

## PART III: CONSUMER INFORMATION

### Pr KALETRA® Tablets lopinavir/ritonavir

This leaflet is PART III of a three-part "Product Monograph" published when KALETRA® was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about KALETRA®. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

- KALETRA® is for adults and children 6 months of age or older who are infected with the human immunodeficiency virus (HIV), the virus which causes AIDS.
- KALETRA® is prescribed for use in combination with other antiretroviral medicines.

##### What it does:

KALETRA® is an inhibitor of the HIV protease enzyme. It helps control HIV infection by inhibiting or interfering with the protease enzyme that HIV needs to multiply.

KALETRA® is not a cure for HIV infection or AIDS. People taking KALETRA® may still develop infections or other serious illnesses associated with HIV disease and AIDS.

KALETRA® does not reduce the risk of passing HIV to others with sexual contact or blood contamination. You should use appropriate precautions, such as practicing safe sex, and not reusing or sharing needles.

##### When it should not be used:

Do not take KALETRA® if you/your child:

- are allergic to lopinavir, ritonavir or to any of the non-medicinal ingredients in KALETRA®. (Refer to the subheading "**What the important non-medicinal ingredients are**" for a complete listing.
- are currently taking any of the following medicines, because they can cause serious problems or death if taken with KALETRA®:
  - alfuzosin (e.g. Xatral®) - used to treat high blood pressure;
  - astemizole\* (e.g. Hismanal®), terfenadine\* (e.g. Seldane®) - used to relieve allergy symptoms;
  - cisapride\* (e.g. Prepulsid®) - used to relieve certain stomach problems;
  - ergotamine, dihydroergotamine (used to treat headaches), ergonovine, methylergonovine\* (used after labor and delivery), such as Cafegot®, Migranal®, D.H.E. 45®, Ergotrate® Maleate\*, Methergine™\*, and others;
  - fusidic acid (e.g. Fucidin®) – antibiotic;
  - pimozide (e.g. Orap®) - used to treat schizophrenia;
  - sildenafil (Revatio®) – used to treat pulmonary arterial

hypertension;

- triazolam, midazolam - used to relieve anxiety and/or trouble sleeping;
- are currently taking rifampin, also known as Rimactane®, Rifadin®, Rifater®, or Rifamate®. Rifampin may lower the amount of KALETRA® in your blood and make it less effective.
- are currently taking St. John's Wort (*Hypericum perforatum*), a herbal product sold as a dietary supplement, or products containing St. John's Wort. Talk with your doctor if you are taking or planning to take St. John's Wort. Taking St. John's Wort may decrease KALETRA® levels and lead to increased viral load and possible resistance to KALETRA® or cross-resistance to other anti-HIV medicines.
- are currently taking the cholesterol-lowering medicines lovastatin (e.g. Mevacor®) or simvastatin (e.g. Zocor®) because of possible serious reactions. Talk to your doctor before you take any cholesterol-lowering medicines with KALETRA®.
- are currently taking the PDE5 Inhibitors vardenafil (Levitra®), used to treat erectile dysfunction, or sildenafil (Revatio®), used for the treatment of pulmonary arterial hypertension (PAH). These drugs may increase the risk of hypotension (low blood pressure), syncope (fainting), visual changes and prolonged erection.
- are currently taking salmeterol, also known as Advair® and Serevent®. Salmeterol may increase the risk of cardiovascular (heart) adverse events.
- are currently taking any of these medications; your doctor may switch your medication.

\* **Products not marketed in Canada.**

##### What the medicinal ingredients are:

lopinavir and ritonavir

##### What the important non-medicinal ingredients are:

KALETRA® 100/25 mg tablets also contain colloidal silicon dioxide, copovidone, polyethylene glycol 3350, polyvinyl alcohol, sodium stearyl fumarate, sorbitan monolaurate, talc, titanium dioxide, and yellow ferric oxide E172.

KALETRA® 200/50 mg tablets also contain colloidal silicon dioxide, copovidone, hypromellose, hydroxypropyl cellulose, polyethylene glycol 400, polyethylene glycol 3350, polysorbate 80, sodium stearyl fumarate, sorbitan monolaurate, talc, titanium dioxide, and yellow ferric oxide E172.

