

MEDICATION GUIDE

**KALETRA® (kuh-LEE-tra)
(lopinavir and ritonavir)
tablets**

**KALETRA® (kuh-LEE-tra)
(lopinavir and ritonavir)
oral solution**

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.** For more information, see "Who should not take KALETRA?"
- **Side Effects in babies taking KALETRA oral solution.** KALETRA oral solution contains alcohol (ethanol) and propylene glycol. Call your healthcare provider right away if your baby appears too sleepy or their breathing changes.
- **Inflammation of your 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-1 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 Hepatitis B or Hepatitis C, 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:
 - loss of appetite
 - yellow skin and whites of eyes (jaundice)
 - dark-colored urine
 - pale colored stools
 - itchy skin
 - stomach area (abdominal) 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 or certain types of heart problems.
 - 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

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

What is KALETRA?

KALETRA is a prescription medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults and children 14 days of age and older.

HIV 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 allergic to lopinavir, ritonavir, or any of the ingredients in KALETRA. See the end of this Medication Guide for a complete list of ingredients in KALETRA.
- if you take any of the following medicines:
 - alfuzosin
 - apalutamide
 - ranolazine
 - dronedarone
 - colchicine, if you have kidney or liver problems.

- rifampin
- lurasidone
- pimozone
- ergot containing medicines including:
 - dihydroergotamine mesylate
 - ergotamine tartrate
 - methylergonovine
- cisapride
- elbasvir/grazoprevir
- lovastatin
- simvastatin
- lomitapide
- sildenafil (Revatio®), when used for the treatment of pulmonary arterial hypertension
- triazolam
- midazolam when taken by mouth
- St. John's Wort (*Hypericum perforatum*®)

Serious problems can happen if you or your child takes any of the medicines listed above with KALETRA.

Before taking KALETRA, tell your healthcare provider about all of your medical conditions, including 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 or Hepatitis C.
- 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. KALETRA may cause increased bleeding.
- are pregnant or plan to become pregnant. It is not known if KALETRA will 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. Tell your healthcare provider if you become pregnant during treatment with KALETRA.
 - KALETRA may reduce how well hormonal birth control works. Females who may become pregnant should use another effective form of birth control or an additional barrier method of birth control during treatment with KALETRA.
 - **Pregnancy Registry:** There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of the pregnancy registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take KALETRA.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Many medicines interact with KALETRA.

Keep a list of your medicines to show your healthcare provider and pharmacist.

You can ask your healthcare provider or pharmacist for a list of medicines that interact with KALETRA.

Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take KALETRA with other medicines. Your healthcare provider may need to change the dose of other medicines during treatment with KALETRA.

How should I take KALETRA?

- Take KALETRA every day exactly as prescribed by your healthcare provider.
- Stay under the care of your healthcare provider during treatment with KALETRA.
- It is important to set up a dosing schedule and follow it every day.

- Do not change your treatment or stop treatment without first talking with your healthcare provider.
- Swallow KALETRA tablets whole. Do not chew, break, or crush KALETRA tablets.
- KALETRA tablets can be taken with or without food.
- KALETRA oral solution must be taken with food.
- If you are taking both didanosine and KALETRA:
 - Didanosine can be taken at the same time as KALETRA tablets, without food.
 - Take didanosine either 1 hour before or 2 hours after taking KALETRA oral solution.
- If you are pregnant:
 - You **should not** take KALETRA tablets on a 1 time each day dose schedule.
 - Avoid use of **KALETRA oral solution**.
- If your child is prescribed KALETRA:
 - Tell your healthcare provider if your child's weight changes.
- KALETRA **should not** be given to children on a 1 time each day dose schedule. When giving KALETRA to your child, give KALETRA exactly as prescribed.
 - Use the dosing cup (supplied) or an oral syringe with mL (milliliter) markings to give the prescribed dose of KALETRA oral solution to your child. Your pharmacist should provide an oral syringe to you.
 - KALETRA oral solution contains propylene glycol and a large amount of alcohol (ethanol). KALETRA oral solution **should not** be given to babies younger than 14 days of age unless your healthcare provider thinks it is right for your baby.
- Talk with your healthcare provider if you plan to take or give KALETRA oral solution through a feeding tube. KALETRA oral solution contains propylene glycol and alcohol (ethanol), and should not be used with certain feeding tubes.
- You may have a greater chance of getting diarrhea if you take KALETRA 1 time each day than if you take it 2 times each day.
- **Do not** miss a dose of KALETRA. This could make the virus harder to treat. If you forget to take KALETRA, take the missed dose right away. If it is almost time for your next dose, **do not** take the missed dose. Instead, follow your regular dosing schedule by taking your next dose at its regular time. **Do not** take more than one dose of KALETRA at one time.
- **If you or your child take more than the prescribed dose of KALETRA, call your healthcare provider or go to the nearest emergency room right away.**

What are the possible side effects of KALETRA?

