## KALETRA® (kuh-LEE-tra) (lopinavir/ritonavir) Tablets KALETRA® (kuh-LEE-tra) (lopinavir/ritonavir) Oral Solution

CONSUMER BRIEF SUMMARY CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

# **MEDICATION GUIDE Patient Information**

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®), midazolam hydrochloride oral syrup
- pimozide (Orap®)
- the cholesterol lowering medicines lovastatin (Mevacor®) or simvastatin (Zocor®)
- sildenafil (Revatio®) only when used for the treatment of pulmonary arterial

hypertension. (See "Medicines that may need changes" and "What are the possible side effects of Kaletra?" for information about the use of sildenafil for erectile problems.)

alfuzosin (Uroxatral®)

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

- the herbal supplement St. John's Wort (hypericum perforatum)
- rifampin (Rimactane®, Rifadin®, Rifater®, or Rifamate®)

## 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®) or rosuvastatin (Crestor®)
- certain other antiretroviral medicines, such as efavirenz (Atripla® and Sustiva®), nevirapine (Viramune®), amprenavir (Agenerase®), fosamprenavir calcium (Lexiva®) and nelfinavir (Viracept®)
- anti-seizure medicines, such as phenytoin (Dilantin®) carbamazepine, (Tegretol®), phenobarbital
- medicines for erectile problems, such as sildenafil (Viagra®, Revatio®), tadalafil (Cialis®), or vardenafil (Levitra®)
- 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®)

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 Epitol®), phenobarbital (Luminol®), 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)
- o dark-colored urine
- o pale colored stools, itchy skin
- o 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 longterm 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.

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, polytheylene 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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036-377027 MASTER



039-373135



## the "official" dish

by Rip & Marsha Naquin-Delain RipandMarsha.COM Email: marsha@ripandmarsha.com

# NOLA Pride: New Orleans Official Pride Brought Some 3,000 Out to the First Pride Street Festival

he last Sunday in June brought out an estimated 2,500-3,000 to the corner of Bourbon and St. Ann for New Orleans first Pride Street Festival. Presented by NOLA Pride, the exciting weeks leading up to the big day were filled with fund-raisers, shows, receptions and galas. The NOLA Pride Committee should be congratulated for trying this new venue, a mini-Southern Decadence style Bourbon Street Extravaganza. It generated much needed revenues throughout the GLBT and gay-friendly communities for area businesses hit hard by the results of BP's Gulf oil spill. It's great to see the communities come together to celebrate Pride, New Orleans style. In addition to the 2nd Line Pride Parade featuring Pride Grand Marshals Steven Forster and Cathy Fox, and Miss Gay Pride Tami Tarmac, the street stage hosted loads of entertainment and moving speeches from political leaders and GLBT celebrities. New Orleans City Councilman Arnie Fielkow presented a city council proclamation recognizing NOLA Pride as New Orleans Official Pride, while New Orleans School Board's Thomas Robichaux presented a proclamation from New Orleans Mayor Mitch Landrieu echoing the same message.

Consider joining in next year's celebration tentatively scheduled for June 24-26, 2011 by joining the NOLA Pride Committee. You can make a difference! Visit NOLAPride.ORG for more information.

## Jean Redmann to Receive Lifetime Achievement Award; Top 5 Fly Fashion Glamour & Cheridon Comedy Award Finalists Selected

he Gay Appreciation Awards (GAA) Board of Directors has selected Jean Redmann to receive the prestigious 23rd Lifetime Achievement Award at the 23rd annual GAA Gala Saturday, July 24 hosted at Oz, 800 Bourbon Street. Jean Redmann grew up in Ocean Springs, a small town on the Mississippi Gulf Coast. Her father was a New Orleans native, so she spent much of her childhood visiting various relatives in the Crescent City. At eighteen, determined to get out of a small town, she headed north to Vassar. During her freshman year, she was asked by the Daughters of the Confederacy to make her debut. She declined their offer, and came out in a very different way.

The day after she graduated from college, she got on a train for New York City. Determined not to become a rich yuppie, Ms. Redmann embarked on a career in theatrical lighting, including a stint as the master electrician for Psycho Beach Party. Richs never darkened her door, even today they remain a far lottery dream away. The New York theatrical world was hit hard by the HIV/AIDS pandemic. In the mid-1980s, Redmann volunteered on the first national hotline.

Moving back to New Orleans, her HIV/AIDS volunteering turned into a full-time job. From 1991 to 1999, Redmann was the HIV Counseling and Testing Coordinator at NO/AIDS Task Force. In 1999 she moved to her current job as Director of Prevention.

As Director of Prevention Redmann has overseen the expansion of the department from five employees to the current twenty-two. During her tenure, the CAN office on Frenchmen Street opened, and NO/AIDS expanded its funding sources to include direct funding from CDC, from SAMHSA and the Office of Minority Health. In addition to direct services, the Prevention Department also collaborates on research activities, including being part of the National HIV Behavior Surveillance (NHBS) project, a Louisiana statewide MSM (Men who have Sex with Men) assessment, research on MSM tourist with Dr. Eric Benotsch on his NIH grant as well as others. Both Redmann and her staff have presented at national conferences.

In addition to a 'day job' in HIV/AIDS, as J.M. Redmann she writes the Micky Knight mystery series. Of the five books published so far, four have been nominated for Lambda Literary Awards and two—*The Intersection of Law and Desire* and *Death of A Dying Man*, her most recent—have won the award. In addition to winning the 'Lammy' *The Intersection of Law and Desire* was an Editor's Choice of the *San Francisco Chronicle* and was featured on *NPR's Fresh Air*. She was recently awarded the Alice B. Medal, an award given annually to living writers who have careers distinguished by consistently well-written stories about lesbians. The award is given once, only, in appreciation of career achievement.

