

PART III: CONSUMER INFORMATION

Pr ZERIT®

Stavudine

This leaflet is Part III of a three-part “Product Monograph” published when ZERIT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ZERIT. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for

ZERIT (Pronounced ZER it) is a prescription medicine used with other medicines to treat HIV, or human immunodeficiency virus in adults. HIV is the virus that causes AIDS (Acquired Immunodeficiency Syndrome).

What it does

ZERIT belongs to a class of medicines called nucleoside analogues. It works by reducing the HIV amount in the blood. It also increases CD4 cells. CD4 cells are type of white blood 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 germs (microorganisms). Continue to see your doctor regularly and report any medical problems that occur.
- Still give HIV. **Do not have any kind of sex without protection.** Discuss with your healthcare professional the precautions needed to avoid infecting other people.

When it should not be used

Do not take ZERIT if you:

- Are allergic to stavudine or any of the ingredients in ZERIT. (See “What the nonmedicinal ingredients are” in this leaflet). Tell your doctor if you think you have had an allergic reaction to any of these ingredients.
- Take didanosine (another HIV medicine) (see “interaction with this medication” section below).

What the medicinal ingredient is:

Stavudine

What the nonmedicinal ingredients are:

ZERIT Capsules: lactose (milk sugar), magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

Capsule shell: gelatin, black iron oxide (20 mg only), printing ink, silicon dioxide, sodium lauryl sulphate, titanium dioxide and yellow and red iron oxides.

What dosage forms it comes in:

Capsules: 15, 20, 30 and 40 mg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

ZERIT can cause serious side effects, including :

- **Buildup of acid in your blood (lactic acidosis) that can be life-threatening.** Lactic acidosis can cause death. It is a medical emergency that 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 had lactic acidosis after taking ZERIT and didanosine.
 - are female
 - are overweight
 - have been treated for a long time with other medicines used to treat HIV.
- **Liver problems:** Some people who have taken ZERIT have had serious liver problems. These problems include liver enlargement (hepatomegaly), liver failure, fat in the liver (steatosis) and death due to liver problems.
- **Swelling of the pancreas (pancreatitis)** that may cause death. Pancreatitis may happen any time during your treatment with ZERIT.

For further information and symptoms see “SIDE EFFECTS AND WHAT TO DO ABOUT THEM”.

Talk to your healthcare professional before using ZERIT if:

- You have kidney, liver problems or history of heavy alcohol use.
- You have had problems with your pancreas (pancreatitis).
- You have had gallstones.
- You have had nerve problems that causes tingling, numbness, and pain in the hands and feet (peripheral neuropathy).
- **You are pregnant or planning on becoming pregnant.** It is not known if ZERIT can harm an unborn baby. In addition, pregnant women have experienced serious side effects when taking ZERIT in combination with didanosine and other HIV medicines (see Serious Warnings and Precautions box above). ZERIT should be used during pregnancy only after discussion with your doctor.

- **You are breastfeeding or planned to breastfeed.** It is not known if ZERIT can be passed to your baby in your breast milk and if it could harm your baby. In addition HIV-infected mothers should not breast-feed because HIV infection can be passed to the baby in the breast milk. **Do not breastfeed while taking ZERIT.**

While you are taking ZERIT:

- Your healthcare professional may check your liver regularly while you are taking ZERIT. Be careful if you have a history of heavy alcohol use or a liver problem.
- If your kidneys are not working properly, your healthcare professional may :
 - check your kidneys
 - lower your dosage of 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.
- **Changes in your immune system (Immune reconstitution inflammatory syndrome)** - Your immune system may get stronger when you start taking HIV medicines. It may begin to fight infections that have been in your body for a long time or your immune system could react against your own body (autoimmune disease). Autoimmune disease may develop at any time, sometimes months after the start of the HIV therapy. Call your healthcare professional right away if you start having high temperature (fever), joint or muscle pain, redness, rash, swelling or fatigue or any new symptoms after starting this ZERIT.

