



# Kaletra

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## WHAT IS KALETRA?

Kaletra is a drug used as part of [antiretroviral therapy \(ART\)](#). Kaletra contains two [antiretroviral drugs \(ARVs\)](#) combined in one tablet:

- lopinavir (LPV)
- [ritonavir \(RTV, Norvir\)](#)

The FDA approved Kaletra in 2000 as an ARV for people with HIV infection. Generic versions have been approved for sale under the [President's Emergency Plan for AIDS Relief \(PEPFAR\)](#). Kaletra is manufactured by [AbbVie Inc.](#)

Both of the drugs in Kaletra are a type of drug called a [protease inhibitor \(PI\)](#). PIs block protease (an HIV enzyme). By blocking protease, PIs prevent new (immature) HIV from becoming a mature virus that can infect other cells.

Although ritonavir is technically a PI, it is rarely used as a PI anymore. Due to frequent and severe side effects, it is difficult for people to tolerate at the full dosage required to inhibit HIV. However, ritonavir is frequently used to increase (boost) blood levels of other HIV medications, including other PIs and the integrase inhibitor [elvitegravir](#). This is similar to the mechanism of action of the [pharmacokinetic \(PK\) enhancer cobicistat \(Tybost\)](#). The dose used for boosting is much smaller than the full anti-HIV dose and causes fewer side effects.

When used in combination with other ARVs to treat HIV infection, Kaletra may help:

- Reduce the amount of HIV in your blood. This is called [viral load](#).
- Increase the number of [CD4 cells](#) in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting [opportunistic infections \(OIs\)](#) that can happen when your immune system is weak. [Read more about viral suppression.](#)

Kaletra [does not cure](#) HIV infection or [AIDS](#). You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

## WHO SHOULD TAKE KALETRA?

Kaletra is a prescription two-drug fixed-dose combination medication to treat HIV infection in adults and children 14 days of age and older.

The safety and effectiveness of Kaletra has not been established in children less than 14 days of age. Kaletra has not been carefully studied in the elderly (65 years of age and older).

All people living HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. [Read more about U.S. ART guidelines.](#)

Kaletra provides 2 drugs in one pill. It can be more convenient to use Kaletra than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Kaletra is used in combination with other ARVs for the treatment of HIV infection.**

## WHO SHOULD NOT TAKE KALETRA?

Do not take Kaletra if you are allergic to lopinavir, ritonavir, or any of the ingredients in this drug.

Do not take Kaletra if you are taking any of the following medicines. Taking Kaletra with these medicines may affect how Kaletra works. Kaletra may cause serious or life-threatening side effects or death when used with these medicines:

- Alpha 1-adrenoreceptor antagonist: alfuzosin
- [Cancer](#) medicine: apalutamide
- Gout medicine: colchicine (if you have liver or kidney problems)
- Antipsychotic medicines: lurasidone, pimozide
- [Tuberculosis \(TB\)](#) medicine: rifampin
- Benzodiazepines: midazolam (when taken by mouth), triazolam

- Cholesterol medicines: lomitapide, lovastatin, simvastatin
- Ergot-containing medicines: dihydroergotamine mesylate, ergotamine tartrate, methylergonovine
- Heart medicines: dronedarone, ranolazine
- Heartburn and reflux medicine: cisapride
- [Hepatitis C virus \(HCV\)](#) medicines: elbasvir, grazoprevir
- Herbal product: St. John's Wort (*Hypericum perforatum*)
- PDE-5 inhibitor: sildenafil (when used for the treatment of pulmonary arterial hypertension [PAH])

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with Kaletra.

### **WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING KALETRA?**

Before you take Kaletra, tell your healthcare provider about all of your medical conditions, and in particular if you:

- have ever had a serious skin rash or an allergic reaction to medicines that contain lopinavir or ritonavir
- have or had pancreas problems
- have liver problems, including [hepatitis B virus \(HBV\)](#) or HCV infection
- have any [heart problems](#), including if you have a condition called Congenital Long QT Syndrome
- have low potassium in your blood
- have [diabetes](#)
- have high cholesterol in your blood
- have hemophilia

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with Kaletra. It is not known if Kaletra can harm your unborn baby.

Kaletra oral solution contains alcohol (ethanol) and propylene glycol. You should not take Kaletra oral solution during pregnancy because there is no safe level of alcohol exposure during pregnancy. Kaletra may reduce how well hormonal birth control works. If you are able to become pregnant, you should use another effective form of birth control or an additional barrier method of birth control during treatment with Kaletra.

There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. [Read more about pregnancy and HIV.](#)

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Kaletra. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby during treatment with Kaletra.

