

## PATIENT INFORMATION Rx ONLY

### ZERIT<sup>®</sup>

(generic name = **stavudine**, also known as **d4T**)

ZERIT<sup>®</sup> (stavudine) Capsules

ZERIT<sup>®</sup> (stavudine) for Oral Solution

#### What is ZERIT?

ZERIT (pronounced ZER it) is a prescription medicine used in combination with other drugs to treat adults and children who are infected with HIV (the human immunodeficiency virus), the virus that causes AIDS. ZERIT belongs to a class of drugs called nucleoside analogues. By reducing the growth of HIV, ZERIT helps your body maintain its supply of CD4 cells, which are important for fighting HIV and other infections.

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 caused by other disease-producing organisms. Continue to see your doctor regularly and report any medical problems that occur.

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

There is limited information on the long-term use of ZERIT.

#### Who should not take ZERIT?

Do not take ZERIT if you are allergic to any of its ingredients, including its active ingredient, stavudine, and the inactive ingredients. (See **Inactive Ingredients** at the end of this leaflet.) Tell your doctor if you think you have had an allergic reaction to any of these ingredients.

#### How should I take ZERIT? How should I store it?

Your doctor will determine your dose (the amount in each capsule or spoonful) based on your body weight, kidney and liver function, and any side effects that you may have had with other medicines. Take ZERIT exactly as instructed. 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. ZERIT may be taken with food or on an empty stomach.

- **Capsules:** ZERIT capsules are usually taken twice a day (every 12 hours). Store ZERIT capsules in a tightly closed container at room temperature away from heat and out of the reach of children and pets. Do NOT store this medicine in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- **Oral solution (for children):** ZERIT for Oral Solution is taken twice a day (every 12 hours). If your child will be taking ZERIT, the doctor should give you written instructions on how to give this medicine. Before measuring each dose, shake the bottle well. Store ZERIT for Oral Solution in a tightly closed container in a refrigerator and throw away any unused portion after 30 days.

**If you have a kidney problem:** If your kidneys are not working properly, your doctor may monitor your kidney function while you take ZERIT. Also, your dosage of ZERIT may be adjusted.

#### What should I do if someone takes an overdose of ZERIT?

If you suspect that someone has taken an overdose of ZERIT, get medical help right away. Contact their doctor or a poison control center.

#### What should I avoid while taking ZERIT?

**Other medicines.** Other medicines, including those you can buy without a prescription, may interfere with the actions of ZERIT. You should not use ZERIT

in combination with zidovudine (AZT). **Do not take any medicine, vitamin, supplement, or other health preparation without first checking with your doctor.** [Taking ZERIT (stavudine) with other drugs that also may cause peripheral neuropathy may increase your risk of getting this serious side effect.]

**Pregnancy:** It is not known if ZERIT can harm a human fetus. Also, pregnant women have experienced serious side effects when taking ZERIT in combination with didanosine and other HIV medicines. ZERIT should be used during pregnancy only after discussion with your doctor. **Tell your doctor if you become pregnant or plan to become pregnant while taking ZERIT.**

**Nursing:** Because studies have shown ZERIT is in the breast milk of animals receiving the drug, it may be present in human breast milk. The Centers for Disease Control and Prevention (CDC) recommends that HIV-infected mothers **not** breast-feed to reduce the risk of passing HIV infection to their babies and the potential for serious adverse reactions in nursing infants. Therefore, do not nurse a baby while taking ZERIT.

#### What are the possible side effects of ZERIT?

Serious side effects of ZERIT may include:

- **Lactic acidosis**, severe increase of lactic acid in the blood, **severe liver enlargement**, including inflammation (pain and swelling) of the liver, and **liver failure**, which can cause death.
- **Peripheral neuropathy**, a nerve disorder of the hands and feet.

People who take ZERIT along with other medicines that may cause similar side effects may have a higher chance of developing these side effects than if they took ZERIT alone. For example, if you use ZERIT in combination with other drugs (including didanosine, with or without hydroxyurea) that may be associated with liver enlargement, peripheral neuropathy, or pancreatitis, you may be at increased risk for these side effects. Children experience side effects that are similar to those experienced by adults.

