portal hypertension (high blood pressure in the vein of the liver)** with symptoms such as:
 - stomach pain, tenderness, abdomen swollen with liquid, and hemorrhoids.
- **vision changes** including loss of colour vision and optic neuritis (inflammation of the optic nerve) with symptoms such as:
 - vision loss, blurred vision, and pain when you move your eyes.
- **kidney problems** including poor function with symptoms such as:

- feeling weak, being short of breath, feeling confused, feeling tired, , swelling of tissues and irregular heartbeat.

At present there is no cure for HIV infection. Even while taking VIDEX EC, you may continue to have HIV-related illnesses, including other infections. 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, the patient infected with HIV must continue to practice safe sex and take precautions to prevent others from coming in contact with their blood and other body fluids.

Tell your doctor if you:

- may be allergic to any medicine.
- are pregnant or planning to become pregnant. Videx EC can harm the fetus and increase birth defects. Talk to your doctor. Tell your doctor if you become pregnant.
- are breastfeeding or planning to breastfeed. It is not known whether Videx EC is found in human breast milk. Videx EC has been found in breast milk of animals given this medicine Experts advise that you not breastfeed if you are HIV positive. Talk to your doctor.

Other warnings you should know about:

Your blood sugar levels or fat levels in your blood may increase with HIV treatment. Your doctor may order blood tests for you.

If you need to watch the quantity of salt you take, VIDEX EC has very low sodium (salt) content. The amount of sodium in VIDEX EC is: 0.53 mg for the 125-mg capsule, 0.85 mg for the 200-mg capsule, 1.06 mg for the 250-mg capsule, and 1.70 mg for the 400-mg capsule.

Your doctor prescribed VIDEX EC for your particular condition. Do not use VIDEX EC for another illness. Do not give it to others.

Tell your doctor all the medicines you take like drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VIDEX EC

Avoid drinking alcoholic beverages while taking VIDEX EC since alcohol may increase your risk of pancreatitis or liver damage. Other medicines, including those you can buy without a prescription, may interfere with the actions of VIDEX EC. Do not take any medicine, vitamin, or health preparation without **first** checking with your doctor.

Some medicines should not be taken at the same time of day that you take VIDEX EC as they may interfere with the action of VIDEX EC or may increase the possibility of experiencing side effects. Check with your doctor. These medicines include: methadone, tenofovir, and ganciclovir.

Do not take allopurinol, stavudine and ribavirin with VIDEX EC.

However, because VIDEX EC capsules do not contain an antacid component, they can be taken with tetracycline or quinolone anti-infective agents. There is also no drug-drug interaction between VIDEX EC capsules and indinavir, therefore, these two products can be taken together.

How to take VIDEX EC

VIDEX EC should only be taken once daily.

Your doctor will determine the strength of your dose based on your body weight, kidney and liver function, and any side effects that you may have had with other medications. Take VIDEX EC exactly as instructed. VIDEX EC should be taken on an empty stomach, at least 1.5 hours before or 2 hours after eating, and should NOT be taken with food.

VIDEX EC capsules should be swallowed intact and not chewed.

Overdose

In case of drug overdose, contact a healthcare practitioner (e.g. doctor), hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed dose

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 resume your regular dosing schedule.

What are possible side effects from using VIDEX EC

VIDEX EC may cause side effects which:

- are mostly non-serious.
- may cause discomfort.
- are most commonly diarrhea, nausea, headache, rash and vomiting.

Talk to your doctor right away if:

- you have fever, rash, redness and swelling.
- you have joint or muscle pain or fatigue.

Starting an HIV medication may affect your immune system by:

- making the immune system stronger.
- starting to fight infections hidden in your body for a long time.
- leading to the start of an autoimmune disease such as:

- Immune Reconstitution Inflammatory Syndrome.
- Grave's disease (thyroid gland).
- Guillain-Barre Syndrome (nervous system).
- polymyositis (muscle disease).

These conditions can happen at any time and can start several months after beginning treatment.

The loss of body fat from legs, arms and face has occurred with those taking VIDEX EC and similar medicines. Tell your doctor if this happens. This fat loss:

- may take months to regain.
- may be permanent.

Your doctor will:

- decide if Videx EC should be continued or stopped.
- decide if other treatment should be used.
- continue to follow your condition.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<p>COMMON</p> <ul style="list-style-type: none"> • Liver problems with symptoms such as abdominal pain, nausea, vomiting, and yellowing of the skin and eyes. Peripheral neuropathy (nerve problems) with symptoms such as tingling, burning, pain or numbness in the hands or feet which may be signs of nerve disorder. 		✓	
<p>UNCOMMON SIDE EFFECTS</p> <ul style="list-style-type: none"> • Pancreatitis (inflammation of the pancreas) with symptoms such as stomach pain, swelling of your stomach area, nausea, vomiting and fever. • Lactic acidosis (too much lactic acid in the blood) with symptoms such as fatigue, shortness of breath, malaise, abdominal pain, and weight loss. • Vision problems such as changes in eye colour, or eye sight with symptoms such as blurred vision, inability to see in dim light, vision disorder, inability to distinguish certain colors, partial or total vision loss, or tunnel vision. • Anaphylactoid reaction (sudden life threatening allergic reaction) 		✓ ✓ ✓ ✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<ul style="list-style-type: none"> Immune Reconstitution Inflammatory Syndrome with symptoms such as high temperature (fever), joint or muscle pain, redness, rash, swelling, or fatigue 		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program

Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage

VIDEX EC should be stored in tightly closed bottles at room temperature (15-30°C).

Keep out of the reach and sight of children.

Discard VIDEX EC when it is outdated or no longer needed by returning the unused medication to your pharmacist for proper disposal.

If you want more information about VIDEX EC

Talk to your healthcare professional

Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website <http://www.bmscanada.ca>, or by calling 1-866-463-6267.

This leaflet was prepared by Bristol-Myers Squibb Canada.

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