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Information, Inspiration and Advocacy for People Living With HIV/AIDS

JUNE 2004

Nelfinavir (Viracept)

reprinted from www.aidsmeds.com, united states

What is Viracept?

- Viracept is an anti-HIV medication. It is in a category of HIV medications called protease inhibitors (PIs). Viracept prevents T-cells that have been infected with HIV from producing new HIV.
- Viracept is manufactured by Agouron Pharmaceuticals, a division of Pfizer Inc. The U.S. Food and Drug Administration (FDA) approved it for the treatment of HIV infection in 1997.

What is known about Viracept?

- Viracept can be taken either three times a day or twice a day:
- The three-times-daily Viracept dosing schedule involves taking three 250mg tablets every eight hours.
- The twice-daily Viracept dosing schedule involves taking two 625mg tablets every 12 hours. An alternative option is to take five 250mg tablets every 12 hours. The twice-daily dosing schedule, using the 625mg tablets, is preferred by many healthcare providers, as it involves taking the fewest number of pills the fewest number of times a day.
- Viracept should be taken with food, preferably a full nutritious meal (e.g., breakfast and dinner). Taking Viracept with food increases the amount of drug in the bloodstream, which could make Viracept more effective against the virus.
- Viracept can be given to HIV-positive children, two years of age and older. The Viracept dose for children depends on body weight and can be taken twice or three times a day. As the child gets older and gains weight, the dose will continually need to be increased. A powdered formulation of Viracept can be prescribed and mixed with water, milk, or pudding for a better taste. Viracept should be taken with a full meal. Viracept should not be used by children younger than two years old.
- Clinical trials have determined that Viracept is safe and effective when combined with other drugs, most notably two nucleoside reverse transcriptase inhibitors (NRTIs).
- For HIV-positive adults beginning anti-HIV drug therapy for the first time, Viracept is listed as an "alternative" protease inhibitor option by the United States Department of Health and Human Services in its treatment guidelines. The protease inhibitor Kaletra® (lopinavir/ritonavir) is listed as the "preferred" option.
- If your viral load becomes detectable while taking a drug regimen that contains Viracept, your doctor can order a drug-resistance test to see which drugs your virus are becoming less sensitive to.

- Many of the currently available protease inhibitors are affected by cross-resistance. This means that, if you've tried and failed a drug regimen in the past that contained a protease inhibitor, your virus might be resistant to Viracept. Similarly, if you take an anti-HIV drug regimen that contains Viracept and your virus becomes resistant to the drug, your virus might also be resistant to many of the other protease inhibitors available. This is why it is very important to use drug-resistance testing to determine which drugs your virus are no longer responding to if you experience a rebound in your viral load while taking an anti-HIV drug regimen. Drug-resistance testing can also help you figure out which protease inhibitors your virus is still sensitive to.

What about drug interactions?

- Viracept is broken down (metabolized) by the liver, like many medications used to treat HIV and AIDS. This means that Viracept can interact with other medications. Viracept can lower or raise the levels of other medications in the body. Similarly, other medications can lower or raise the levels of Viracept in the body. While many interactions are not a problem, some can cause your medications to be less effective or increase the risk of side effects.
- Tell your doctors and pharmacists about all medicines you take. This includes those you buy over-the-counter and herbal or natural remedies, such as St. John's Wort. Bring all your medicines when you see a doctor, or make a list of their names, how much you take, and how often you take them. Your doctor can then tell you if you need to change the dosages of any of your medications.
- The following medications should not be taken while you are being treated with Viracept:
  Acid reflux/heartburn medications: Propulsid® (cisapride)
  Antibiotics: Priftin® (rifapentine) and Rifadin® (rifampin)
  Antimigraine medications: Ergostat®, Cafergot®, Ercaf®, Wigraine® (ergotamine) or D.H.E. 45® (dihydroergotamine)
  Antihistamines: Hismanal® (astemizole) or Seldane® (terfenadine)
  Cholesterol-lowering drugs (statins): Zocor® (simvastatin) and Mevacor® (lovastatin)
  Antipsychotics: Orap® (pimozide)
  Sedatives: Versed® (midazolam) and Halcion® (triazolam)
- Anticonvulsants, such as Tegretol® (carbamazepine), phenobarbital, and Dilantin® (phenytoin), may decrease the amount of Viracept in the bloodstream. It might be necessary to increase your dose of Viracept if you are taking any of these drugs.
- Anti-HIV protease inhibitors can interact with Viracept. We know that Norvir® (ritonavir) increases the amount of Viracept in the bloodstream (the recommended dose is two or three 250mg Viracept tablets combined with four 100mg Norvir capsules). Kaletra® (lopinavir/ritonavir) can also increase Viracept levels, but Viracept decreases blood levels of the lopinavir in Kaletra (no dose has been recommended). Viracept increases Agenerase® (amprenavir) and Lexiva® (fosamprenavir) levels in the bloodstream (no dose has been recommended). When Viracept is combined with either Fortovase® (soft gel saquinavir) or Invirase® (hard gel saquinavir), blood levels of both drugs are increased (the Fortovase or Invirase dose should be reduced to 1200 mg twice daily and combined with the usual dose of Viracept). Viracept also increases Crixivan® (indinavir) levels, but no dose has been confirmed.
- Anti-HIV non-nucleoside reverse transcriptase inhibitors (NNRTIs) can also interact with Viracept. Sustiva® (efavirenz), Viramune® (nevirapine), and Rescriptor® (delavirdine) can all increase Viracept levels in the bloodstream, although it's probably not necessary to change the doses.
- Viracept can interact with some medications used to treat TB, MAC and other bacterial infections. Rifadin® (rifampin) can decrease Viracept levels in the bloodstream; these two drugs should not be used together. Viracept can increase Mycobutin® (rifabutin) levels and Mycobutin can decrease Viracept

levels (the Mycobutin dose should be reduced to 150mg every day and the Viracept dose should be increased to four 250mg tablets three times a day). It is not known if Viracept effects Biaxin® (clarithromycin) levels in the bloodstream.

