

Medication Guide
VIDEX (VY-dex)
(didanosine, USP)
pediatric powder for oral solution

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

VIDEX can cause serious side effects, including:

- **Inflammation of your pancreas (pancreatitis)** can happen in people who take VIDEX and can lead to death. People who take VIDEX in combination with the medicine stavudine may be at an increased risk for pancreatitis. **Do not take VIDEX 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 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 and ZERIT (stavudine). Do not take VIDEX with stavudine.
- **Call your healthcare provider right away if you have any of the following symptoms which could be signs of lactic acidosis:**
 - 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
 - weight loss
- **Severe liver problems**, including liver failure, can happen in people who take VIDEX. Your liver may become large (hepatomegaly), you may develop fat in your liver (steatosis), or you may have high blood pressure in the large vein of your liver (portal hypertension). Severe liver problems can lead to liver transplantation or death in some people taking VIDEX. Taking VIDEX 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?”.

What is VIDEX?

VIDEX 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 if you take a medicine that contains:

- allopurinol
- ribavirin
- stavudine

Before you take VIDEX, 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 will harm your unborn baby.
Pregnancy Registry: There is a pregnancy registry for women who take antiretroviral medicines, including VIDEX 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 if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - It is not known if VIDEX can pass into your breast milk and if it could harm your baby.

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.

Some medicines interact with VIDEX. 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.
- **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 with other medicines.

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.
- Take VIDEX on an empty stomach at least 30 minutes before or 2 hours after you eat.
- Your healthcare provider may change your dose if you have certain side effects. Do not change your dose of VIDEX without talking to your healthcare provider.
- Shake the bottle well before taking each dose of VIDEX.
- Be sure to close the bottle tightly after each use.
- Do not miss a dose of VIDEX. If you miss a dose of VIDEX, take it as soon as possible.
- It is important to take VIDEX 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 dose of VIDEX if your kidneys are not working well.
- If you take too much VIDEX, go to the nearest emergency room right away.

What are the possible side effects of VIDEX?

VIDEX can cause serious side effects, including:

- See “What is the most important information I should know about VIDEX?”
- **Numbness, tingling, or pain in your hands or feet (peripheral neuropathy).** Peripheral neuropathy is common during treatment with VIDEX 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.
- **Vision changes.** Call your healthcare provider if you have changes in vision, such as blurred vision. You should have regular eye exams during treatment with VIDEX.
- **Changes in your immune system (immune reconstitution syndrome)** can happen when you start taking HIV-1 medicines. 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 any new symptoms after starting your HIV-1 medicine.
- **Loss of body fat (lipoatrophy)** from the arms, legs, or face can happen during treatment with VIDEX. Your healthcare provider will monitor you for changes in your body fat. It is important to tell your healthcare provider if you notice any changes.

The most common side effects of VIDEX include:

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|--------------------------|------------|
| • diarrhea | • headache |
| • stomach (abdomen) pain | • rash |
| • nausea | • vomiting |

These are not all the possible side effects of VIDEX.

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. Do not give VIDEX 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 that is written for health professionals.

What are the ingredients in VIDEX?

Active ingredient: didanosine, USP

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).

Distributed by: Bristol-Myers Squibb Company Princeton, NJ 08543 USA

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For more information, go to www.bms.com/products/Pages/home.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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Revised: January 2018