

KALETRA® (kuh-LEE-tra) (lopinavir/ritonavir) Tablets

KALETRA® (kuh-LEE-tra) (lopinavir/ritonavir) Oral Solution

CONSUMER BRIEF SUMMARY
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FULL PRESCRIBING INFORMATION

Patient Information

Read the Medication Guide that comes with KALETRA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment. You and your doctor should talk about your treatment with KALETRA before you start taking it and at regular check-ups. You should stay under your doctor's care when taking KALETRA.

What is the most important information I should know about KALETRA?

KALETRA may cause serious side effects, including:

- **Interactions with other medicines.** It is important to know the medicines that should not be taken with KALETRA. Read the section "What should I tell my doctor before taking KALETRA?"
- **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:
 - already have a history of abnormal heart rhythm or other types of heart disease.
 - take other medicines that can affect your heart rhythm while you take KALETRA.

Tell your doctor right away if you have any of these symptoms while taking KALETRA:

- dizziness
- lightheadedness
- fainting
- sensation of abnormal heartbeats

See the section below "What are the possible side effects of KALETRA?" for more information about serious side effects.

What is KALETRA?

KALETRA is a prescription anti-HIV medicine that contains two medicines: lopinavir and ritonavir. KALETRA is called a protease inhibitor that is used with other anti-HIV-1 medicines to treat people with human immunodeficiency virus (HIV-1) infection. HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if KALETRA is safe and effective in children under 14 days old.

Who should not take KALETRA?

- Do not take KALETRA if you are taking certain medicines. For more information about medicines you should not take with KALETRA, please see "Can I take other medicines with KALETRA?" and consult with your doctor about all other medicines you take.

- Do not take KALETRA if you have an allergy to KALETRA or any of its ingredients, including ritonavir and lopinavir.

What should I tell my doctor before taking KALETRA?

KALETRA may not be right for you. Tell your doctor about all your medical conditions, including if you:

- have any heart problems, including if you have a condition called Congenital Long QT Syndrome.
- have liver problems, including Hepatitis B or Hepatitis C.
- have diabetes.
- have hemophilia. People who take KALETRA may have increased bleeding.
- have low potassium in your blood.
- are pregnant or plan to become pregnant. It is not known if KALETRA will harm your unborn baby. Birth control pills or patches may not work as well while you take KALETRA. To prevent pregnancy while taking KALETRA, women who take birth control pills or use estrogen patch for birth control should either use a different type of birth control or an extra form of birth control. Talk to your doctor about how to prevent pregnancy while taking KALETRA.
- take KALETRA during pregnancy, talk with your doctor about how you can take part in an antiretroviral pregnancy registry. The purpose of the pregnancy registry is to follow the health of you and your baby.
- are breast-feeding. Do not breast-feed if you are taking KALETRA. You should not breast-feed if you have HIV-1. If you are a woman who has or will have a baby while taking KALETRA, talk with your doctor about the best way to feed your baby. If your baby does not already have HIV-1, there is a chance that HIV-1 can be passed to your baby through your breast milk.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Many medicines interact with KALETRA. Do not start taking a new medicine without telling your doctor or pharmacist. Your doctor can tell you if it is safe to take KALETRA with other medicines. Your doctor may need to change the dose of other medicines while you take KALETRA.

Medicines you should not take with KALETRA.

Serious problems or death can happen if you take these medicines with KALETRA:

- ergot containing medicines, including:
 - ergotamine tartrate (Cafergot®, Migergot, Ergomar, Ergostat, Medihaler Ergotamine, Wigraine, Wigrettes)
 - dihydroergotamine mesylate (D.H.E. 45®, Embolex, Migranal®)
 - ergonovine, ergonovine and methylergonovine (Ergotrate, Methergine), ergotamine and methylergonovine
 - Ergotrate Maleate, methylergonovine maleate (Methergine)
- triazolam (Halcion®), midazolam hydrochloride oral syrup
- pimozone (Orap®)
- the cholesterol lowering medicines lovastatin (Mevacor®) or simvastatin (Zocor®)
- sildenafil (Revatio®) only when used for the treatment of pulmonary arterial hypertension. (See "Medicines that may need changes" and "What are the possible side effects of Kaletra?" for information about the use of sildenafil for erectile problems.)
- alfuzosin (Uroxatral®)

Medicines that you should not take with KALETRA since they may make KALETRA not work as well:

- the herbal supplement St. John's Wort (hypericum perforatum)
- rifampin (Rimactane®, Rifadin®, Rifater®, or Rifamate®)

Medicines that may need changes:

- birth control pills that contain estrogen ("the pill") or the birth control (contraceptive) patches
- certain anticancer medicines, such as nilotinib (Tasigna®) and dasatinib (Sprycel®)
- certain cholesterol lowering medicines, such as atorvastatin (Lipitor®) or rosuvastatin (Crestor®)
- certain other antiretroviral medicines, such as efavirenz (Atripla® and Sustiva®), nevirapine (Viramune®), amprenavir (Agenerase®) and nelfinavir (Viracept®)
- anti-seizure medicines, such as phenytoin (Dilantin®) carbamazepine, (Tegretol®), phenobarbital
- medicines for erectile problems, such as sildenafil (Viagra®), tadalafil (Cialis®), or vardenafil (Levitra®)