##### What dosage forms it comes in:

KALETRA® is available as film-coated tablets containing the following combinations of lopinavir and ritonavir: 100 mg/25 mg; 200 mg/50 mg.

KALETRA® is also available as an oral solution. Each mL of KALETRA® contains 80 mg of lopinavir and 20 mg of ritonavir.

**WARNINGS AND PRECAUTIONS****Serious Warnings and Precautions**

**Tell your doctor if you or your child develop symptoms such as:**

- **nausea**
- **vomiting**
- **abdominal pain.**

**These may be signs of problems with your pancreas (pancreatitis). Your doctor must decide if these are related to pancreatitis and what to do about them.**

Do not take KALETRA<sup>®</sup> once daily if you:

- are currently taking the anticonvulsants carbamazepine (e.g. Tegretol<sup>®</sup>), phenytoin (e.g. Dilantin<sup>®</sup>) and phenobarbital.
- are currently taking HIV medications efavirenz (e.g. Sustiva<sup>®</sup>), nevirapine (e.g. Viramune<sup>®</sup>), fosamprenavir (e.g. Telzir<sup>®</sup>) and nelfinavir (e.g. Viracept<sup>®</sup>).

**BEFORE you use KALETRA<sup>®</sup> talk to your doctor or pharmacist if:**

- you/your child have liver problems or are infected with hepatitis B or hepatitis C
- you/your child have diabetes, or symptoms such as frequent urination, and/or increase in thirst
- you/your child have hemophilia. Patients taking KALETRA<sup>®</sup> may have increased bleeding.
- you/your child are taking or planning to take other medicines, **including prescription, herbal and other medicines** you can buy without a prescription
- you have heart disease or a heart condition, including conditions of Congenital Long QT Syndrome
- you have low potassium levels in your blood.
- you are pregnant or breast-feeding. Pregnant or breast-feeding mothers should not take KALETRA<sup>®</sup> unless specifically directed by the doctor. Be sure to tell your doctor immediately if you are or may be pregnant or if you are breast-feeding a baby. It is recommended that HIV-infected women should not breast-feed their infants because of the possibility the baby could be infected with HIV through the breast milk.

Changes in body fat have been seen in some patients taking antiretroviral therapy. See **SIDE EFFECTS AND WHAT TO DO ABOUT THEM.**

**INTERACTIONS WITH THIS MEDICATION**

KALETRA<sup>®</sup> may interact with certain other medications with possible clinical effects. The use of the following medicines together with KALETRA<sup>®</sup> should only take place on the basis of medical advice:

- medicines used to treat erectile dysfunction such as sildenafil (e.g. Viagra<sup>®</sup>) or tadalafil (e.g. Cialis<sup>®</sup>). Vardenafil (e.g. Levitra<sup>®</sup>) should not be taken with KALETRA<sup>®</sup>;
- medicines used to treat pulmonary arterial hypertension such as bosentan (e.g. Tracleer<sup>®</sup>) or tadalafil (e.g. Adcirca<sup>®</sup>); medicines used to lower blood cholesterol such as rosuvastatin (e.g. Crestor<sup>®</sup>), atorvastatin (e.g. Lipitor<sup>®</sup>), Lovastatin (e.g. Mevacor<sup>®</sup>) or simvastatin (e.g. Zocor<sup>®</sup>) should not be taken with KALETRA<sup>®</sup>;
- some medicines affecting the immune system such as cyclosporin, sirolimus (e.g. Rapamune<sup>®</sup>) and tacrolimus;
- some medicines used to treat seasonal allergies and ear and eye infections such as dexamethasone and fluticasone propionate (e.g. Flonase<sup>®</sup>);
- contraceptives used to prevent pregnancy (e.g. ethinyl estradiol);
- medicines used to treat AIDS and related infections such as amprenavir\* (e.g. Agenerase<sup>®</sup>), fosamprenavir (e.g. Telzir<sup>®</sup>), indinavir (e.g. Crixivan<sup>®</sup>), nelfinavir (e.g. Viracept<sup>®</sup>), saquinavir (e.g. Invirase<sup>®</sup>), didanosine (e.g. Videx<sup>®</sup>), tenofovir (e.g. Viread<sup>®</sup>), efavirenz (e.g. Sustiva<sup>®</sup>), nevirapine (e.g. Viramune<sup>®</sup>) and rifabutin (e.g. Mycobutin<sup>®</sup>);
- medicines used to treat depression such as trazodone (e.g. Desyrel<sup>®</sup>) and bupropion (e.g. Wellbutrin<sup>®</sup> SR);
- certain heart medicines such as calcium channel antagonists including felodipine (e.g. Plendil<sup>®</sup>), nifedipine (e.g. Adalat<sup>®</sup>) and nicardipine\* (e.g. Cardene<sup>®</sup>);
- medicines used to correct heart rhythm such as amiodarone (e.g. Cordarone<sup>®</sup>), flecainide (e.g. Tambacor<sup>®</sup>), bepridil\* (e.g. Vasacor<sup>®</sup>), systemic lidocaine, propafenone hydrochloride (e.g. Rythmol<sup>®</sup>), quinidine and digoxin;
- antifungals such as ketoconazole (e.g. Nizoral<sup>®</sup>), itraconazole (e.g. Sporanox<sup>®</sup>) and voriconazole (e.g. Vfend<sup>®</sup>);
- morphine-like medicines (e.g. methadone);
- anticonvulsants such as carbamazepine (e.g. Tegretol<sup>®</sup>), phenytoin (e.g. Dilantin<sup>®</sup>) and phenobarbital;
- warfarin and certain antibiotics such as clarithromycin (e.g. Biaxin<sup>®</sup>);
- medicines used to treat cancer such as dasatinib (e.g. Sprycel<sup>®</sup>), nilotinib (e.g. Tasigna<sup>®</sup>), vincristine and vinblastine as KALETRA<sup>®</sup> may increase the concentrations of these drugs and increase adverse effects;
- fentanyl (e.g. Duragesic<sup>®</sup>) in all forms as this interaction may reduce breathing.
- colchicine used for the treatment of gout.

