

- medicines for tuberculosis (TB), such as rifabutin (Mycobutin®)
- inhaled steroid medicines, such as fluticasone propionate (Flonase®)
- inhaled medicines such as salmeterol (Serevent®) or salmeterol in combination with fluticasone propionate (Advair®). Your doctor may need to change to a different medicine
- medicines for gout, such as colchicine (Colcrys®)
- medicines to treat pulmonary arterial hypertension (PAH), such as bosentan (Tracleer®) or tadalafil (Adcirca®)
- pain medicines, such as fentanyl (Duragesic®), lonsys™, Fentora®) and methadone

**If you are not sure if you are taking a medicine above, ask your doctor.**

#### How should I take KALETRA?

- Take KALETRA every day exactly as prescribed by your doctor.
- It is very 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 doctor.
- Swallow KALETRA tablets whole. Do not chew, break, or crush KALETRA tablets.
- KALETRA tablets can be taken with or without food.
- If you are taking both Videx® (didanosine) and KALETRA:
  - didanosine can be taken at the same time as KALETRA tablets, without food.
  - take didanosine either one hour before or two hours after taking KALETRA oral solution.
- 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 take more than the prescribed dose of KALETRA, call your local poison control center or emergency room right away.
- Take KALETRA oral solution with food to help it work better.
- If KALETRA is being used for your child, tell your doctor if your child's weight changes.
- KALETRA **should not** be given one time each day in children. When giving KALETRA to your child, give KALETRA exactly as prescribed.
- KALETRA oral solution contains a large amount of alcohol.
  - If a young child drinks more than the recommended dose, it could make them sick from too much alcohol. Contact your local poison control center or emergency room right away.
  - Talk with your doctor if you take or plan to take metronidazole or disulfiram. You can have severe nausea and vomiting if you take these medicines with KALETRA.

- When your KALETRA supply starts to run low, get more from your doctor or pharmacy. It is important not to run out of KALETRA. The amount of HIV-1 virus in your blood may increase if the medicine is stopped for even a short time. The virus may become resistant to KALETRA and become harder to treat.
- KALETRA can be taken with acid reducing agents used for heartburn or reflux such as omeprazole (Prilosec®) and ranitidine (Zantac®) with no dose adjustment.
- KALETRA should not be administered once daily in combination with carbamazepine (Tegretol® and Eptol®), phenobarbital (Luminal®), or phenytoin (Dilantin®).

Avoid doing things that can spread HIV infection. KALETRA does not stop you from passing HIV infection to others. Do not share needles, other injection equipment or personal items that can have blood or body fluids on them, like toothbrushes and razor blades. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

#### What are the possible side effects of KALETRA?

##### KALETRA can cause serious side effects.

- See "What is the most important information I should know about KALETRA?"
- **Liver problems.** Liver problems, including death, can happen in people who take KALETRA. Blood tests in people who take KALETRA may show possible liver problems. People with liver disease such as Hepatitis B and Hepatitis C who take KALETRA may have worsening liver disease. Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems:
  - loss of appetite
  - yellow skin and whites of eyes (jaundice)
  - dark-colored urine
  - pale colored stools, itchy skin
  - stomach area (abdominal) pain.
- **Inflammation of the pancreas (pancreatitis).** Some people who take KALETRA get inflammation of the pancreas which may be serious and cause death. You have a higher chance of getting pancreatitis if you have had it before. Tell your doctor if you have nausea, vomiting, or abdominal pain while taking KALETRA. These may be signs of pancreatitis.
- **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. The long-term chance of getting complications such as heart attacks or stroke due to increases in triglycerides and cholesterol caused by protease inhibitors is not known at this time.
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including KALETRA get new or more serious diabetes, or high blood sugar. Tell your doctor if you notice an increase in thirst or urinate often while taking KALETRA.

- **Changes in body fat.** Changes in body fat 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 trunk. Loss of fat from the legs, arms and face may also happen. The cause and long-term health effects of these conditions are not known at this time.

- **Increased bleeding for hemophiliacs.** Some people with hemophilia have increased bleeding with protease inhibitors including KALETRA.

##### **Increased risk of certain problems when you take medicines used for the treatment of erectile problems such as sildenafil (Viagra®), tadalafil (Cialis®), or vardenafil (Levitra®) with KALETRA:**

- **low blood pressure.** If you get dizzy or faint, you need to lie down. Tell your doctor if you feel dizzy, or have fainting spells.
- **vision changes.** Tell your doctor right away if you have vision changes.
- **penis erection lasting more than 4 hours.** If you are a male and have an erection that lasts longer than 4 hours, get medical help right away to avoid permanent damage to your penis. Your doctor can explain these symptoms to you.
- **Allergic reactions.** Skin rashes, some of them severe, can occur in people who take KALETRA. Tell your healthcare provider if you had a rash when you took another medicine for your HIV infection or if you notice any skin rash when you take KALETRA.

Common side effects of KALETRA include:

- diarrhea
- nausea
- stomach area (abdominal) pain
- feeling weak
- vomiting
- headache
- upset stomach

These are not all of the possible side effects of KALETRA. For more information, ask your doctor or pharmacist. Tell your doctor about any side effect that bothers you or that does not go away.

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 59°F to 86°F (15°C to 30°C).
- 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.