ZERIT for Oral Solution should be protected from excessive moisture and stored in tightly closed containers at 25° C (77° F). Excursions between 15° C and 30° C (59° F and 86° F) are permitted (see USP Controlled Room Temperature). After constitution, store tightly closed containers of ZERIT for Oral Solution in a refrigerator, 2° C to 8° C (36° F to 46° F). Discard any unused portion after 30 days.

Bristol-Myers Squibb Company
Princeton, NJ 08543 USA

XXXXXXXX
Rev. _____

PATIENT INFORMATION

ZERIT®

(generic name = **stavudine**, also known as **d4T**)
ZERIT® (stavudine) Capsules
ZERIT® (stavudine) for Oral Solution

What is ZERIT?

ZERIT (pronounced *ZAIR 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 reverse transcriptase inhibitors (NRTIs). 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 (stavudine) 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 person 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 overdosage of ZERIT?

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

What important information should I know about taking ZERIT with other medicines?

- Do not take zidovudine (AZT) while taking ZERIT, because AZT may interfere with the actions of ZERIT. Products containing AZT include Combivir®, Retrovir®, and Trizivir®.

- If you are taking ribavirin or interferon, your doctor may need to monitor your therapy more closely or may consider a change in your therapy.

Tell your doctor or pharmacist about any other medicine, vitamin, supplement, or herbal preparation you are taking.

What about pregnancy and nursing (breast-feeding)?

- It is not known if ZERIT can harm a human fetus. Pregnant women have experienced serious side effects when taking stavudine (the active ingredient in 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.**
- 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?

- **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, have been reported among patients taking ZERIT. ***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 (including pregnant women), overweight patients, and those who have had lengthy treatment with nucleoside medicines are more likely to develop lactic acidosis. The combination of ZERIT, didanosine, and hydroxyurea may increase your risk for liver damage, which may

cause death. This combination should be avoided. Your doctor should closely monitor your liver function if you are taking this combination or if you are taking ZERIT and have a history of heavy alcohol use or a liver condition.

- **Peripheral neuropathy** is a nerve disorder of the hands and feet. If not recognized promptly, this disorder may worsen. ***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. 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** 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.

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 (stavudine) alone.

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, nausea, and vomiting. Other side effects may include abdominal pain, muscle pain, insomnia, loss of appetite, chills or fever, allergic reactions, blood disorders, and high blood sugar (hyperglycemia or diabetes).

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.

Bristol-Myers Squibb Company
Princeton, NJ 08543 USA

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

XXXXXXXX
Rev. _____