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

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.
- o take other medicines that can affect your heart rhythm while

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 vou 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
- · 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
- 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®, Migergot, Ergomar, Ergostat, Medihaler Ergotamine, Wigraine, Wigrettes) o dihydroergotamine mesylate (D.H.E. 45®, Embolex, Migranal®)
- o 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 KALÉTRA 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 anticancer medicines, such as nilotinib (Tasigna®) and dasatinib (Sprycel®)

- 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®) and nelfinavir (Viracept®)
- anti-seizure medicines, such as phenytoin (Dilantin®) carbamazepine, (Tegretol®), phenobarbital
- medicines for erectile problems, such as sildenafil (Viagra®), tadalafil (Cialis®), or vardenafil (Levitra®)
- medicines for tuberculosis (TB), such as rifabutin (Mycobutin®)
- inhaled steroid medicines, such as fluticasone propionate
- 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
- . 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:
- o 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 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.
- 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 (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

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
- o 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
- 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
- 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

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?".

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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.

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the "official" dish

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

SDGMs 37 Misael Rubio & Tiffany Alexander will lead 40th Anniversary of Southern Decadence

estivities move into full swing with the announcement of Southern
Decadence Grand Marshals XXXVII Misael Rubio and Tiffany
Alexander at Club LAX in Metairie. Outgoing SDGMs Toby Lefort and

Julien Artressia made their choices known at Coronation 2011 bringing many segments in the GLBT community together for the occasion. Rubio, the proprietor of Quartermaster: The Nellie Deli, and Alexander, Bourbon Pub Parade Show Director, announced this year's theme, *Viva New Orleans:* What Happens in New Orleans. The official colors are fuchsia pink, black and silver.

The 40th anniversary of Southern Decadence is set for Wednesday, August 31st through Labor Day, Monday, September 5th. There will be a flurry of activities and events leading up to the 37th annual South-



SDGMs XXXVII Misael Rubio & Tiffany Alexander

ern Decadence Parade on Sunday, September 4th. As the parade winds through the streets of the French Quarter, you will get to see all the outrageous fun led by SDGMs XXXVII Misael Rubio and Tiffany Alexander followed by the annual Southern Decadence Bead Toss at *Ambush* Headquarters, 828 Bourbon Street. For additional information, visit <u>SouthernDecadence.COM</u>.

Chuck Turner & Bill Miller to Receive 24th Lifetime Achievement Award, GAA Top 5 Finalists Announced

he Board of Directors of the Gay Appreciation Awards has chosen businessmen Chuck Turner and Bill Miller as recipients of the 24th Lifetime Achievement Award, the highest honor bestowed at the annual awards presentation. Turner and Miller are proprietors of 4 Seasons in Metairie, Billy's in Slidell, and Double Play in New Orleans. The couple, who recently celebrated their 40th anniversary, have been long time supporters of the GLBT community and through their clubs and efforts have helped raise over \$150,000 for area charities including NO/AIDS Task Force, Gay Easter Parade and Food For Friends.

Public online voting in the various categories of the Gay Appreciation Awards took place June 7-13. The Top 5 Finalist in each category appear below, and the winner in each category will be announced at the 24th GAA Gala on Saturday, July 23, 8-10pm, at Oz, 800 Bourbon Street. VIP Tables with four seats are \$150. All proceeds benefit the William Fanning Foundation (Buzzy's Boys & Girls). Contact Rip Naquin for table sales at marsha@ripandmarsha.com or 504.522.8049.

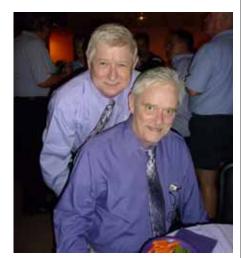
Top 5 Finalists include:

- Circuit Party/Event of the Year Gay Easter Parade, Gay Easter Parade Purple Party, Halloween, Southern Decadence, White Party/Oz
- Hair Salon of the Year Beauty Lounge, Bobby Blue, Headquarters, Mickey Nolan's Salon, 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 4 Seasons/Metairie, Kajun's Pub, Cafe Lafitte in Exile, JohnPaul's, Tubby's Golden Lantern

Darrin Ferris, Toby Lefort, Tony Leggio, Chris Leonard, NO/AIDS Task Force
• Bitch of the Year - Lady Hope.