**\* Product not available in Canada.**

Patients taking KALETRA<sup>®</sup> should not take products containing St. John’s Wort (*Hypericum perforatum*) as this may stop KALETRA<sup>®</sup> from working properly.

KALETRA<sup>®</sup> can be taken with acid-reducing agents (such as omeprazole and ranitidine) with no dose adjustment.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

The most commonly reported side effects of KALETRA<sup>®</sup> are abdominal pain, diarrhea (abnormal stool, and/or bowel movement), feeling weak or tired, headache, nausea, vomiting and rash.

- If you have liver disease such as Hepatitis B and Hepatitis C, taking KALETRA<sup>®</sup> may worsen your liver disease.
- Some patients have large increases in triglycerides and cholesterol (forms of fat that are found in your blood).
- Diabetes and high blood sugar (hyperglycemia) may occur in patients taking protease inhibitors such as KALETRA<sup>®</sup>. Symptoms of diabetes or high blood sugar may include frequent urination or increased thirst. Let your doctor know if you have or develop these symptoms while taking KALETRA<sup>®</sup>.
- Some patients with hemophilia have increased bleeding with protease inhibitors.
- Changes in body fat have been seen in some patients taking antiretroviral therapy. These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breasts, 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.

**PROPER USE OF THIS MEDICATION**

It is important that you/your child take KALETRA<sup>®</sup> every day exactly as your doctor prescribed it. Even if you feel better, do not stop taking KALETRA<sup>®</sup> without talking to your doctor. Using KALETRA<sup>®</sup> as recommended should give you the best chance to delay the development of resistance to the product.

It is therefore important that you remain under the supervision of your doctor while taking KALETRA<sup>®</sup>.

**Usual Dose:**

The usual dose for adults is two 200/50 mg tablets (400/100 mg) twice a day (morning and night), in combination with other anti-HIV medicines. The doctor may prescribe KALETRA<sup>®</sup> as four 200/50 mg tablets (800/200 mg) once daily in combination with other anti-HIV medicines for some patients.

The dose for children from 6 months to 18 years of age will be determined by your doctor based on the child’s height and weight. KALETRA<sup>®</sup> should not be administered once daily in pediatric patients less than 18 years of age.

KALETRA<sup>®</sup> tablets (all strengths) can be taken with or without food. KALETRA<sup>®</sup> tablets should be swallowed whole and not chewed, broken, or crushed.

**Overdose:**

If you/your child realize you have taken more KALETRA<sup>®</sup> than you were supposed to, contact your doctor or local poison control centre right away, even if you have no symptoms. If you cannot reach your/your child’s doctor, go to the hospital.

