



STAVUDINE (Zerit)

WHAT IS STAVUDINE?

Stavudine (Zerit®) is a drug used as part of antiretroviral therapy (ART). It is manufactured by Bristol-Myers Squibb. In July 2005, the FDA approved a generic version, and in December 2005 a liquid version, both made by Aurobindo Pharma for sale outside the US. Stavudine d4T is also known as d4T or dideohydrodeoxythymidine.

Stavudine is a nucleoside analog reverse transcriptase inhibitor, or nuke. These drugs block the reverse transcriptase enzyme. This enzyme changes HIV's genetic material (RNA) into the form of DNA. This has to occur before HIV's genetic code gets inserted into an infected cell's own genetic codes.

WHO SHOULD TAKE STAVUDINE?

Stavudine was approved in 1994 as an antiretroviral drug (ARV) for people with HIV infection from newborns through adults.

There are no absolute rules about when to start ART. You and your health care provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your attitude about taking ART. Fact Sheet 404 has more information about guidelines for the use of ART.

If you take stavudine with other ARVs, you can reduce your viral load to extremely low levels, and increase your CD4 cell counts. This should mean staying healthier longer.

Pregnant women face special risks when taking stavudine. See the information below on lactic acidosis and drug reactions.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. They are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called "developing

resistance" to the drug. See Fact Sheet 126 for more information on resistance. Sometimes, if your virus develops resistance to one drug, it will also have resistance to other ARVs. This is called "cross-resistance."

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS STAVUDINE TAKEN?

Stavudine is available in capsules of 15mg, 20mg, 30mg, and 40mg. The normal adult dose depends on body weight. If you weigh more than 60 kilograms (132 pounds), the dose is 40 mg twice daily. If you weigh less, the dose is 30 mg twice daily. A liquid version is available outside the US for newborns through adolescents.

An extended release version of this drug was approved in December 2002. However, due to manufacturing problems, it is not available for sale.

There are no food restrictions with stavudine.

Be sure your health care provider knows if you have had liver problems. Your liver will have to be watched carefully if you take stavudine, and your health care provider might decide that you should not use stavudine at all.

WHAT ARE THE SIDE EFFECTS?

When you start any ART, you may have temporary side effects such as headaches, high blood pressure, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most serious side effects of stavudine are peripheral neuropathy, lipodystrophy and lactic acidosis.

Peripheral neuropathy is a form of nerve damage. It usually shows up as tingling, numbness, or a sharp burning sensation in the feet, legs, or hands. The nerve damage is usually temporary and will go

away if you stop taking stavudine, or reduce the dose. **If you continue to take stavudine after nerve damage shows up, it may become permanent.** See Fact Sheet 555 for more information.

Lipodystrophy is a collection of changes in body shape and blood chemistry. See Fact Sheet 553 for more information. Several studies found that stavudine is strongly linked to the loss of fat in the legs, arms and face. Many drugs seem to contribute to lipodystrophy and we don't fully understand how it occurs. However, some people are avoiding stavudine because of its link to lipodystrophy.

Lactic acidosis is a buildup of lactic acid in the blood. This is a by-product of abnormal energy production by the cells. It may be caused by damage to the mitochondria. See Fact Sheet 556 for more information on mitochondrial toxicity. Lactic acidosis can cause severe damage to the pancreas and liver. Symptoms of lactic acidosis can include weight loss, abdominal pain, and severe fatigue. The risk of lactic acidosis is higher for women and people who have taken nucleoside analog drugs for a long time or who are obese.

HOW DOES STAVUDINE REACT WITH OTHER DRUGS?

Stavudine can interact with other drugs or supplements you are taking. **These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. Make sure that your health care provider knows about ALL drugs and supplements you are taking.**

Stavudine should not be taken with AZT (zidovudine, Retrovir®) or didanosine (ddl, Videx®).

Stavudine's side effects may be worse if taken with ganciclovir or pentamidine.

Pregnant women should not take stavudine and didanosine at the same time due to an increased risk of lactic acidosis.

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