

babies younger than 14 days of age unless your doctor thinks it is right for your baby.

- If a young child drinks more than the recommended dose, it could make them sick. 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 (Tegreto® 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.
- **Babies taking KALETRA oral solution may have side effects.** KALETRA oral solution contains alcohol and propylene glycol. Call your doctor right away if your baby appears too sleepy or their breathing has changed.

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.
- KALETRA oral solution that is stored at room temperature (less than 77°F or 25°C) should be used within 2 months.
- Keep KALETRA 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 KALETRA

KALETRA does not cure HIV-1 or AIDS. The long-term effects of KALETRA are not known at this time. People taking KALETRA may still get opportunistic infections or other conditions that happen with HIV-1 infection. Some of these conditions are pneumonia, herpes virus infections, and Mycobacterium avium complex (MAC) infections.

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.

This Medication Guide summarizes the most important information about KALETRA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about KALETRA that is written for health professionals. For more information about KALETRA call 1-800-633-9110 or go to www.KALETRA.com.

What are the ingredients in KALETRA?

Active ingredient: lopinavir and ritonavir

Inactive ingredients:

KALETRA 200 mg lopinavir and 50 mg ritonavir tablets:

copovidone, sorbitan monolaurate, colloidal silicon dioxide, and sodium stearyl fumarate. The film coating contains: hypromellose, titanium dioxide, polyethylene glycol 400, hydroxypropyl cellulose, talc, colloidal silicon dioxide, polyethylene glycol 3350, yellow ferric oxide 172, and polysorbate 80.

KALETRA 100 mg lopinavir and 25 mg ritonavir tablets:

copovidone, sorbitan monolaurate, colloidal silicon dioxide, and sodium stearyl fumarate. The film coating contains: polyvinyl alcohol, titanium dioxide, talc, polyethylene glycol 3350, and yellow ferric oxide E172.

KALETRA oral solution: acesulfame potassium, alcohol, artificial cotton candy flavor, citric acid, 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 42.4% alcohol (v/v). "See How should I take KALETRA?"

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KALETRA Tablets, 200 mg lopinavir/50 mg ritonavir

Manufactured by Abbott Pharmaceuticals PR Ltd.,
Barceloneta, PR 00617

for Abbott Laboratories, North Chicago, IL 60064, U.S.A.

KALETRA Tablets, 100 mg lopinavir/25 mg ritonavir and KALETRA Oral Solution

Abbott Laboratories, North Chicago, IL 60064, U.S.A.

Ref: 03-A465-R10

Revised: February, 2011

036-553815 MASTER

039-565606

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