Redmann is one of the few lesbian writers who 'crossed over' into the mainstream publishers from the smaller presses, with two of her books, *The Intersection of Law and Desire* and *Lost Daughters*, published by W.W. Norton.

Her books have been translated into German, Spanish, Dutch and Norwegian. The next book, *Water Mark*, will be released in September from Bold Strokes Books.

The GAA Board of Directors also have selected the Top 5 Finalists in two categories. The Fly Fashion Glamour Award finalists include Tiffany Alexander, Nicole DuBois, Mercedes Ellis Loreal, Rhonda Roget and Tami Tarmac. The Cheridon Comedy Award finalists include Barry Bareass, Blanche Debris, Zsa Zsa d'LaHor, Sister Mary Isawhore and Persona Shoulders. The winner in each of these categories will be announced along with the nineteen previously voted on by the public at the GAA Gala July 24th. The show starts promptly at 8pm, with doors opening at 7pm at Oz. All VIP Tables are sold out.

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GAA Gala Issue out July 20

**DEADLINE: Tuesday, July 13** 

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General admission is \$10 at the door. All proceeds benefit the William Fanning Foundation (Buzzy's Boys & Girls).

Board members Lisa Beaumann and Teryl-Lynn Foxx will emcee the affair. Entertainment will include the return of 2009 Entertainers of the Year Coca and Ama Rosa, and GAA Founder Marcy Marcell. Additionally, Show Club of the Year Finalists Bourbon Pub & Parade, JohnPaul's, Oz, Tubby's Golden Lantern, and Starlight By The Park are scheduled to do a production number. All stage performance tips also benefit Buzzy's Boys & Girls.

The Top 5 Finalists voted on by the public include:

- Circuit Party/Event of the Year: Gay Easter Parade, Halloween, PFLAG's 20th Anniversary Champagne Reception, Red Party/Lafitte's, Southern Decadence
- Hair Salon of the Year: Bobby Blue Contemporary Barber & Beauty Parlor, Headquarters, Mickey Nolan's Salon, Paris Parker, Salon D'Malta
- Gay Mardi Gras Ball of the Year:
   Krewe of Amon-Ra, Krewe of Armeinius,
   Krewe of Petronius, Lords of Leather, Mystic Krewe of Satyricon
- Neighborhood Bar of the Year: 700
   Club, Cafe Lafitte in Exile, Good Friends
   Bar, JohnPaul's, Tubby's Golden Lantern
- Buzzy Fanning AIDS Award [organization/individual doing outstanding service in the AIDS arena]: Michael Hickerson, Toby Lefort, Tony Leggio, Chris Leonard, NO/AIDS Task Force
- Bitch of the Year: Aletha Bryant, Paul Chiriaco, Ken Grandpre, Princesse Stephaney, Persana Shoulders
- Show Club of the Year: Bourbon Pub & Parade, JohnPaul's, Oz, Tubby's Golden Lantern, Starlight By The Park
- Donnie Jay Performing Arts Award [play, chorus or theatrical group/no individuals]: *GLITZ: The Art of Female Impersonation, I Am My Own Wife*, New Orleans Gay Men's Chorus, Outworks 2010/LSU Theatre Department, Running With Scissors
- Restaurant/Deli/Coffee House of the Year: Bywater Restaurant, Deli & BBQ; Clover Grill; Mona Lisa Restaurant, Quartermaster: The Nellie Deli; Verti Mart
- Dance Club of the Year: Bourbon Pub & Parade, JohnPaul's, Oz, Rubyfruit Jungle, Splash/Baton Rouge
- Bartender of the Year: Aletha Bryant/ Cafe Lafitte in Exile, Darrin Duplissey/ JohnPaul's, Lance Pippin/Tubby's Golden Lantern, Jeff Palmquist/Cafe Lafitte in Ex-

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Gulf South Entertainment/Travel Guide Since 1982 • Texas-Florida Official Gay Easter Parade Guide Official Gay Mardi Gras Guide Official Gay New Orleans Guide Official Southern Decadence Guide

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**Newly crowned Amon-Ra Prom** King & Queen Nick Olivares & Deja Deja Vu @ JohnPaul's



Ed, Gary & Miss Louisiana Leatherette Cathy Fox join Who's **My Daddy Contest** 



**Bartenders Bruce & Ashlee serve** cocktails for The Corner Pocket's 28th Anniversary



Joe & Marshall join new Bywater Patio Bar bartender Chris



Kenny, Mary Ellen & Jerry @ **Amon-Ra's Prom Night** 



Lords of Leather's Who's My Daddy contestants @ Phoenix



Lynne, David, Lou, Muriel & Yvette celebrate @ Big Daddy's Grand **Re-Opening** 



GM Tommy & dancer Joey @ Oz's 18th Anniversary Neon Party

**Neon Party** 



Steven & Lance celebrate @



Lords of Leather Pres. Michael & Miss Gay Pride Tami Tarmac



Salon D'Malta's Monica & Pitty Pat



join Big Daddy's Grand Re-Opening



Jay & Adeaux in for Big Daddy's **Grand Re-Opening** 





Armeinius' Nick, Bruce & Rick @ **Amon-Ra's Prom Night** 



Leo ties for 2nd place in the Sugar

Michael serves up his famous stuffed grape leaves for The Corner Pocket's 28th Anniversary



Kevin & Dudley getting a cold one



Moms Mini Mart's Sydney &

Bartender Jim @ Cutter's



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