

frequent urination, excessive thirst, extreme hunger or unusual weight loss and/or an increased blood sugar while on KALETRA as they may require a change in their diabetes treatment or new treatment.

- KALETRA might produce changes in the electrocardiogram (e.g., PR and/or QT prolongation). Patients should consult their physician if they experience symptoms such as dizziness, lightheadedness, abnormal heart rhythm or loss of consciousness.
- They should seek medical assistance immediately if they develop a sustained penile erection lasting more than 4 hours while taking KALETRA and a PDE 5 Inhibitor such as Viagra, Cialis or Levitra.
- Redistribution or accumulation of body fat may occur in patients receiving antiretroviral therapy and that the cause and long term health effects of these conditions are not known at this time.
- Patients should be informed that there may be a greater chance of developing diarrhea with the once daily regimen as compared with the twice daily regimen.

## 17.2 Medication Guide

### MEDICATION GUIDE

**KALETRA® (kuh-LEE-tra)**

(lopinavir/ritonavir)

**Tablets**

**KALETRA® (kuh-LEE-tra)**

(lopinavir/ritonavir)

**Oral Solution**

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<sup>®</sup>, Migergot, Ergomar, Ergostat, Medihaler Ergotamine, Wigraine, Wigrettes)
  - dihydroergotamine mesylate (D.H.E. 45<sup>®</sup>, Embolex, Migranal<sup>®</sup>)
  - ergonovine, ergonovine and methylergonovine (Ergotrate, Methergine), ergotamine and methylergonovine
  - Ergotrate Maleate, methylergonovine maleate (Methergine)
- triazolam (Halcion<sup>®</sup>), midazolam hydrochloride oral syrup
- pimozide (Orap<sup>®</sup>)
- the cholesterol lowering medicines lovastatin (Mevacor<sup>®</sup>) or simvastatin (Zocor<sup>®</sup>)

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

- the herbal supplement St Johns Wort (*hypericum perforatum*)
- rifampin (Rimactane<sup>®</sup>, Rifadin<sup>®</sup>, Rifater<sup>®</sup>, or Rifamate<sup>®</sup>)

#### **Medicines that may need changes:**

- birth control pills that contain estrogen ("the pill") or the birth control (contraceptive) patches
- certain cholesterol lowering medicines, such as atorvastatin (Lipitor<sup>®</sup>) or rosuvastatin (Crestor<sup>®</sup>)
- certain other antiretroviral medicines, such as efavirenz (Atripla<sup>®</sup> and Sustiva<sup>®</sup>), nevirapine (Viramune<sup>®</sup>), amprenavir (Agenerase<sup>®</sup>), fosamprenavir calcium (Lexiva<sup>®</sup>) and nelfinavir (Viracept<sup>®</sup>)
- anti-seizure medicines, such as phenytoin (Dilantin<sup>®</sup>) carbamazepine, (Tegretol<sup>®</sup>), phenobarbital
- sildenafil (Viagra<sup>®</sup>, Revatio<sup>®</sup>), tadalafil (Cialis<sup>®</sup>), or vardenafil (Levitra<sup>®</sup>)
- medicines for tuberculosis (TB), such as rifabutin (Mycobutin<sup>®</sup>)

- inhaled steroid medicines, such as fluticasone propionate (Flonase®)

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 Prilosec® (omeprazole) and Zantac® (ranitidine) with no dose adjustment.

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 such as sildenafil (Viagra®), Revatio®), 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.

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](http://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?"**

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.

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

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