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Medication Guide

VIDEX[®] (VY-dex) (didanosine, also known as ddI) 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 and your healthcare provider should talk about your treatment with VIDEX before you start taking it and at regular check-ups. 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 at any time during your treatment with VIDEX.** Before you start taking VIDEX, tell your healthcare provider if you:

- have had pancreatitis
- have advanced HIV (human immunodeficiency virus) infection
- have kidney problems
- drink alcoholic beverages
- take a medicine called ZERIT[®] (stavudine)

It is important to call your healthcare provider right away if you have:

- stomach pain
- swelling of your stomach
- nausea and vomiting
- fever

2. **Build-up of acid in your blood (lactic acidosis). Lactic acidosis must be treated in the hospital as it may cause death.** The risk for lactic acidosis may be higher if you:

- have liver problems
- are pregnant. There have been deaths reported in pregnant women who get lactic acidosis after taking VIDEX and ZERIT (stavudine).
- are overweight
- have been treated for a long time with other medicines to treat HIV

550 **It is important to call your healthcare provider right away if you:**

- 551 • feel weak or tired
- 552 • have unusual (not normal) muscle pain
- 553 • have trouble breathing
- 554 • have stomach pain with nausea and vomiting
- 555 • feel cold, especially in your arms and legs
- 556 • feel dizzy or light-headed
- 557 • have a fast or irregular heartbeat

558 3. **Liver problems.** Some people (including pregnant women) who have taken VIDEX have
559 had serious liver problems. These problems include liver enlargement (hepatomegaly), fat in
560 the liver (steatosis), liver failure, and high blood pressure in the large vein of the liver (portal
561 hypertension). Severe liver problems can lead to liver transplantation or death in some people
562 taking VIDEX. Your healthcare provider should check your liver function while you are
563 taking VIDEX. You should be especially careful if you have a history of heavy alcohol use
564 or liver problems.

565 **It is important to call your healthcare provider right away if you have:**

- 566 • yellowing of your skin or the white of your eyes (jaundice)
- 567 • dark urine
- 568 • pain on the right side of your stomach
- 569 • swelling of your stomach
- 570 • easy bruising or bleeding
- 571 • loss of appetite
- 572 • nausea or vomiting
- 573 • vomiting blood or dark colored stools (bowel movements)

574 **What is VIDEX?**

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

578 VIDEX will not cure your HIV infection. At present there is no cure for HIV infection. Even
579 while taking VIDEX, you may continue to have HIV-related illnesses, including infections with

580 other disease-producing organisms. Continue to see your healthcare provider regularly and report
581 any medical problems that occur.

582 **Who should not take VIDEX?**

583 **Do not take VIDEX if you take:**

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

586 **What should I tell my healthcare provider before taking VIDEX?**

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

- 588 • have or had kidney problems
- 589 • have or had liver problems (such as hepatitis)
- 590 • have or had persistent numbness, tingling, or pain in the hands or feet (neuropathy)
- 591 • have any other medical conditions
- 592 • are pregnant or plan to become pregnant. It is not known if VIDEX will harm your
593 unborn baby. Tell your healthcare provider right away if you become pregnant while
594 taking VIDEX. You and your healthcare provider will decide if you should take VIDEX
595 while you are pregnant.

596 **Pregnancy Registry:** There is a pregnancy registry for women who take antiviral
597 medicines during pregnancy. The purpose of the registry is to collect information about
598 the health of you and your baby. Talk to your doctor about how you can take part in this
599 registry.

- 600 • are breast-feeding or plan to breast-feed. **Do not breast-feed while you take VIDEX.** It
601 is not known if VIDEX passes into your breast milk. The Centers for Disease Control and
602 Prevention (CDC) recommends that HIV-infected mothers **not** breast-feed to avoid the
603 risk of passing HIV infection to your baby.

604 **Tell your healthcare provider about all the medicines you take**, including prescription and
605 non-prescription medicines, vitamins and herbal supplements. VIDEX may affect the way other
606 medicines work, and other medicines may affect how VIDEX works.

607 **Especially tell your healthcare provider if you take:**

- 608 • VIREAD[®] (tenofovir disoproxil fumarate)
- 609 • DROXIA[®], HYDREA[®] (hydroxyurea)
- 610 • RESCRIPTOR[®] (delavirdine mesylate)
- 611 • CYTOVENE[®], VALCYTE[®] (ganciclovir)

- 612 • CRIXIVAN[®] (indinavir)
- 613 • DOLOPHINE[®] HYDROCHLORIDE, METHADOSE[®] (methadone)
- 614 • VIRACEPT[®] (nelfinavir)
- 615 • antacids
- 616 • antifungal medicines such as NIZORAL[®] (ketoconazole) or SPORANOX[®]
- 617 (itraconazole)
- 618 • quinolone antibiotics such as CIPRO[®], PROQUIN[®] XR (ciprofloxacin)
- 619 • tetracycline antibiotics such as BRISTACYCLINE[®], SUMYCIN[®] (tetracycline)
- 620 • alcoholic beverages

621 Know the medicines you take. Keep a list of your medicines and show it to your healthcare
622 provider and pharmacist when you get a new medicine.

