



NELFINAVIR (Viracept)

WHAT IS NELFINAVIR?

Nelfinavir, also called Viracept®, is a drug used as part of antiretroviral therapy (ART). It is manufactured by Agouron Pharmaceuticals. Nelfinavir is a protease inhibitor. These drugs prevent the protease enzyme from working. HIV protease acts like a chemical scissors. It cuts the raw material for HIV into specific pieces needed to build a new virus. Protease inhibitors “gum up” these scissors.

WHO SHOULD TAKE NELFINAVIR?

Nelfinavir was approved in 1997 as an antiretroviral drug (ARV) for people with HIV infection of any age. In August 2007, an impurity called EMS was found in several batches of nelfinavir. The European Medicines Agency recalled the drug and it is not currently available in Europe. In the US, the FDA has not recalled nelfinavir. The FDA is working with the manufacturer, Pfizer, to control levels of EMS in nelfinavir. However, the FDA recommends that nelfinavir not be used by any pregnant woman unless there are no choices for antiviral therapy.

In late September 2007, The European Medicines Agency recommended the lifting of the ban on nelfinavir. This may not take effect until early 2008.

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 nelfinavir 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.

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 NELFINAVIR TAKEN?

Nelfinavir is taken by mouth as a capsule. It should be taken with a meal or a light snack. The original dose was 750 milligrams (mg) three times a day. Using 250 mg capsules, this meant taking 3 capsules at a time.

Late in 1999, the FDA approved twice-daily dosing of nelfinavir at 1250 mg per dose. This meant taking 5 capsules at a time. In April 2003 the FDA approved a 625 mg tablet. This cut the pill count to 2 tablets, twice a day.

If you want to change how often you take nelfinavir, talk to your health care provider. Different doses are used in some combinations. Be sure you know how much nelfinavir your health care provider has prescribed for you, and when and how to take each dose.

The former capsules dissolved quickly and were difficult to swallow. A film-coated tablet was approved in March 2000. It replaced the old capsules. The film coating is also used on the newer 625 mg tablets.

Nelfinavir should be stored at room temperature and protected from moisture, freezing, or excessive heat.

WHAT ARE THE SIDE EFFECTS?

The most common side effects of nelfinavir are diarrhea, weakness, headache, nausea, and abdominal pain. None of these side effects seem to be very serious. The diarrhea in most cases can be controlled with over-the-counter medications.

HOW DOES NELFINAVIR REACT WITH OTHER DRUGS?

Nelfinavir can interact with other drugs or supplements that you are taking. **These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are being identified all the time.**

Drugs to watch out for include other ARVs, drugs to treat tuberculosis (see fact sheet 518), for erectile dysfunction (such as Viagra), for heart rhythm (antiarrhythmics), and for migraine headaches. Interactions are also possible with several antihistamines (allergy medications), sedatives, drugs to lower cholesterol, and anti-fungal drugs. **Make sure that your health care provider knows about ALL drugs and supplements you are taking.**

If you are taking **nelfinavir and ddl**, you should take **ddl** one hour before or two hours after nelfinavir.

Nelfinavir decreases blood levels of **Kaletra**.

Taking nelfinavir with **delavirdine** increases blood levels of both drugs. Avoid this combination.

Nelfinavir decreases **methadone** levels. Watch for signs of excessive sedation if you take nelfinavir with **buprenorphine**.

Some **birth control pills** may not work if you are taking nelfinavir. Talk to your health care provider about how to prevent an unwanted pregnancy.

The herb **St. John's Wort** (See Fact Sheet 729) lowers the blood levels of some protease inhibitors. Do not take it with nelfinavir.