**Missed Dose:**

If you/your child miss a dose of KALETRA<sup>®</sup>, it should be taken as soon as possible, and the next scheduled dose taken at its regular time. If it is almost time for your/your child’s next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Diarrhea	√		
	Rash	√		
	Headache	√		
	Nausea	√		
	Vomiting	√		
	Tingling feeling in hands, feet and around lips	√		
Uncommon	Chest pain		√	
	Pancreatitis		√	
	- Abdominal pain		√	
	- Nausea		√	
	- Vomiting		√	

*This is not a complete list of side effects. For any unexpected effects while taking KALETRA<sup>®</sup>, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Keep KALETRA<sup>®</sup> and all other medicines out of the reach of children.

KALETRA<sup>®</sup> film-coated tablets should be stored between 15 and 25°C. It is recommended that the product be stored and dispensed in the original container.

It is important to keep KALETRA<sup>®</sup> in the original package. Do not transfer to any other container.

Do not use after the expiry date stated on the pack.

Adalat<sup>®</sup>, Adcirca<sup>®</sup>, Advair<sup>®</sup>, Agenerase<sup>®</sup>, Cafegot<sup>®</sup>, Cardene<sup>®</sup>, Cialis<sup>®</sup>, Cordarone<sup>®</sup>, Crestor<sup>®</sup>, Crixivan<sup>®</sup>, Desyrel<sup>®</sup>, D.H.E. 45<sup>®</sup>, Dilantin<sup>®</sup>, Duragesic<sup>®</sup>, Ergostrate<sup>®</sup> Maleate, Flonase<sup>®</sup>, Fucidin<sup>®</sup>, Halcion<sup>®</sup>, Hismanal<sup>®</sup>, Levitra<sup>®</sup>, Lipitor<sup>®</sup>, Invirase<sup>®</sup>, Mevacor<sup>®</sup>, Migranal<sup>®</sup>, Mycobutin<sup>®</sup>, Nizoal<sup>®</sup>, Orap<sup>®</sup>, Plendil<sup>®</sup>, Prepulsid<sup>®</sup>, Rapamune<sup>®</sup>, Revatio<sup>®</sup>, Rifadin<sup>®</sup>, Rifater<sup>®</sup>, Rifamate<sup>®</sup>, Rimactane<sup>®</sup>, Seldane<sup>®</sup>, Serevent<sup>®</sup>, Sporanox<sup>®</sup>, Sprycel<sup>®</sup>, Sustiva<sup>®</sup>, Tambocor<sup>®</sup>, Tasigna<sup>®</sup>, Tegretol<sup>®</sup>, Telzir<sup>®</sup>, Tracleer<sup>®</sup>, Vasacor<sup>®</sup>, Versed<sup>®</sup>, Vfend<sup>®</sup>, Videx<sup>®</sup>, Viracept<sup>®</sup>, Viramune<sup>®</sup>, Viread<sup>®</sup>, Viagra<sup>®</sup>, Wellbutrin<sup>®</sup> SR, Xatral<sup>®</sup> and Zocor<sup>®</sup> are trademarks of their respective owners and are not trademarks of Abbott Laboratories, Limited.

**REPORTING SUSPECTED SIDE EFFECTS**

**You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:**

- **Report on line at: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)**
  - **Call toll-free at 1-866-234-2345**
  - **Complete a Canada Vigilance Reporting Form and:**
    - **Fax toll-free to 1-866-678-6789**
    - **Mail to : Canada Vigilance Program**  
**Health Canada**  
**Postal Locator 0701C**  
**Ottawa, ON K1A 0K9**
- Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).**

*Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full Product Monograph, prepared for health professionals can be found at:

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited, Saint-Laurent, Qc H4S 1Z1 at:  
1-800-699-9948.

This leaflet was prepared by Abbott Laboratories, Limited.

Last revised: December 9, 2011

## PART III: CONSUMER INFORMATION

### Pr KALETRA<sup>®</sup> Oral Solution lopinavir/ritonavir

This leaflet is PART III of a three-part "Product Monograph" published when KALETRA<sup>®</sup> was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about KALETRA<sup>®</sup>. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

- KALETRA<sup>®</sup> is for adults and children 6 months of age or older who are infected with the human immunodeficiency virus (HIV), the virus which causes AIDS.
- KALETRA<sup>®</sup> is prescribed for use in combination with other antiretroviral medicines.

