

PHARMACISTS: Detach and dispense the enclosed Medication Guide to each patient.

Medication Guide

ZERIT[®] (Zair-it)

(stavudine)

ZERIT[®] Capsules and

ZERIT[®] for Oral Solution

Read this Medication Guide before you start taking ZERIT 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 ZERIT before you start taking it and at regular check-ups. You should stay under your healthcare provider's care when taking ZERIT.

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

ZERIT can cause serious side effects, including:

1. Build up of acid in your blood (lactic acidosis). Lactic acidosis can cause death and must be treated in the hospital. The risk of 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 ZERIT and VIDEX, or ZERIT and VIDEX EC (didanosine).
- are female
- are overweight
- have been treated for a long time with other medicines used to treat HIV

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

- 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

2. Liver problems. Some people (including pregnant women) who have taken ZERIT have had serious liver problems. These problems include liver enlargement (hepatomegaly), fat in the liver (steatosis), liver failure, and death due to liver problems. Your healthcare provider should check your liver function while you are taking ZERIT. You should be especially careful if you have a history of heavy alcohol use or liver problems. Use of ZERIT with VIDEX EC or VIDEX (didanosine) may increase your risk for liver damage.

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

- yellowing of your skin or the white of your eyes (jaundice)
- dark urine
- pain on the right side of your stomach
- swelling of your stomach
- easy bruising or bleeding
- loss of appetite
- nausea or vomiting

3. Swelling of the pancreas (pancreatitis) that may cause death has occurred when ZERIT was used with VIDEX EC or VIDEX (didanosine). Pancreatitis can happen at any time during your treatment with ZERIT.

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

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

What is ZERIT?

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

ZERIT will not cure your HIV infection. At present there is no cure for HIV infection. Even while taking ZERIT, you may continue to have HIV-related illnesses, including infections with other disease-producing organisms. Continue to see your healthcare provider regularly and report any medical problems that occur.

Who should not take ZERIT?

Do not take ZERIT if you:

- are allergic to stavudine or any of the ingredients in ZERIT. See the end of this Medication Guide for a complete list of the ingredients in ZERIT.

What should I tell my healthcare provider before taking ZERIT?

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

- have or had liver problems (such as hepatitis)
- have or had problems with your pancreas (pancreatitis)
- have or had kidney problems
- have or had persistent numbness, tingling, or pain in the hands or feet (neuropathy)
- have gallstones
- drink alcoholic beverages
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ZERIT will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking ZERIT. You and your healthcare provider will decide if you should take ZERIT 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 breast-feeding or plan to breast-feed. **Do not breast-feed while you take ZERIT** It is not known if ZERIT passes into your breast milk. The Centers for Disease Control and Prevention (CDC) recommends that HIV-infected mothers **not** breast-feed to avoid the risk of passing HIV infection to your baby.

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, or herbal supplements. ZERIT may affect the way other medicines work, and other medicines may affect how ZERIT works.

Especially tell your healthcare provider if you take:

- COMBIVIR[®], RETROVIR[®], TRIZIVIR[®] (zidovudine or AZT)
- VIDEX[®] or VIDEX EC[®] (didanosine)
- ADRIAMYCIN[®], RUBEX[®] (doxorubicin)
- COPEGUS[®], REBETOL[®], RIBASPHERE[®], RIBAVIRIN[®], VIRAZOLE[®] (ribavirin)
- ROFERON-A[®], INTRON-A[®], and others (interferon)
- HYDREA[®], DROXIA[®] (hydroxyurea)

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 ZERIT?

- Take ZERIT exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much ZERIT to take and when to take it.
- If your child will be taking ZERIT, your child's healthcare provider should give you instructions on how to give this medicine. If your child is taking ZERIT oral solution, shake the bottle well before measuring each dose.
- Your healthcare provider may change your dose. Do not change your dose of ZERIT without talking to your healthcare provider.