• Buzzy Fanning AIDS Award -

- Bitch of the Year Lady Hope, Tony Leggio, Opal Masters, Princesse Stephaney, Persana Shoulders
- Show Bar of the Year Bourbon
 Pub & Parade, Club LAX/Metairie,
 JohnPaul's, Oz, Tubby's Golden Lantern
- Donnie Jay Performing Arts Award
 Big Bell Productions/After Dark, La
 Familia Variety Drag Show, New Orleans Gay Men's Chorus, Running With
 Scissors, Silk Dress Productions'
 Who's Afraid of Virginia Woolf
- Restaurant/Deli/Coffee House of the Year - Clover Grill, Eat, Mona Lisa Restaurant, Quartermaster: The Nellie Deli; Who Dat Coffee Cafe
- Dance Club of the Year Bourbon
 Pub & Parade, Club LAX, Corner
 Pocket, JohnPaul's, Oz,
- Bartender of the Year Bobby Fisher/JohnPaul's, Chuck Hinkley/4 Seasons, Lance Pippin/Tubby's Golden Lantern, Jeff Palmquist/Cafe Lafitte in Exile, Frankie Wingerter/Oz
- DJ of the Year E (Eddie Mitchell)/ Club LAX, Myke Kolb/Cafe Lafitte in Exile, Tim Pflueger/Oz, Richie Rich/ JohnPaul's, Jeff Waguespack/Cafe Lafitte in Exile
- Leather Bar of the Year Club LAX/Metairie, JohnPaul's, Phoenix, Rawhide 2010, Tonic/Lafayete
- Cheridon Comedy Award Zsa Zsa d'LaHor, Tony Leggio, Sister Mary Isahor, Princesse Stephaney, Persana Shoulders
- Fly Fashion Glamour Award -Starr Alexander, Elizabeth Bouvier, Do-



Chuck Turner & Bill Miller 24th Lifetime Achivement Award

Summer/Restaurant Guide out July 5th DEADLINE: Tues., June 28th

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Gulf South Entertainment/Travel Guide Since 1982 828-A Bourbon St. • New Orleans, LA 70116-3137 • 504.522.8049 marsha@ripandmarsha.com minique DeLorean, Raven Kennedy, Princesse Stephaney

- GLBT Business of the Year -Formal Connection/LaPlace, Krazy Katz, La Mina Sterling, Spa Atlantis, Rab Dab Clothing & Gifts
- Leather Person of the Year Michael Albracht, Jose Gonzales, Toby Lefort, Troy Powell, Gary Vandeventer
- Transgender of the Year Regina Adams, Dee Cooley, Jasmine Essex, JoAnn Guidos, Rikki Redd
- Lesbian of the Year Misti Ates, Koo Gaffney, Gino New Orleans, Sandy Sachs, Sherran Thomas
- Gay Man of the Year Tommy Elias, Darrin Ferris, Toby Lefort, Tony Leggio, Chuck Turner

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THE OFFICIAL MAG AMBUSH

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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STAFF: PUBLISHER/EDITOR

R. Rip Naquin-Delain, New Orleans
PRODUCTION DIRECTOR
M. Marsha Naquin-Delain, New Orleans
GULF SOUTH/NEW ORLEANS AD SALES
Rip Naquin-Delain • 504.522.8049
THEATRE/PERFORMING ARTS CRITIC