##### What it does:

KALETRA<sup>®</sup> is an inhibitor of the HIV protease enzyme. It helps control HIV infection by inhibiting or interfering with the protease enzyme that HIV needs to multiply.

KALETRA<sup>®</sup> is not a cure for HIV infection or AIDS. People taking KALETRA<sup>®</sup> may still develop infections or other serious illnesses associated with HIV disease and AIDS.

KALETRA<sup>®</sup> does not reduce the risk of passing HIV to others with sexual contact or blood contamination. You should use appropriate precautions, such as practicing safe sex, and not reusing or sharing needles.

##### When it should not be used:

Do not take KALETRA<sup>®</sup> if you/your child:

- are allergic to lopinavir, ritonavir or to any of the non-medicinal ingredients in KALETRA<sup>®</sup>. (Refer to the subheading "What the important non-medicinal ingredients are" for a complete listing.)
- are currently taking any of the following medicines, because they can cause serious problems or death if taken with KALETRA<sup>®</sup>:
  - alfuzosin (e.g. Xatral<sup>®</sup>) - used to treat high blood pressure;
  - astemizole\* (e.g. Hismanal<sup>®</sup>), terfenadine\* (e.g. Seldane<sup>®</sup>) - used to relieve allergy symptoms;
  - cisapride\* (e.g. Prepulsid<sup>®</sup>) - used to relieve certain stomach problems;
  - ergotamine, dihydroergotamine (used to treat headaches), ergonovine, methylergonovine\* (used after labor and delivery), such as Cafegot<sup>®</sup>, Migranal<sup>®</sup>, D.H.E. 45<sup>®</sup>, Ergotrate<sup>®</sup> Maleate\*, Methergine<sup>™</sup>\*, and others;
  - fusidic acid (e.g. Fucidin<sup>®</sup>) – antibiotic;
  - pimozide (e.g. Orap<sup>®</sup>) - used to treat schizophrenia;
  - sildenafil (Revatio<sup>®</sup>) – used to treat pulmonary arterial

hypertension;

- triazolam, midazolam - used to relieve anxiety and/or trouble sleeping;
- are currently taking rifampin, also known as Rimactane<sup>®</sup>, Rifadin<sup>®</sup>, Rifater<sup>®</sup>, or Rifamate<sup>®</sup>. Rifampin may lower the amount of KALETRA<sup>®</sup> in your blood and make it less effective.
- are currently taking St. John's Wort (*Hypericum perforatum*), a herbal product sold as a dietary supplement, or products containing St. John's Wort. Talk with your doctor if you are taking or planning to take St. John's Wort. Taking St. John's Wort may decrease KALETRA<sup>®</sup> levels and lead to increased viral load and possible resistance to KALETRA<sup>®</sup> or cross-resistance to other anti-HIV medicines.
- are currently taking the cholesterol-lowering medicines lovastatin (e.g. Mevacor<sup>®</sup>) or simvastatin (e.g. Zocor<sup>®</sup>) because of possible serious reactions. Talk to your doctor before you take any cholesterol-lowering medicines with KALETRA<sup>®</sup>.
- are currently taking the PDE5 Inhibitors vardenafil (Levitra<sup>®</sup>), used to treat erectile dysfunction, or sildenafil (Revatio<sup>®</sup>), used for the treatment of pulmonary arterial hypertension (PAH). These drugs may increase the risk of hypotension (low blood pressure), syncope (fainting), visual changes and prolonged erection.
- are currently taking salmeterol, also known as Advair<sup>®</sup> and Serevent<sup>®</sup>. Salmeterol may increase the risk of cardiovascular (heart) adverse events.
- are currently taking any of these medications; your doctor may switch your medication.

\* **Products not marketed in Canada.**

##### What the medicinal ingredients are:

lopinavir and ritonavir

##### What the important non-medicinal ingredients are:

KALETRA<sup>®</sup> oral solution also contains acesulfame potassium, alcohol, artificial cotton candy flavour, natural and artificial vanilla flavour, citric acid, glycerin, Magnasweet-110 flavour, high fructose corn syrup, menthol, polyoxyl 40 hydrogenated castor oil, peppermint oil, povidone, propylene glycol, saccharin sodium, sodium chloride, and sodium citrate.