### **WHAT ABOUT DRUG RESISTANCE?**

Many new copies of HIV are mutations. These new copies 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. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. [Read more about HIV drug 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 KALETRA TAKEN?**

Kaletra is taken by mouth as a tablet or oral solution. Kaletra tablets are available in 2 dose strengths:

- 200/50 mg: 200 mg of lopinavir and 50 mg of ritonavir
- 100/25 mg: 100 mg of lopinavir and 25 mg of ritonavir

Kaletra oral solution contains 80 mg of lopinavir and 20 mg of ritonavir per milliliter.

Kaletra can be given in once daily or twice daily dosing regimens. Your healthcare provider will determine what regimen is best for you based on your individual circumstances. The recommended dosages for adults are given in the chart below.

<b>Kaletra dosage form</b>	<b>Once-daily dosing regimen</b>	<b>Twice-daily dosing regimen</b>
200/50 mg tablets	800/200 mg (4 tablets) once daily	400/100 mg (2 tablets) twice daily
80/20 mg/mL oral solution	800 mg/200 mg (10 mL) once daily	400/100 mg (5 mL) twice daily

Your healthcare provider may tell you to take Kaletra differently than what is listed above. Always take Kaletra exactly as your healthcare provider tells you to.

The recommended dosage for children 14 days of age and older varies based on the child's weight and age. Your healthcare provider will determine the correct dosage.

Kaletra tablets may be taken with or without food. The tablets should be swallowed whole and not chewed, broken, or crushed. Kaletra oral solution must be taken with food.

### **WHAT ARE THE SIDE EFFECTS?**

When you start any ARV, you may have temporary [side effects](#) such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Kaletra are [diarrhea](#), nausea, vomiting, and increased fats in the blood (triglycerides or cholesterol).

Kaletra can cause serious side effects including:

**Inflammation of the pancreas (pancreatitis).** Kaletra can cause pancreatitis which may be serious and may lead to death. People who have high levels of a certain fat (triglycerides) have a risk for developing pancreatitis. If you have advanced HIV disease, you may have an increased risk of high triglyceride levels in your blood, and pancreatitis. If you have a history of pancreatitis, you may have an increased risk of it coming back again during treatment with Kaletra. Tell your healthcare provider if you have any signs or symptoms of pancreatitis including:

- Nausea
- Vomiting
- Stomach-area (abdominal) pain

**Liver problems.** Liver problems, including death, can happen in people who take Kaletra. Your healthcare provider should do [blood tests](#) before and during your treatment with Kaletra to check your liver function. If you have HBV, HCV, or other liver problems, you may have an increased risk for developing new or worsening of liver problems during treatment with Kaletra. Tell your healthcare provider right away if you have any signs and symptoms of liver problems including:

- Your skin or the white part of your eyes turns yellow
- Dark or "tea-colored" urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea or vomiting
- Stomach-area pain

**Changes in your heart rhythm and the electrical activity of your heart.** These changes may be seen on an EKG (electrocardiogram) and can lead to serious heart problems. Your risk for these problems may be higher if you have a history of abnormal heart rhythm, certain types of heart problems, or if you take other medicines that can affect your heart rhythm during treatment with Kaletra. Tell your healthcare provider right away if you have any of these symptoms:

- Dizziness
- Fainting
- Lightheadedness
- Sensation of abnormal heartbeats

**Diabetes and high blood sugar (hyperglycemia).** You may develop new or worsening diabetes or high blood sugar during treatment with Kaletra. Your healthcare provider may need to start you on medicine to treat high blood sugar or change your diabetes medicines. Tell your healthcare provider if you get any of the following signs or symptoms:

- Urinate more often than usual
- Increased hunger or thirst
- Unusual weight loss
- Increase in your blood sugar levels

**Immune Reconstitution Inflammatory Syndrome (IRIS).** [IRIS](#) is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting treatment with Kaletra.

**Increases in certain fat (triglycerides and cholesterol) levels in your blood.** Large increases of triglycerides and cholesterol can be seen in blood test results of some people who take Kaletra. Your healthcare provider should do [blood tests](#) to check your cholesterol and triglyceride levels before you start taking Kaletra and during your treatment.

**Changes in body fat.** [Changes in body fat distribution or accumulation](#) have happened in some people taking HIV medicines, including an increased amount of fat in the upper back and neck (buffalo hump), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not

known.

**Increased bleeding in people with hemophilia.** Some people with hemophilia have increased bleeding with Kaletra or similar medicines.

**Skin rash, which can be severe.** Tell your healthcare provider if you have a history of skin rash with other medicines used to treat your HIV infection or if you get any skin rash during treatment with Kaletra.

**Kidney stones.**

These are not all the possible side effects of Kaletra. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**HOW DOES KALETRA REACT WITH OTHER DRUGS?**

All ARVs can [interact](#) with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Kaletra with other medicines.

See above for a list of medications that should not be taken with Kaletra.

**MORE INFORMATION**

Visit the [Kaletra website](#).

Download the full [Prescribing Information](#).

Download the [Medication Guide](#).

Get a [Kaletra Savings Card](#).

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