Brian Sands
AD REPS/JOURNALISTS/PHOTOGRAPHERS

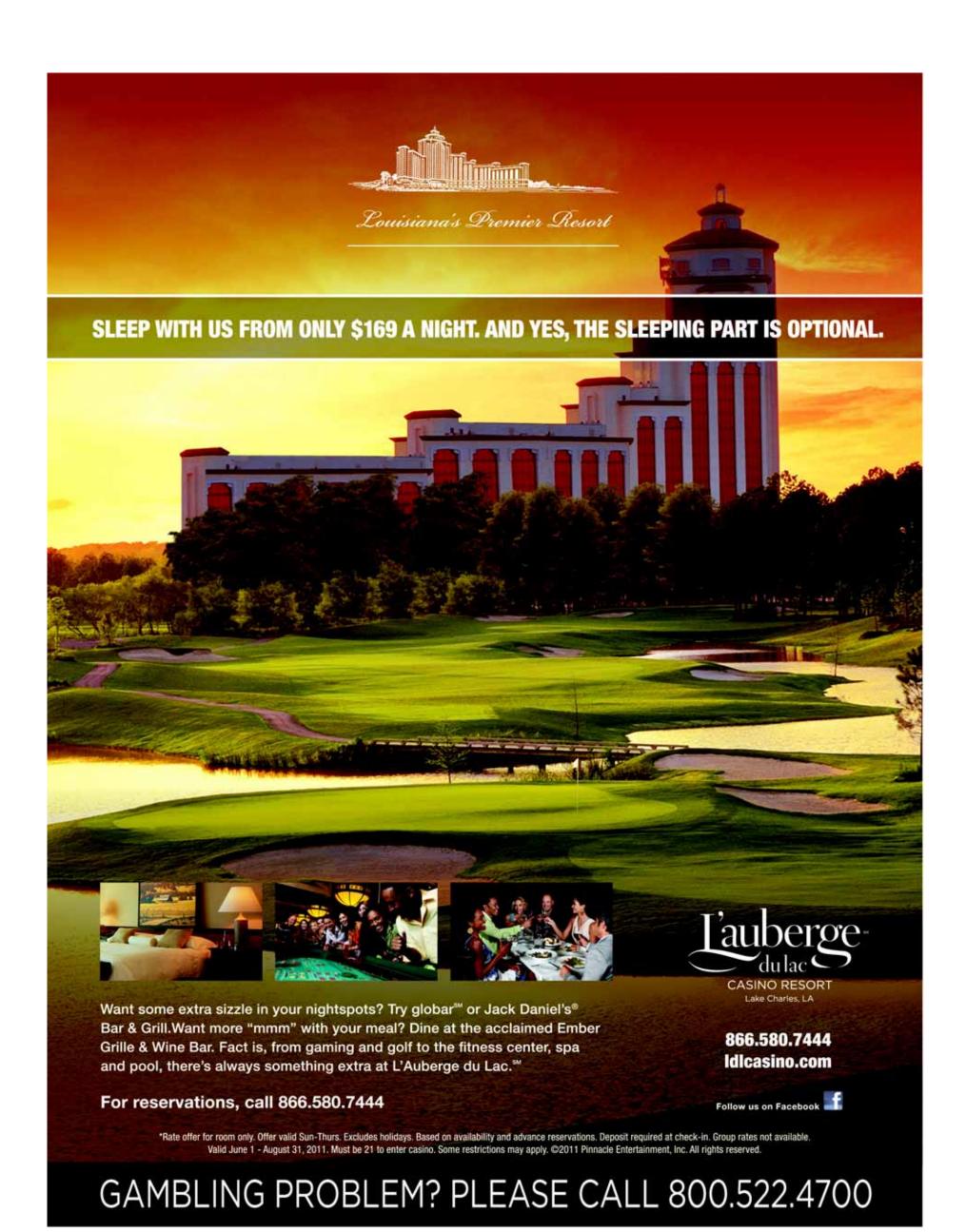
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Wingerter-New Orleans

Bob Brunson, Cieanne & John, Leon Weekley-Mobile, AL

> Lauren Mitchell-Pensacola, FL Roy Williams-Pensacola, FL NATIONAL ADVERTISING REP Rivendell Media-212.242.6863

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the "official" dish ...from 8

• Marcy Marcell Entertainer of the Year - Big Mama, Elizabeth Bouvier, Monique Michaels, Princesse Stephaney, Tittie Toulouse

Entertainment for the GAA Gala will include production numbers from

the Top 5 Finalists in the Show Bar of the Year category, as well as last year's Entertainer of the Year Elizabeth Bouvier. The exciting duo of Lisa Beaumann and Teryl-Lynn Fox will emcee the affair.

Sponsored by *Ambush*, the awards thanks those in the Gay Lesbian Bisexual Transgender Community who are often not recognized for the outstanding services and efforts they perform. These individuals and businesses have made the

GLBT Community into the viable, successful and powerful community it is today across the Gulf South.

The Marsha Delain Award of Excellence, the Drag Ambassador Award, is presented by Marsha Naquin-Delain.

For additional information, visit AmbushMag.COM.

New Orleans Official Pride Celebration June 24th-26th

OLA Pride presents New Orleans official Pride celebration Friday-Sunday, June 24th-26th. Led by Pride Grand Marshals Chris Leonard and Misti Ates, and Honorary Pride Grand Marshal Jason Dottley, the weekend is chockful of activities and events.

The schedule includes:

Friday: June 24, begin Pride Weekend with a Pub Crawl. Registration 6:30-7:30pm. \$25 covers the progressive cocktail party with a shot or drink at each participating bar and a NOLA PRIDE 2011 T-shirt. Start of crawl is Tubby's Golden Lantern, 1239 Royal St. – finish upstairs at Lafitte's, 901 Bourbon St.

Saturday: 11am June 25, Family Day in City Park in the picnic area open to the public.

Noon: Kids Softball Skills will be taught by members of the NOLA Softball League.

1pm: Drag Softball Game (City Park – Field 18 – corner of Marconi & Harrison)

If you prefer to stay in the Quarter, there will be a Harrah's Casino Block Party 2-7pm

7-10pm: Pride Grand Marshal Reception at K-Joe's, 720 St. Louis Street, French Quarter. Meet Pride Grand Marshals Misti Ates and Chris Leonard, and Honorary Grand Marshal Jason Dottley. Featured at the reception will be royalty from LGBT krewes. Tickets: \$25

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