##### What dosage forms it comes in:

KALETRA<sup>®</sup> is available as an oral solution. Each mL of KALETRA<sup>®</sup> contains 80 mg of lopinavir and 20 mg of ritonavir.

KALETRA<sup>®</sup> is also available as film-coated tablets containing the following combinations of lopinavir and ritonavir: 100 mg/25 mg; 200 mg/50 mg.

**WARNINGS AND PRECAUTIONS****Serious Warnings and Precautions**

**Tell your doctor if you or your child develop symptoms such as:**

- **nausea**
- **vomiting**
- **abdominal pain.**

**These may be signs of problems with your pancreas (pancreatitis). Your doctor must decide if these are related to pancreatitis and what to do about them.**

Do not take KALETRA<sup>®</sup> once daily if you:

- are currently taking the anticonvulsants carbamazepine (e.g. Tegretol<sup>®</sup>), phenytoin (e.g. Dilantin<sup>®</sup>) and phenobarbital.
- are currently taking the HIV medications efavirenz (e.g. Sustiva<sup>®</sup>), nevirapine (e.g. Viramune<sup>®</sup>), fosamprenavir (e.g. Telzir<sup>®</sup>) and nelfinavir (e.g. Viracept<sup>®</sup>).

**BEFORE you use KALETRA<sup>®</sup> talk to your doctor or pharmacist if:**

- you/your child have liver problems or are infected with hepatitis B or hepatitis C
- you/your child have diabetes, or symptoms such as frequent urination, and/or increase in thirst
- you/your child have hemophilia. Patients taking KALETRA<sup>®</sup> may have increased bleeding.
- you/your child are taking or planning to take other medicines, **including prescription, herbal and other medicines** you can buy without a prescription
- you have heart disease or a heart condition, including conditions of Congenital Long QT Syndrome
- you have low potassium levels in your blood
- you are pregnant or breast-feeding. Pregnant or breast-feeding mothers should not take KALETRA<sup>®</sup> unless specifically directed by the doctor. Be sure to tell your doctor immediately if you are or may be pregnant or if you are breast-feeding a baby. It is recommended that HIV-infected women should not breast-feed their infants because of the possibility the baby could be infected with HIV through the breast milk.
- you have hereditary fructose intolerance as this product contains fructose
- you have kidney problems or inability to metabolize propylene glycol as this medication contains propylene glycol
- you suffer from alcoholism, liver problems, epilepsy or brain injury, as this medication contains alcohol

Changes in body fat have been seen in some patients taking antiretroviral therapy. See **SIDE EFFECTS AND WHAT TO DO ABOUT THEM.**

**INTERACTIONS WITH THIS MEDICATION**

KALETRA<sup>®</sup> may interact with certain other medications with possible clinical effects. The use of the following medicines together with KALETRA<sup>®</sup> should only take place on the basis of medical advice:

