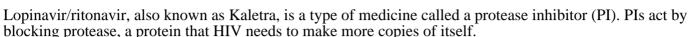
Lopinavir/Ritonavir

low-PIN-a-veer, rit-ON-uh-veer

Brand Name: Kaletra

Drug Class: Protease Inhibitors





Lopinavir/ritonavir in capsule and oral solution form was approved by the FDA on September 15, 2000, for use with other antiretrovirals in the treatment of HIV infection in adults and children 6 months of age or older. Lopinavir/ritonavir in tablet form was approved by the FDA on October 28, 2005. In March 2006, the capsule form of the medicine was phased out in the U.S. in favor of the new tablet. Lopinavir alone quickly breaks down in the body. Ritonavir slows down this process and increases the time that lopinavir stays in the bloodstream.

This medicine does not cure or prevent HIV infection or AIDS and does not reduce the risk of passing the virus to other people.

Dosage Form/Administration

Lopinavir/ritonavir comes in tablet and oral solution forms and is taken by mouth. The tablet can be taken with or without food. The oral solution and capsule forms should be taken with food.

Some film-coated lopinavir/ritonavir tablet contain 200 mg of lopinavir and 50 mg of ritonavir. Low dose lopinavir/ritonavir tablets contain 100mg of lopinavir and 25 mg of ritonavir. Every 5 ml of lopinavir/ritonavir oral solution contains 400 mg of lopinavir and 100 mg of ritonavir.

Recommended Daily Dose

The recommended dose of lopinavir/ritonavir in treatment-experienced adults is 2 tablets (400 mg/100 mg) twice daily taken with or without food or 5 ml of oral solution twice daily taken with food. The recommended doses of lopinavir/ritonavir in treatment-naive adults are 2 tablets (400 mg/100 mg) twice daily taken with or without food or 4 tablets (800 mg/200 mg) once daily taken with or without food.

No dosing adjustment in treatment-naive patients is necessary when lopinavir/ritonavir tablets are

administered as part of a twice-daily regimen with efavirenz, nevirapine, amprenavir, fosamprenavir, or nelfinavir. A dose increase should also be considered when lopinavir/ritonavir in tablet form is used in combination with efavirenz, nevirapine, fosamprenavir without ritonavir, or nelfinavir in certain treatment-experienced patients. Lopinavir/ritonavir should not be used once daily in combination with efavirenz, nevirapine, amprenavir, fosamprenavir, or nelfinavir. When lopinavir/ritonavir in oral solution or capsule form is used twice daily in combination with efavirenz or nevirapine, the lopinavir/ritonavir dose should be increased. Dosing of lopinavir/ritonavir in children is based on weight.

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of Health and Human Services

Some patients may benefit from different doses of lopinavir/ritonavir. Patients should always take lopinavir/ritonavir as prescribed by their doctors.

Contraindications

Individuals should tell a doctor about any medical problems before taking this medicine.

Possible Side Effects

Along with its desired effects, this medicine can cause some serious unwanted effects. Individuals should tell a doctor if they have any of the following side effects: disease of the pancreas (symptoms include bloating; chills; constipation; darkened urine; fast heartbeat; fever; indigestion; loss of appetite; pains in stomach, side, or back; yellow eyes or skin), diabetes, or high blood sugar (symptoms include blurred vision, dry mouth, fruity mouth odor, increased hunger or thirst, increased urination, fainting, nausea, stomachache, sweating, tiredness, trouble breathing, or unusual weight loss). Other serious side effects include body fat changes, high cholesterol, and increased bleeding in hemophilia patients. Individuals should tell a doctor if they have any of these side effects.

Other side effects may not be serious and may lessen or disappear with continued use of the

Lopinavir/Ritonavir



Possible Side Effects (cont.)

medicine. Less serious side effects of this medicine include diarrhea, headache, nausea, rash, trouble sleeping, vomiting, and weakness. Diarrhea may occur more frequently in patients taking lopinavir/ritonavir once daily. Individuals should tell a doctor if these side effects continue or are bothersome.

Drug and Food Interactions

A doctor should be notified of any other medications being taken, including prescription, nonprescription (over-the-counter), or herbal medications.

Clinical Trials

For information on clinical trials that involve Lopinavir/Ritonavir, visit the ClinicalTrials.gov web site at http://www.clinicaltrials.gov. In the Search box, enter: Lopinavir/Ritonavir AND HIV Infections.

Manufacturer Information

Lopinavir/Ritonavir Abbott Laboratories One Hundred Abbott Park Rd Abbott Park, IL 60064-3500 (800) 633-9110

Kaletra

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For More Information

Contact your doctor or an AIDSinfo Health Information Specialist:

- Via Phone: 1-800-448-0440 Monday Friday, 12:00 p.m. (Noon) 5:00 p.m. ET
- Via Live Help: http://aidsinfo.nih.gov/live_help Monday - Friday, 12:00 p.m. (Noon) - 4:00 p.m. ET