

Medication Guide

VIDEX® (VY-dex) (didanosine, also known as ddl) 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 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 in people:

- who take VIDEX by itself, and in people who also take other antiviral medicines along with VIDEX to treat their HIV-1 infection **and**
- who have never taken anti-HIV medicines before, and also in people who have taken antiviral medicines to treat their HIV-1 infection.

People who take VIDEX with the medicine stavudine (ZERIT®), and people with kidney problems may have an increased risk for developing pancreatitis. People who have advanced HIV-1 infection, especially the elderly, have an increased risk of developing pancreatitis. Your dose of VIDEX may need to be decreased by your healthcare provider, or your healthcare provider may need to hold or stop your treatment with VIDEX if you develop pancreatitis.

Before you start taking VIDEX, tell your healthcare provider if you:

- have had pancreatitis
- have kidney problems
- drink alcoholic beverages
- take the medicine stavudine (ZERIT)

Call your healthcare provider right away if you develop:

- stomach-area (abdomen) pain
- swelling of your stomach area
- nausea and vomiting
- fever

2. Build-up of acid in your blood (lactic acidosis). Lactic acidosis can happen in some people who take VIDEX alone or with other antiviral medicines. Lactic acidosis is a serious medical emergency that can lead to death. Death has happened in pregnant women who take VIDEX and the medicine stavudine (ZERIT), along with other antiviral medicines. The risk for lactic acidosis may be higher if you:

- are pregnant
- are taking stavudine (ZERIT)
- have liver problems
- are overweight
- are taking HIV medicines for a long time

Lactic acidosis treatment usually requires hospitalization.

Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. Call your healthcare provider right away if you get the following symptoms which could be signs of lactic acidosis:

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- feel very 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. **Severe liver problems.** Severe liver problems can happen in people, including pregnant women, who take VIDEX alone or with other antiviral medicines. In some cases, these severe liver problems can lead to the need for you to have a liver transplant, or cause death. Your liver may become large (hepatomegaly), you may develop fat in your liver (steatosis), liver failure, or high blood pressure in the large vein of your liver (portal hypertension). Your healthcare provider should examine you and check your liver function while you are taking VIDEX.

It is not known if VIDEX is safe and effective in people with HIV-infection who also have liver disease.

Call your healthcare provider right away if you develop:

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

You may be more likely to develop severe liver problems if you:

- are a woman
- are pregnant
- are overweight
- have been treated for a long time with other medicines to treat HIV

What is VIDEX?

VIDEX is a prescription medicine used with other antiretroviral medicines to treat human immunodeficiency virus type 1 (HIV-1) infection in children and adults. VIDEX belongs to a class of drugs called nucleoside analogues.

When used with other HIV medicines, VIDEX may help:

- reduce the amount of HIV in your blood. This is called “viral load.”
- increase the number of white blood cells called CD4+ (T) cells in your blood, which may help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

VIDEX does not cure HIV-1 infection or AIDS. You must stay on continuous HIV-1 therapy to control infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV to other people.

Who should not take VIDEX?

Do not take VIDEX if you take:

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

What should I tell my healthcare provider before taking VIDEX?

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

- have had pancreatitis
- 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)
- drink alcoholic beverages
- 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 healthcare provider about how you can take part in this registry.

- **are breastfeeding or plan to breastfeed. Do not breastfeed if you take VIDEX.** You should not breastfeed because of the risk of passing HIV to your baby. It is not known if VIDEX passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking VIDEX.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter 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:

- tenofovir disoproxil fumarate (VIREAD[®], ATRIPLA, COMPLERA, STRIBILD, TRUVADA)
- hydroxyurea (DROXIA[®], HYDREA[®])
- delavirdine mesylate (RESCRIPTOR[®])
- ganciclovir (CYTOVENE[®], VALCYTE[®])
- indinavir (CRIXIVAN[®])
- methadone hydrochloride (DOLOPHINE[®] HYDROCHLORIDE, METHADOSE[®])
- nelfinavir (VIRACEPT[®])
- antacids that contain magnesium or aluminum
- the antifungal medicines ketoconazole (NIZORAL[®]) and itraconazole (SPORANOX[®], ONMEL)
- a type of antibiotic called a “quinolone,” such as ciprofloxacin (CIPRO[®])
- an antibiotic that contains tetracycline
- stavudine (ZERIT)

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.
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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.
- VIDEX comes as a Powder for Oral Solution. Your pharmacist will give you a bottle that contains VIDEX as a solution that has been mixed with acid-reducing medicines (antacids).
- Shake the bottle well before taking each dose of VIDEX.
- Be sure to close the bottle tightly after each use.
- Try not to miss a dose of VIDEX, but if you do, take it as soon as possible. If it is almost time for the next dose, skip the missed dose. Then 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 dose of VIDEX if your kidneys are not working well.
- **If you take too much VIDEX,** call a poison control center or go to an emergency room right away.

What are the possible side effects of VIDEX?

VIDEX can cause serious side effects.

- See “What is the most important information I should know about VIDEX?”
- **Vision changes.** Contact your healthcare provider if you have changes in vision, such as dry eyes and/or blurred vision. You should have regular eye exams while you take VIDEX.
- **Nerve damage.** Symptoms include numbness, tingling, or pain in your hands or feet. These are common with VIDEX, but are more likely to happen in people who have had these problems before, in people who take medicines that can affect the nerves, including stavudine (ZERIT), and in people who have advanced HIV disease. A child may not notice the symptoms. Ask your healthcare provider about the signs and symptoms of nerve problems that you should look for in your child during and after treatment with VIDEX.
- **Changes in your immune system (immune reconstitution syndrome)** can happen when you start taking HIV-1 medicine. 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 symptoms after starting to take HIV-1 medicine.
- **Changes in body fat** can happen in people who take HIV-1 medicines. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (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.

The most common side effects of VIDEX include:

- diarrhea
- stomach-area (abdomen) 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 VIDEX oral solution 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.

General information about the safe and effective use of VIDEX

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.

If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about VIDEX that is written for health professionals. For more information, go to www.bms.com/products/Pages/home.aspx or call 1-800-321-1335.

What are the ingredients in VIDEX?

Active ingredient: didanosine

Pediatric Oral Solution inactive ingredients: Purified Water, USP and an antacid containing aluminum hydroxide (400 mg per 5 mL), magnesium hydroxide (400 mg per 5 mL), and simethicone (40 mg per 5 mL).

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

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