623 Ask your healthcare provider if you are not sure if you take one of the medicines listed above.

624 **How should I take VIDEX?**

- 625 • Take VIDEX exactly as your healthcare provider tells you to take it.
- 626 • Your healthcare provider will tell you how much VIDEX to take and when to take it.
- 627 • Your healthcare provider may change your dose. Do not change your dose of VIDEX
- 628 without talking to your healthcare provider.
- 629 • **Do not take VIDEX with food.** Take VIDEX on an empty stomach at least 30 minutes
- 630 before or 2 hours after you eat.
- 631 • Try not to miss a dose, but if you do, take it as soon as possible. If it is almost time for the
- 632 next dose, skip the missed dose and continue your regular dosing schedule.
- 633 • **Some medicines should not be taken at the same time of day that you take VIDEX.**
- 634 Check with your healthcare provider.
- 635 • If your kidneys are not working well, your healthcare provider will need to do regular blood
- 636 and urine tests to check how they are working while you take VIDEX. Your healthcare
- 637 provider may also lower your dosage of VIDEX if your kidneys are not working well.
- 638 • **If you take too much VIDEX,** contact a poison control center or emergency room right
- 639 away.

640 **What should I avoid while taking VIDEX?**

- 641 • **Alcohol.** Do not drink alcohol while you take VIDEX. Alcohol may increase your risk of
- 642 getting pain and swelling of your pancreas (pancreatitis) or may damage your liver.

643 **What are the possible side effects of VIDEX?**

644 VIDEX can cause pancreatitis, lactic acidosis, and liver problems. See “**What is the most**
645 **important information I should know about VIDEX?**” at the beginning of this Medication
646 Guide.

- 647 • **Vision changes.** You should have regular eye exams while you take VIDEX.
- 648 • **Peripheral neuropathy. Symptoms include:** numbness, tingling, or pain in your hands or
649 feet. This condition is more likely to happen in people who have had it before, in patients
650 taking medicines that affect the nerves, and in people with advanced HIV disease. A child
651 may not notice these symptoms. Ask your child’s healthcare provider for the signs and
652 symptoms of peripheral neuropathy in children.
- 653 • **Changes in your immune system (immune reconstitution syndrome).** Your immune
654 system may get stronger and begin to fight infections that have been hidden in your body for
655 a long time. Tell your healthcare provider if you start having new or worse symptoms of
656 infection after you start taking HIV medicine.
- 657 • **Changes in body fat (fat redistribution).** Changes in body fat have been seen in people
658 who take antiretroviral medicines. These changes may include:
- 659 • more fat in or around your
- 660 – upper back and neck (buffalo hump)
- 661 – breasts or chest
- 662 – trunk
- 663 • less fat in your
- 664 – legs
- 665 – arms
- 666 – face

667 Tell your healthcare provider if you have any of the symptoms listed above.

668 The most common side effects of VIDEX include:

- 669 • diarrhea
- 670 • stomach pain
- 671 • nausea
- 672 • vomiting
- 673 • headache
- 674 • rash

675 Tell your healthcare provider if you have any side effect that bothers you or that does not go
676 away.

677 These are not all the possible side effects of VIDEX. For more information, ask your healthcare
678 provider or pharmacist.

679 Call your doctor for medical advice about side effects. You may report side effects to FDA at
680 1-800-FDA-1088.

681 **How should I store VIDEX?**

682 Store the VIDEX liquid mixture in a tightly closed container in the refrigerator between 36° F to
683 46° F (2° C to 8° C) for up to 30 days.

- 684 • Safely throw away any unused VIDEX after 30 days.

685 **Keep VIDEX and all medicines out of the reach of children and pets.**

686 **General Information about the safe and effective use of VIDEX.**

687 VIDEX has not been shown to prevent a patient infected with HIV from passing the virus to
688 other people. To protect others, you must continue to practice safer sex and take precautions to
689 prevent others from coming in contact with your blood and other body fluids.

690 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
691 Do not use VIDEX for a condition for which it was not prescribed. Do not give VIDEX to other
692 people, even if they have the same symptoms as you have. It may harm them. Do not keep
693 medicine that is out of date or that you no longer need. Dispose of unused medicines through
694 community take-back disposal programs when available or place VIDEX in an unrecognizable
695 closed container in the household trash.

696 This Medication Guide summarizes the most important information about VIDEX. If you would
697 like more information, talk with your healthcare provider. You can ask your healthcare provider
698 or pharmacist for information about VIDEX that is written for health professionals. For more
699 information, go to http://packageinserts.bms.com/pi/pi_videx.pdf or call 1-800-321-1335.

700 **What are the ingredients in VIDEX?**

701 **Active Ingredients:** didanosine

702 **Inactive Ingredients:**

703 **Pediatric Oral Solution:** Maximum Strength Mylanta[®] Liquid.

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705 trademarks are the property of their respective owners.

706 Bristol-Myers Squibb Company

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