

## [National AIDS Treatment Advocacy Project](#)

### **VIRACEPT APPROVED for Adults and Children and RITONAVIR APPROVED for Children**

Today, Friday March 14, the FDA approved Viracept (nelfinavir) for both adults and children. At the same time, the FDA approved ritonavir (Norvir) for children. This is a milestone for pediatrics treatment of HIV because these are the first approved protease inhibitors for children.

The pediatrics approvals are for children 2 years and older. The dosing regimens for children can be different than the one used for adults. These dosing recommendations should be in the package insert for you and your doctor to read. The package insert is available at your pharmacy where you purchase the drug. Agouron said nelfinavir will be available in your pharmacy within days of the approval. By Thursday March 21 your pharmacy should have it.

Agouron announced a patient assistance program for adults and children: call toll-free- 1-888-777-6637

Abbott's Adult PAP can be reached at 1-800-659-9050

Over the course of the next year protease-protease combinations will be explored: ritonavir/nelfinavir indinavir/nelfinavir 141W94 with saquinavir, indinavir, or nelfinavir saquinavir/nelfinavir ABT-378/ritonavir.

The combination of nelfinavir/saquinavir has a small pilot study in progress. Larger scale clinical studies are planned. Those in the nelfinavir/saquinavir pilot study are out to 5 months: 7/13 are undetectable (500 copies); CD4 increases are about 70; HIV RNA reductions are about 2 log. A more detailed report will follow.

Of course you know ritonavir/saquinavir's 6-month data. It's on this web site.

ABT-378 is the new Abbott protease which so far has been tested only in animals and unhealthy volunteers. You can read about it in the [NATAP newsletter](#).

The combination of two protease inhibitors can raise the blood levels of one or both of the drugs. Therefore, in some cases a tid (three times per day) protease dosing regimen may become a bid (twice daily) regimen. This will be explored in the studies.

Potentially, we may be able to discover more potent combinations which may be able to suppress virus resistant to protease inhibitors. By '98 we should have some data from these protease-protease studies.