KALETRA can cause serious side effects, including:

- See “**What is the most important information I should know about KALETRA?**”
- **Diabetes and high blood sugar (hyperglycemia).** You may develop new or worsening diabetes or high blood sugar during treatment with KALETRA. 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
 Your healthcare provider may need to start you on medicine to treat high blood sugar or change your diabetes medicines.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Call your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- **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** can happen in some people who take antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known at this time.

- **Increased bleeding in people with hemophilia.** Some people with hemophilia have increased bleeding with KALETRA or similar medicines.
- **Skin rash, which can be severe,** can happen in people who take KALETRA. Tell your healthcare provider if you have a history of skin rash with other medicine used to treat your HIV-1 infection or if you get any skin rash during treatment with KALETRA.
- **Kidney stones**

Common side effects of KALETRA include:

- diarrhea
- nausea
- vomiting
- increased fats in blood (triglycerides or cholesterol)

These are not all of the possible side effects of KALETRA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store KALETRA?

KALETRA tablets:

- Store KALETRA tablets at room temperature, between 68°F to 77°F (20°C to 25°C).
- Store KALETRA tablets in the original container.
- Do not keep KALETRA tablets out of the container it comes in for longer than 2 weeks, especially in areas where there is a lot of humidity.
- Keep the container closed tightly.

KALETRA oral solution:

- Store KALETRA oral solution in a refrigerator, between 36°F to 46°F (2°C to 8°C). KALETRA oral solution that is kept refrigerated may be used until the expiration date printed on the label.
- KALETRA oral solution that is stored at room temperature (less than 77°F or 25°C) should be used within 2 months.
- Keep KALETRA oral solution away from high heat.
- Throw away any medicine that is out of date or that you no longer need.

Keep KALETRA and all medicines out of the reach of children.

General information about the safe and effective use of KALETRA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use KALETRA for a condition for which it was not prescribed. Do not give KALETRA to other people, even if they have the same condition you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about KALETRA that is written for health professionals.

What are the ingredients in KALETRA?

Active ingredients: lopinavir and ritonavir

Inactive ingredients:

KALETRA 200 mg lopinavir and 50 mg ritonavir yellow tablets: colloidal silicon dioxide, copovidone, sodium stearyl fumarate, and sorbitan monolaurate. The film coating contains: colloidal silicone dioxide, hydroxypropyl cellulose, hypromellose, polyethylene glycol 400, polyethylene glycol 3350, polysorbate 80, talc, titanium dioxide, and yellow ferric oxide E172.

KALETRA 200 mg lopinavir and 50 mg ritonavir red tablets: colloidal silicon dioxide, copovidone, sodium stearyl fumarate, and sorbitan monolaurate. The film coating contains: colloidal silicone dioxide, hydroxypropyl cellulose, hypromellose, polyethylene glycol 400, polyethylene glycol 3350, polysorbate 80, talc, titanium dioxide, and red ferric oxide E172.

KALETRA 100 mg lopinavir and 25 mg ritonavir pale yellow tablets: colloidal silicon dioxide, copovidone, sodium stearyl fumarate, and sorbitan monolaurate. The film coating contains: polyethylene glycol 3350, polyvinyl alcohol, talc, titanium dioxide, and yellow ferric oxide E172.

KALETRA 100 mg lopinavir and 25 mg ritonavir pink tablets: colloidal silicon dioxide, copovidone, sodium stearyl fumarate, and sorbitan monolaurate. The film coating contains: polyethylene glycol 3350, polyvinyl alcohol, talc, titanium dioxide, and red ferric oxide E172.

KALETRA oral solution: acesulfame potassium, artificial cotton candy flavor, citric acid, ethanol (a type of alcohol), glycerin, high fructose corn syrup, Magnasweet-110 flavor, menthol, natural and artificial

vanilla flavor, peppermint oil, polyoxyl 40 hydrogenated castor oil, povidone, propylene glycol, saccharin sodium, sodium chloride, sodium citrate, and water.

KALETRA oral solution contains approximately 42% ethanol (a type of alcohol) and approximately 15% propylene glycol. **“See How should I take KALETRA?”**

For more information about KALETRA call 1-800-633-9110 or go to www.KALETRA.com

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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