**Lactic acidosis and severe liver enlargement:** Lactic acidosis and severe liver enlargement, including deaths, have been reported among patients taking ZERIT (including pregnant women). **Symptoms of lactic acidosis may include:**

- **nausea, vomiting, or unusual or unexpected stomach discomfort;**
- **feeling very weak and tired;**
- **shortness of breath;**
- **weakness in arms and legs.**

**If you notice these symptoms or if your medical condition has suddenly changed, stop taking ZERIT and call your doctor right away.** Lactic acidosis is a medical emergency that must be treated in a hospital. Women, overweight patients, and those who have had lengthy treatment with nucleoside medicines are more likely to develop lactic acidosis. Your doctor should check your liver function periodically while you are taking ZERIT, especially if you have a history of heavy alcohol use or a liver problem. The combination of ZERIT, didanosine, and hydroxyurea may increase your risk for liver damage, which may be fatal. Your doctor should closely monitor your liver function if you are taking this combination.

**Peripheral neuropathy:** This nerve disorder is rare, but may be serious. **Tell your doctor right away if you or a child taking ZERIT has continuing numbness, tingling, burning, or pain in the feet and/or hands.** A child may not recognize these symptoms or know to tell you that his or her feet or hands are numb, burning, tingling, or painful. Ask your child's doctor for instructions on how to find out if your child develops peripheral neuropathy.

Let your doctor know if you or a child taking ZERIT has ever had peripheral neuropathy, because this condition occurs more often in patients who have had it previously. Peripheral neuropathy is

also more likely to occur in patients taking drugs that affect the nerves and in patients with advanced HIV disease, but it can occur at any disease stage. If you develop peripheral neuropathy, your doctor may tell you to stop taking ZERIT (stavudine). In some cases the symptoms worsen for a short time before getting better. Once symptoms of peripheral neuropathy go away completely, ZERIT may be started again at a lower dose.

**Pancreatitis:** Pancreatitis is a dangerous inflammation of the pancreas. It may cause death. **Tell your doctor right away if you develop stomach pain, nausea, or vomiting. These can be signs of pancreatitis.** Let your doctor know if you have ever had pancreatitis, regularly drink alcoholic beverages, or have gallstones. Pancreatitis occurs more often in patients with these conditions. It is also more likely in people with advanced HIV disease, but can occur at any disease stage. The combination of ZERIT and didanosine, with or without hydroxyurea, may increase your risk for pancreatitis.

**Other side effects:** In addition to peripheral neuropathy, the most frequent side effects observed in studies of adults taking the recommended dose of ZERIT were headache, diarrhea, rash, and nausea and vomiting. Other side effects may include abdominal pain, muscle pain, insomnia, loss of appetite, chills or fever, allergic reactions, and blood disorders.

Changes in body fat have been seen in some patients taking antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the 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 at this time.

#### What else should I know about ZERIT?

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

#### Inactive Ingredients:

**ZERIT Capsules:** microcrystalline cellulose, sodium starch glycolate, lactose (milk sugar), and magnesium stearate in a hard gelatin shell.

**ZERIT for Oral Solution:** methylparaben, propylparaben, sodium carboxymethylcellulose, sucrose (table sugar), and flavoring agents.

This medicine was prescribed for your particular condition. Do not use ZERIT for another condition or give it to others. Keep ZERIT and all other medicines out of the reach of children. Throw away ZERIT when it is outdated or no longer needed by flushing it down the toilet or pouring it down the sink.

This summary does not include everything there is to know about ZERIT. Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. If you have questions or concerns, or want more information about ZERIT, your physician and pharmacist have the complete prescribing information upon which this leaflet was based. You may want to read it and discuss it with your doctor or other healthcare professional. Remember, no written summary can replace careful discussion with your doctor.

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Princeton, NJ 08543  
U.S.A.

This Patient Information Leaflet has been approved by the U.S. Food and Drug Administration.

F9-B001B-2-02  
Printed USA

Based on 1099813A4 (1/02)  
Revised January 2002