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 <u>know the</u> <u>medicines that should not be</u> <u>taken with KALETRA</u>. 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

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

 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[®])
- 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

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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
- certain choiesteroi 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

- 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

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 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
 (humanuluaemia) Come people who

 Not chew, break, or crush KALETRA tablets. KALETRA tablets can be taken with or without food. 	once daily in combination with carbamazepine (Tegretol® and Epitol®), phenobarbital (Luminol®), or phenytoin (Dilantin®).	(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
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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 <u>4 hours.</u> 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:

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 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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Ref: 03-A363-R7

Revised: April, 2010 This Medication Guide has been approved by the U.S. Food and Drug Administration.

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039-373135

Store KALETRA tablets at room	oxide 172, and polysorbate 80.
 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 	KALETRA 100 mg lopinavir and 25 mg ritonavir tablets: copovidone, sorbitan monolaurate, colloidal silicon dioxide,

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the "official" dish

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

23rd GAA Gala Announces Winners July 24 @ Oz

he 23rd annual Gay Appreciation Awards (GAA) Gala is Saturday, July 24 announcing the winners in 23 award categories. Hosted at Oz, 800 Bourbon Street, the gala will also honor Jean Redmann as the 23rd recipient of the prestigious Lifetime Achievement Award. Doors open at 7pm and the gala show and awards ceremony begins promptly at 8pm. Admission is \$10 with all proceeds from the evening's festivities benefiting Buzzy's Boys & Girls. Since 1997 the galas have raised \$36,273 for charity.

GAA 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 awards thanks those in the Gay Lesbian Bisexual Transgender community who are many times 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 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 Exile, Cody Warembourg/700 Club

 DJ of the Year: Chris Allen/Bourbon Pub & Parade, DJ Myke/Cafe Lafitte in Exile, Johnny Love/Cafe Lafitte in Exile, Tim Pflueger/Oz, Richie Rich/JohnPaul's

 Leather Bar of the Year: Dallas Eagle/Dallas, JohnPaul's, Phoenix, Ramrod/Ft. Lauderdale, Rawhide 2010

• GLBT Business of the Year [no bars/restaurants/delis/hair salons]: Alternatives, La Mina Sterling, Moms Mini Mart, Rab Dab Clothing & Gifts, Scully'z Recordz

· Leather Person of the Year: Michael Albracht, Cathy Fox, Jose Gonzales, Toby Lefort, Gary Vandeventer

• Transgender of the Year: Regina Adams, Dee Cooley, Stephanie Lee, Rikki Redd, Jasmine SX

. Lesbian of the Year: Marty Curtin, Mae Falgout, Red Hanson, Pat McCardle, Sandy Sachs

 Gay Man of the Year: Tommy Elias, Ken Grandpre, Toby Lefort, Tony Leggio, John Vignone

• Entertainer of the Year: [female/male impersonator/drag star or entertainer]: Big Mama, Elizabeth Bouvier, Blanche Debris, Passion Armani Cassidine, Coca

The GAA Board of Directors chose the Top 5 Finalists in two categories:

• Fly Fashion Glamour Award: Tiffany Alexander, Nicole DuBois, Mercedes Ellis Loreal, Rhonda Roget, Tami Tarmac

inside

GAA Winners Issue out August 3 **DEADLINE: Tuesday, July 27**

celebrazzi paparazzi/alexandria under the gaydar/new orleans snap paparazzi/new orleans paparazzi/pensacola the pink pastor/new orleans 39th southern decadence snap paparazzi/new orleans gay appreciation awards gala classifieds

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The Board of Directors includes Lisa Beaumann, Teryl-Lynn Foxx, Rip and Marsha Naquin-Delain, and Toni Pizanie. Sponsored by Ambush, visit AmbushMag.COM/GAA for more info.