- Viracept decreases the amount of oral contraceptives (taken by women to help avoid pregnancy) in the bloodstream. This means that there may be a higher risk of becoming pregnant if Viracept and oral contraceptives are taken at the same time. To reduce the risk of pregnancy, barrier protection (e.g., condoms) should be used.
- Methadone, commonly used to treat drug addiction, can interact with Viracept. Methadone levels in the bloodstream can decrease when combined with Viracept. Because of this, it might be necessary to increase the dose of methadone.
- Cholesterol-lowering drugs, also known as "statins," can interact with Viracept. There are two statins that should not be used with Viracept: Zocor® (simvastatin) and Mevacor® (lovastatin). Levels of these two drugs can become significantly increased in the bloodstream if they are combined with Viracept, which increases the risk of side effects. The two statins that are considered to be the safest in combination with Viracept are Pravachol® (pravastatin) and Lescol® (fluvastatin). It is also possible to take Viracept with Lipitor® (atorvastatin), although Viracept can increase Lipitor levels in the bloodstream. If Lipitor is prescribed, it's best to begin treatment with the lowest possible dose of the drug and then increase the dose if necessary. Little is known about the newest statin, Crestor® (rosuvastatin), although it is not expected to have any serious drug interactions with Viracept or the other protease inhibitors.
- Viagra® (sildenafil), Levitra® (vardenafil) and Cialis® (tadalafil) levels in the bloodstream likely increase when combined with Viracept. In turn, it is best to use a lower dose of these drugs in order to reduce the risk of side effects.
- Herbal products can also interact with Viracept. St. John's wort should not be used with Viracept, since it can greatly reduce the amount of Viracept in the bloodstream. HIV-positive people should also be cautious about using garlic supplements or milk thistle with Viracept—test tube studies suggest that both herbal products can interact with the same liver enzyme system (cytochrome P450 3A4) responsible for metabolizing Viracept. This may alter the amount of Viracept in the bloodstream. These and other herbal products should be used with caution, until further studies are conducted.
- A number of other negative drug interactions are possible if Viracept is combined with Norvir® (ritonavir).

What about side effects?

- Diarrhea is the most common side effect of Viracept. To learn some tips and tricks that can help reduce the severity of diarrhea, click here.
- Other short-term side effects include appetite loss, headaches, feeling crummy (malaise), nausea, and vomiting. Very often, these side effects improve within a few months/weeks of starting Viracept.
- Anti-HIV drug regimens containing protease inhibitors, including Viracept, can cause increased fat levels (cholesterol and triglycerides) in the blood, abnormal body-shape changes (lipodystrophy; including increased fat around the abdomen, breasts, and back of the neck, as well as decreased fat in the face, arms, and legs), and diabetes.

Who should not take Viracept?

- Before taking this medication, tell your doctor if you have kidney disease or liver disease. You may not be able to take Viracept, or you may require a dosage adjustment or special monitoring during treatment if you have any of these conditions.
- Viracept is classified by the FDA as a pregnancy category B drug. All the FDA-approved anti-HIV drugs are classified as either category B or C.

For more treatment information, call Project Inform's toll-free National HIV/AIDS Treatment Information Hotline at 1-800-822-7422.

Pregnancy category B means that animal studies have failed to demonstrate a risk to the fetus, but there are no adequate and well-controlled studies in pregnant women. Pregnancy category C means that animal studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. HIV-positive women who become pregnant should discuss the benefits and possible side effects of anti-HIV treatment to help protect their babies from HIV.

- It is not known whether Viracept passes into breast milk and what effects it may have on a nursing baby. However, to prevent HIV transmission of the virus to uninfected babies, it is recommended that HIV-positive mothers not breast-feed.

Where can I learn more about clinical trials that are using Viracept?

- If you would like to find out if you are eligible for any clinical trials that include Viracept, there is an interactive web site run by amfAR, the American Foundation for AIDS Research.
- Another useful service for finding clinical trials is *AIDSinfo.nih.gov*, a site run by the U.S. National Institutes of Health. They have "health information specialists" you can talk to at their toll-free number at 1-800-HIV-0440 (1-800-448-0440).

a note about this publication

This publication is reprinted here from another source (*www.aidsmeds.com*). We do not always have the resources at Project Inform to produce our own treatment information on every treatment topic. In these cases, we try to provide reliable information from other sources but cannot confirm that every fact in these publications is accurate. References to other materials have been pulled. This information is designed to support, not replace, the relationship that exists between you and your doctor or medical provider.

TEXT LAST UPDATED: JUNE 2004