☐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.

KALETRA Tablets, 200 mg lopinavir and 50 mg ritonavir

Manufactured by AbbVie LTD, Barceloneta, PR 00617

for AbbVie Inc., North Chicago, IL 60064 USA

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

AbbVie Inc., North Chicago, IL 60064 USA

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MEDICATION GUIDE

KALETRA® (kuh-LEE-tra)

(lopinavir and ritonavir)

tablets

KALETRA® (kuh-LEE-tra)

(lopinavir and ritonavir)

oral solution

Read this Medication Guide before you start taking KALETRA 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.** For more information, see "Who should not take 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 "What are the possible side effects of KALETRA?" for more information about serious side effects.

What is KALETRA?

KALETRA is a prescription HIV-1 medicine that is used with other HIV medicines to treat HIV-1 (Human Immunodeficiency Virus) infection in adults and children 14 days of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). KALETRA is a type of HIV medicine called a protease inhibitor. KALETRA contains two medicines: lopinavir and ritonavir.

When used with other HIV medicines, KALETRA may help to reduce the amount of HIV in your blood (called "viral load"). KALETRA may also help to increase the number of white blood cells called CD4 (T) cell which help fight off other infections. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

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

KALETRA does not cure HIV infection or AIDS. People taking KALETRA may develop infections or other conditions associated with HIV infection, including opportunistic infections (for example, pneumonia and herpes virus infections).

Avoid doing things that can spread HIV-1 infection to others:

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.**

- **Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

Who should not take KALETRA?

Do not take KALETRA if you take any of the following medicines:

- alfuzosin (Uroxatral®)
- cisapride (Propulsid®, Quicksolv®)
- colchicine (Colcrys®), if you have kidney and/or liver problems
- dronedarone (Multaq®)
- elbasvir/grazoprevir (Zepatier®)
- ergot containing medicines including
  - ergotamine tartrate (Cafergot®, Migergot®, Ergomar®, Ergostat®, Medihaler®, Ergotamine, Wigraine®, Wigrettes®)
  - dihydroergotamine mesylate (D.H.E. 45®, Migranal®)
  - methylergonovine (Methergine®)
- lovastatin (Advicor®, Altoprev®, Mevacor®)
- midazolam oral syrup
- lurasidone (Latuda®), pimozide (Orap®)
- rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- sildenafil (Revatio®), when used for the treatment of pulmonary arterial hypertension
- simvastatin (Zocor®, Vytorin®, Simcor®)
- St. John's Wort (Hypericum perforatum)
- triazolam (Halcion®)

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

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 or had pancreas problems.
- 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. Taking KALETRA during pregnancy has not been associated with an increased risk of birth defects. You and your doctor should decide if KALETRA is right for you.
  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 doctor 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 doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take, including prescription and over-the-counter 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.

Especially tell your doctor if you take:

- medicine to treat HIV
- estrogen-based contraceptives (birth control pills and patches). KALETRA may reduce the effectiveness of estrogen-based contraceptives. During treatment with KALETRA, you should use a different type or an extra form of birth control. Talk to your doctor about what types of birth control you can use to prevent pregnancy while taking KALETRA.
- medicines to prevent organ transplant rejection
- medicines to treat cancer
- amiodarone (Cordarone®, Pacerone®)
- atorvastatin (Lipitor®)
- atovaquone (Marlarone®, Mepron®)
- avanafil (Stendra®), sildenafil (Viagra®), tadalafil (Cialis®), or vardenafil (Levitra®) for the treatment of erectile dysfunction (ED). If you get dizzy or faint (low blood pressure), have vision changes or have an erection that last longer than 4 hours, call your doctor or get medical help right away.
- bedaquiline (Sirturo®)
- bepridil (Bepadin®, Vascor®)
- boceprevir (Victrelis®)
- bosentan (Tracleer®)
- budesonide (Rhinocort®, Symbicort®, Pulmicort®, Entocort EC®)
- bupropion (Aplenzin®, Forfivo XL®, Wellbutrin®, Zyban®)
- carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®)
- clarithromycin (Biaxin®, Prevpac®)

- colchicine (Colcrys®)
- dexamethasone (Maxidex®, Ozurdex®)
- disulfiram
- felodipine
- fentanyl (Abstral®, Actiq®, Duragesic®, Fentora®, Lazanda®, Onsolis®, Subsys®)
- fluticasone (Cutivate®, Flonase®, Flovent®, Flovent Diskus®, Flovent HFA®, Veramyst®)
- itraconazole (Onmel®, Sporanox®)
- isavuconazonium (Cresemba®)
- ketoconazole (Extina®, Ketozole®, Nizoral®, Xolegel®)
- lamotrigine (Lamictal®)
- lidocaine
- methadone hydrochloride (Dolphine hydrochloride, Methadose®)
- metronidazole
- nicardipine (Cardene®)
- nifedipine (Adalat CC®, Afeditab CR®, Procardia®)
- ombitasvir/parataprevir/ritonavir and dasabuvir (Viekira Pak®)
- phenobarbital
- phenytoin (Dilantin®, Phenytek®)
- prednisone
- quinidine (Quinidex®)
- quetiapine (Seroquel®)
- rifabutin (Mycobutin®)
- rivaroxaban (Xarelto®)
- rosuvastatin (Crestor®)
- salmeterol (Serevent®) or salmeterol when taken in combination with fluticasone (Advair Diskus®, Advair HFA®)
- simeprevir (Olysio®)
- tadalafil (Adcirca®) for the treatment of pulmonary arterial hypertension
- trazodone (Oleptro®)
- valproate (Depakote®, Depakene®, Depacon®)
- voriconazole (Vfend®)
- warfarin (Coumadin®, Jantoven®)

KALETRA should not be administered once daily in combination with carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®), phenobarbital, or phenytoin (Dilantin®, Phenytek®)

Ask your doctor or pharmacist if you are not sure if your medicine is one that is listed above.

Know all the medicines that you take. Keep a list of them with you to show doctors and pharmacists when you get a new medicine.

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.
- KALETRA tablets **should not** be taken 1 time each day if you are pregnant. You **should not** take KALETRA oral solution if you are pregnant.
- 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 didanosine (Videx®) 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 doctor or go to the nearest emergency room right away.
- Take KALETRA oral solution with food to help it work better.
- If your child is prescribed KALETRA, 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 propylene glycol and a large amount of alcohol. KALETRA oral solution **should not** be given to 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.

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?"**
- **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.

- **Liver problems.** Liver problems, including death, can happen in people who take KALETRA. Your doctor should do blood tests before and during your treatment with KALETRA to check your liver function. Some people with liver disease such as Hepatitis B and Hepatitis C who take KALETRA may have worsening liver disease. Tell your doctor 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
- **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 your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV 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 doctor right away if you start having new symptoms after starting your HIV 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 doctor should do blood tests to check your cholesterol and triglyceride levels before you start taking KALETRA and during your treatment.
- **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.
- **Allergic reactions.** Skin rashes, some of them severe, can occur in people who take KALETRA. Tell your doctor if you had a rash when you took another medicine for your HIV-1 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
- increased fats in blood (triglycerides or cholesterol)
- vomiting

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all of the possible side effects of KALETRA. For more information, ask your doctor 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 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

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 ingredients: 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?".

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

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