- ZERIT may be taken with or without food.
- 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 continue your regular dosing schedule.
- Some medicines may require your healthcare provider to monitor your therapy or change your therapy. 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 ZERIT. Your healthcare provider may also lower your dosage of ZERIT if your kidneys are not working well.
- **If you take too much ZERIT**, contact a poison control center or emergency room right away.

What should I avoid while taking ZERIT?

- **Alcohol. You should avoid drinking alcohol while taking ZERIT.** Alcohol may increase your risk of getting pain and swelling of your pancreas (pancreatitis) or may damage your liver.

What are the possible side effects of ZERIT?

ZERIT can cause serious side effects including:

- ZERIT can cause lactic acidosis, liver problems, and pancreatitis. See “**What is the most important information I should know about ZERIT?**”
- **Neurologic symptoms. Symptoms include: weakness of your legs, feet, arms, or hands (motor weakness) and numbness or tingling in your hands or feet (neuropathy).** These problems can happen more often in people who have advanced HIV disease, have a history of peripheral neuropathy, or in people who take other medicines that also are associated with neuropathy including didanosine. In some cases, neuropathy may temporarily worsen after you stop taking ZERIT. Neuropathy can be difficult to notice in children who take ZERIT. Ask your child’s healthcare provider for the signs and symptoms of peripheral neuropathy in children.

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

- numbness in your hands or feet
- tingling in your hands or feet

- weakness in your legs, feet, arms, or hands
- **Changes in body fat (fat redistribution).** Changes in body fat (lipoatrophy or lipodystrophy) have been seen in some people taking HIV medicines including ZERIT. Loss of body fat (lipoatrophy) happens more often in people who take ZERIT than in people who take other similar HIV medicines.

These changes may include:

- more fat in or around your
 - trunk
 - upper back and neck (buffalo hump)
 - breast or chest
- loss of fat in your
 - legs
 - arms
 - face

Your healthcare provider will monitor you for changes in your body fat. It is important to tell your healthcare provider if you notice any of these changes.

- **Changes in your immune system (immune reconstitution syndrome).** Your immune system may begin to fight infections that have been 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.

The most common side effects of ZERIT include:

- headache
- diarrhea
- rash
- nausea
- vomiting

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 ZERIT. 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 ZERIT?

- **Capsules:**
 - Store ZERIT capsules in a tightly closed container at room temperature at 59°F to 86°F (15°C to 30°C).
- **Oral solution:**
 - Store ZERIT oral solution in the refrigerator at 36°F to 46°F (2°C to 8°C)
 - Store ZERIT oral solution in a tightly closed container.
 - Throw away any unused medicine after 30 days.

Keep ZERIT and all medicines out of the reach of children and pets.

General Information about the safe and effective use of ZERIT.

If you have diabetes mellitus: ZERIT for Oral Solution contains 50 mg of sucrose (sugar) per mL.

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

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

This Medication Guide summarizes the most important information about ZERIT. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider

or pharmacist for information about ZERIT that is written for health professionals. For more information, go to <http://www.bms.com/products/Pages/prescribing.aspx> or call 1-800-321-1335.

What are the ingredients in ZERIT?

Active Ingredient: stavudine

Inactive Ingredients:

ZERIT Capsules: microcrystalline cellulose, sodium starch glycolate, lactose, and magnesium stearate.

The gelatin shell contains: gelatin, titanium oxide, and iron oxide.

ZERIT for Oral Solution: methylparaben, propylparaben, sodium carboxymethylcellulose, sucrose, and antifoaming and flavoring agents.

ZERIT[®], VIDEX[®], VIDEX EC[®], HYDRE A[®], and DROXIA[®] are registered trademarks of Bristol-Myers Squibb Company. All other trademarks are the property of their respective owners.

Distributed by:

Bristol-Myers Squibb Company

Princeton, NJ 08543 USA

XXXXXXXX Rev

December 2010

XXXX

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