Southern Decadence **Press Party Unveils Official Poster, Song &** Sponsors @ the Parade

he annual Southern Decadence Press Party brought out over a

hundred participants for the unveiling of the Official Poster, Song and Sponsors. This year, Southern Decadence Grand Marshals XXXVI Julien Artressia and Toby Lefort chose the Parade above the Bourbon Pub for the event which was the largest attended press party since 2004.

It was a fun filled evening where guests from the French Quarter, Marigny, Bywater, Westbank, Metairie and Slidell were able to mingle with the new grand marshals while enjoying cocktails and a delicious buffet (courtesy of Quartermaster: The Nellie Deli). As the evening progressed, it was time for the big moments for the 39th Southern Decadence celebration.

The poster was unveiled by Julien and Toby showcasing the handywork of reowned photographer Larry Graham. The





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ANNUAL READERSHIP: 650,000+ in print/3.5 Million+ On-line NATIONAL CIRCULATION: USA. . Alabama-Birmingham, Foley, Mobile Florida - Pensacola Louisiana - Baton Rouge, Houma, Lafayette, Lake Charles, Metairie, New Orleans, Shreveport, Slidell Mississippi - Biloxi, Hattiesburg Texas - Austin

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Naquin-Delain, President. Advertising, Copy & Photo DEADLINE is alternate Tuesdays, 4pm, prior to publication week, accepted via e-mail only: marsha@ripandmarsha.com, except for special holidays. The Publisher assumes no responsibility for the claims of advertisers and has the right to anv ertising. individual's name or photograph in this publication implies nothing about that individual's sexual orientation. Letters, stories, etc., appearing herein are not necessarily the opinion of the Publisher or Staff of AMBUSH Mag. Subscription rate is \$45 for 1/2 Year; \$75 for 1 year. Sample Copy is \$3 First Class Mail. ©1982-2010, AMBUSH, INC., ALL RIGHTS RESERVED. NOTHING HEREIN MAY BE RE-PRODUCED WITHOUT WRITTEN PERMISSION OF THE PUBLISHER INCLUDING AD LAYOUTS. MAPS and PHOTOS. AMgrant - AMbush Advertising Grant Donation

 Cheridon Comedy Award: Barry Bareass, Blanche Debris, Zsa Zsa d'LaHor, Sister Mary Isawhore, Persona Shoulders.

The Marsha Delain Award of Excellence will be presented by Marsha Naguin-Delain at the GAA Gala as well.

Past Lifetime Achievement Award recipients include Jimmie Callaway, the late Dan Fountain [Betty Buttons], the late Andy Boudreaux, the late Buzzy Fanning, the late Dirty Dottie, the late Miss Fury, Rip & Marsha Naquin-Delain, the late Dan Romero, the late Miss Do, the late Louise McFarland, Miss Dixie Fasnacht, Alice Brady & John Dodt, Gene Adams, the late Charlene Schneider, the late Steve Mettner, Marty Curtin & Koo Gaffney, the late Donald "Donnie Jay" James, Kitty Blackwell, Michael "Fish" Hickerson, Marcy Marcell, Mary L. Lathouwers and Don Evans.

poster is reminiscent of the front page of a magazine showing a glamorous Julien and leatherman Toby along with several high-

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are," "Are they really decadent or just looking for good times?," "Bringing our community together, one bar at a time," and finally, "Putting the French back in The French Quarter."

Several phrases set the tone for this Deca-

dence including: "Taking PRIDE in who we

Next the official song: "Tu Es Foutu" You Promised Me! by InGrid, English/ French version was played. The Grand Marshals announced the official charity as NO/AIDS Task Force; and official sponsors including Ambush Mag,

partnered with New Orleans Courtyard and French Quarter Suites Hotels to stage an exciting contest giving away a room for two for Southern Decadence weekend. The contest winner would get deluxe accommodations for two for four nights, Friday-Monday, September 3-6 valued at almost \$1,000. It includes the use of two beautiful pools, Wi-Fi Internet

Weekend, Register NOW

outhernDecadence.COM has

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Clarkie

DJ Karizma

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