INTERACTIONS WITH THIS MEDICATION

Always keep a list of all the medicines, including prescription and non-prescription medicines, vitamins, herbals or other health products and show it to your healthcare professional when you get a new medicine. ZERIT may affect the way other medicines work, and other medicines may affect how ZERIT works.

Especially tell your healthcare professional if you are taking:

- Other HIV medications such as:

- didanosine. The following serious side effects which may cause death may occur when ZERIT is used with didanosine (see Serious Warnings box above).
 - liver problems,
 - swelling of the pancreas (pancreatitis)
 - lactic acidosis (a condition where lactic acid buildup in the blood)
 - nerve problems (peripheral neuropathy)
- zidovudine (AZT)
- doxorubicin, used to treat cancer
- ribavirin, used to treat hepatitis C infection
- hydroxyurea, used to treat cancer

- Rash,
- Nausea and vomiting.

Other side effects may include:

- Abdominal pain,
- Muscle pain,
- Difficulty sleeping,
- Loss of appetite,
- Chills or fever,
- Allergic reactions,
- Blood disorders.

PROPER USE OF THIS MEDICATION

Usual dose

- Your healthcare professional will tell you how much ZERIT to take and when to take it.
- Do not stop taking ZERIT or change your dosage unless directed to do so by your healthcare professional.
- You may take ZERIT with food or on an empty stomach.

Overdose

If you take too much ZERIT, contact a healthcare professional (e.g. your doctor), hospital emergency department or regional poison control centre, even if there are no symptoms

Missed Dose

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. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

ZERIT may cause side effects that must be treated right away before they become serious (see “Serious Warnings and Precautions” box above and “Serious and side effects” table below). Always tell your health care professional about any symptoms that you are having even symptoms that may not seem serious.

The most common side effects of ZERIT are:

- Headache,
- Diarrhea,

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor right away		Stop taking drug and call your doctor
	Only if severe	In all cases	
Lactic acidosis : <ul style="list-style-type: none"> • stomach pain • nausea and vomiting • feeling very weak and tired • unusual muscle pain • shortness of breath • feeling cold, especially in your arms and legs • feeling dizzy or light-headed • fast or irregular heart beat • weight loss 			✓
Liver problems <ul style="list-style-type: none"> • Yellowing of your skin or eyes • Dark urine or light-colored bowel movements • Stomach pain or stomach swelling • Nausea and vomiting • Loss of appetite 			✓

Swelling of the pancreas (pancreatitis) <ul style="list-style-type: none"> • Severe stomach pain, swelling of your stomach • Fever • Nausea, or vomiting. 			✓
Nerve problems (peripheral neuropathy): numbness, tingling, burning or pain in the feet and/or hands Children: Neuropathy can be difficult to notice in children who take ZERIT. Ask your child's healthcare professional for the signs of peripheral neuropathy in children.		✓	✓
Changes in body fat (Fat redistribution): Changes may include <ul style="list-style-type: none"> • More fat in or around your: <ul style="list-style-type: none"> ○ upper back and neck ("buffalo hump"), ○ breasts ○ trunk. • Loss of fat in your legs, arms, and face 		✓	

This is not a complete list of side effects. For any unexpected effects while taking ZERIT, contact your doctor or pharmacist

HOW TO STORE IT

ZERIT capsules:

- store at room temperature (15° to 30°C)
- protect from excessive moisture.
- keep the bottle tightly closed

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

Do NOT store ZERIT in a damp place such as a bathroom medicine cabinet or near the kitchen sink.

To help protect the environment, please return all unused medication to the pharmacist for proper disposal.

This medicine was prescribed for your particular condition. Do not use ZERIT for another condition or give it to others.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information or for the full Product Monograph on ZERIT, contact the sponsor, Bristol-Myers Squibb, at: 1-866-463-6267.

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