

LOPINAVIR (KALETRA)



THE SIMPLE FACTS PROJECT

Drug interactions: The following drugs should NOT be taken with Kaletra: astemizole (trade name Hismanal), cisapride (Propulsid), flecainide (Tambocor), midazolam (Versed), propafenone (Rythmal), pimozide (Orap), terfenadine (Seldane), triazolam (Halcion) and a class of migraine drugs called ergot derivatives. Great care should also be taken about using Viagra. Kaletra is likely to greatly increase levels of Viagra in the body which could lead to serious side effects. Taking the fat-lowering drugs lovastatin (Mevacor) or simvastatin (Zocor) with Kaletra is not recommended. Kaletra may increase the levels of other fat-lowering drugs such as atorvastatin (Lipitor), potentially increasing the chances of side effects. Kaletra increases levels of the antibiotic rifabutin (Mycobutin) making a 75% reduction of the normal rifabutin dose necessary. Kaletra decreases the levels of methadone in the body and methadone doses may need to be increased if these drugs are used together. The herbal supplement St. John's Wort should not be taken as it is likely to significantly decrease Kaletra levels. The TB drug rifampin should be avoided as it also reduces Kaletra levels. Other potential drug interactions are listed in the label that comes with Kaletra which can be downloaded from the Internet at www.Kaletra.com.

The manufacturer of Kaletra has set up a patient assistance program for people having trouble accessing or affording the drug. Call (800) 659-9050 for more information.

The Simple Facts Project is a program of the AIDS Treatment Data Network (The Network). This information does not intend to promote or endorse any specific treatment for any health related condition.

Lopinavir (trade name Kaletra) is the newest of the class of anti-HIV drugs called protease inhibitors. These drugs work by blocking a part of HIV called protease. When protease is blocked, HIV makes copies of itself that can't infect new cells. Kaletra was approved for prescription on September 15, 2000.

Taking the drug: The standard dose of Kaletra is three pills taken twice a day with food. Each Kaletra pill contains 133mg of Kaletra and 33mg of the protease inhibitor Norvir (ritonavir). If you're taking Kaletra at the recommended dose, it's important to know that you'll also be taking a total of 200mg of Norvir each day. If you're allergic to Norvir it may not be possible for you to take Kaletra - check with your doctor. Kaletra is also available in a liquid form for children.

Trial results: Kaletra has shown a strong anti-HIV effect in clinical trials. A large, ongoing study is comparing Kaletra to the protease inhibitor Viracept (nelfinavir). Both protease inhibitors are being taken in combination with d4T (Zerit) and 3TC (Epivir). The study includes 653 people that have never taken HIV drugs before. Participants started with an average T-cell count of 260 and an average viral load close to 100,000 copies. After about 10 months of treatment, 84% (about 8 out of 10) of participants in the Kaletra group that have stayed on treatment have viral loads less than 50 copies. In the Viracept group, 70% (7 out of 10) of the participants that have stayed on treatment have viral loads less than 50 copies. The average increase in T-cells is 190 in the Kaletra group and 177 in the Viracept group. About 15% (1 in 7) of the people that were taking Kaletra have dropped out of the study, compared to 20% (1 in 5) of the people that were taking Viracept.

Another study involved people who had previously taken one protease inhibitor in combination with NRTIs (NRTI anti-HIV drugs are: AZT/trade name Retrovir, ddI/Videx, ddC/HIVID, d4T/Zerit, 3TC/Epivir and abacavir/Ziagen). No-one in this study had taken NNRTI drugs (NNRTI anti-HIV drugs are: nevirapine/Viramune, efavirenz/Sustiva, delavirdine/Rescriptor). The study gave Kaletra in combination with the NNRTI drug Viramune and two NRTIs. After 72 weeks of treatment, 75% of the 36 people taking the approved dose of Kaletra have viral load levels less than 400 copies. T-cells have increased by an average of 174 cells. About 9% (1 in 11) of the participants dropped out of this study because of side effects.

One reason a doctor might prescribe Kaletra is because of its strength and because it may work for people whose HIV has become resistant to other protease inhibitors. Up until now, when someone has taken a lot of different anti-HIV drugs that have stopped working, it has been complicated to figure out what regimen to take next. Because of its strength, and including Norvir which some people find difficult to take, the side effects of Kaletra may be stronger as well.

Side effects: Kaletra side effects can include diarrhea, significant increases in blood fats (cholesterol and triglycerides), liver toxicity (with increased liver enzymes), stomach pain, feeling weak or tired, headache, nausea and vomiting. Diarrhea was reported by about a quarter of participants in Kaletra studies. Increases in cholesterol and triglycerides were also reported in up to a quarter of study participants. In some cases increases in cholesterol and triglycerides were very large, and regular monitoring of these blood fats is essential for anyone who takes Kaletra. People co-infected with hepatitis B and/or C may be at greater risk of developing liver toxicity from Kaletra.

Kaletra may also be linked to a side effect called pancreatitis. Pancreatitis is a potentially dangerous inflammation of an organ called the pancreas. Currently this side effect has been seen in less than 1% (1 out of 100) people taking Kaletra. It is not yet certain if Kaletra causes pancreatitis. All cases have involved people taking other drugs. Researchers are now investigating to find out if Kaletra played a role. The manufacturer recommends monitoring triglycerides and amylase in people taking Kaletra to watch for signs of pancreatitis.

Combining Kaletra with other anti-HIV drugs: There are no serious interactions between Kaletra and NRTI anti-HIV drugs. However, it's recommended that the NRTI drug ddI (Videx) be taken one hour before or two hours after Kaletra. The NNRTI anti-HIV drugs efavirenz (Sustiva) and nevirapine (Viramune) lower Kaletra levels in the body. When taking Sustiva or Viramune with Kaletra it is recommended that you increase the Kaletra dose to 4 pills twice-daily. The NNRTI drug delavirdine (Rescriptor) has not been studied with Kaletra. Based on what is already known about the drugs, it is likely that Rescriptor will increase Kaletra levels.

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