- medicines used to treat erectile dysfunction such as sildenafil (e.g. Viagra<sup>®</sup>) or tadalafil (e.g. Cialis<sup>®</sup>). Vardenafil (e.g. Levitra<sup>®</sup>) should not be taken with KALETRA<sup>®</sup>;
- medicines used to treat pulmonary arterial hypertension such as bosentan (e.g. Tracleer<sup>®</sup>) or tadalafil (e.g. Adcirca<sup>®</sup>);
- medicines used to lower blood cholesterol such as rosuvastatin (e.g. Crestor<sup>®</sup>), atorvastatin (e.g. Lipitor<sup>®</sup>), Lovastatin (e.g. Mevacor<sup>®</sup>) or simvastatin (e.g. Zocor<sup>®</sup>) should not be taken with KALETRA<sup>®</sup>;
- some medicines affecting the immune system such as cyclosporin, sirolimus (e.g. Rapamune<sup>®</sup>) and tacrolimus;
- some medicines used to treat seasonal allergies and ear and eye infections such as dexamethasone and fluticasone propionate (e.g. Flonase<sup>®</sup>);
- contraceptives used to prevent pregnancy (e.g. ethinyl estradiol);
- medicines used to treat AIDS and related infections such as amprenavir\* (e.g. Agenerase<sup>®</sup>), fosamprenavir (e.g. Telzir<sup>®</sup>), indinavir (e.g. Crixivan<sup>®</sup>), nelfinavir (e.g. Viracept<sup>®</sup>), saquinavir (e.g. Invirase<sup>®</sup>), didanosine (e.g. Videx<sup>®</sup>), tenofovir (e.g. Viread<sup>®</sup>), efavirenz (e.g. Sustiva<sup>®</sup>), nevirapine (e.g. Viramune<sup>®</sup>) and rifabutin (e.g. Mycobutin<sup>®</sup>);
- medicines used to treat depression such as trazodone (e.g. Desyrel<sup>®</sup>), and bupropion (e.g. Wellbutrin<sup>®</sup> SR);
- certain heart medicines such as calcium channel antagonists including felodipine (e.g. Plendil<sup>®</sup>), nifedipine (e.g. Adalat<sup>®</sup>) and nicardipine\* (e.g. Cardene<sup>®</sup>);
- medicines used to correct heart rhythm such as amiodarone (e.g. Cordarone<sup>®</sup>), flecainide (e.g. Tambocor<sup>®</sup>), bepridil\* (e.g. Vasacor<sup>®</sup>), systemic lidocaine, propafenone hydrochloride (e.g. Rythmol<sup>®</sup>), quinidine and digoxin;
- antifungals such as ketoconazole (e.g. Nizoral<sup>®</sup>), itraconazole (e.g. Sporanox<sup>®</sup>) and voriconazole (e.g. Vfend<sup>®</sup>);
- morphine-like medicines (e.g. methadone);
- anticonvulsants such as carbamazepine (e.g. Tegretol<sup>®</sup>), phenytoin (e.g. Dilantin<sup>®</sup>) and phenobarbital;
- warfarin and certain antibiotics such as clarithromycin (e.g. Biaxin<sup>®</sup>);
- medicines used to treat cancer such as dasatinib (e.g. Sprycel<sup>®</sup>), nilotinib (e.g. Tasigna<sup>®</sup>), vincristine and vinblastine as KALETRA<sup>®</sup> may increase the concentrations of these drugs and increase adverse effects;
- fentanyl (e.g. Duragesic<sup>®</sup>) in all forms as this interaction may reduce breathing.
- colchicine used for the treatment of gout.

**\* Product not available in Canada.**

Patients taking KALETRA® should not take products containing St. John’s Wort (*Hypericum perforatum*) as this may stop KALETRA® from working properly.

KALETRA® can be taken with acid-reducing agents (such as omeprazole and ranitidine) with no dose adjustment.

**PROPER USE OF THIS MEDICATION**

It is important that you/your child take KALETRA® every day exactly as your doctor prescribed it. Even if you feel better, do not stop taking KALETRA® without talking to your doctor. Using KALETRA® as recommended should give you the best chance to delay the development of resistance to the product.

It is therefore important that you remain under the supervision of your doctor while taking KALETRA®.

**Usual Dose:**

The usual dose for adults is 5.0 mL of the oral solution twice a day (morning and night), in combination with other anti-HIV medicines. The doctor may prescribe KALETRA® as 10.0 mL of the oral solution once daily in combination with other anti-HIV medicines for some patients.

The dose for children from 6 months to 18 years of age will be determined by your doctor based on the child’s height and weight. KALETRA® should not be administered once daily in pediatric patients less than 18 years of age.

Take KALETRA® oral solution with food to help it work better.

**Overdose:**

If you/your child realize you have taken more KALETRA® than you were supposed to, contact your doctor or local poison control centre right away, even if you have no symptoms. If you cannot reach your/your child’s doctor, go to the hospital.

KALETRA® oral solution contains 42% alcohol and 15% propylene glycol and accidental ingestion could be toxic and potentially lethal to a young child.

**Missed Dose:**

If you/your child miss a dose of KALETRA®, it should be taken as soon as possible, and the next scheduled dose taken at its regular time. If it is almost time for your/your child’s next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

The most commonly reported side effects of KALETRA® are abdominal pain, diarrhea (abnormal stool, and/or bowel movement), feeling weak or tired, headache, nausea, vomiting and rash.

- If you have liver disease such as Hepatitis B and Hepatitis C, taking KALETRA® may worsen your liver disease.
- Some patients have large increases in triglycerides and cholesterol (forms of fat that are found in your blood).
- Diabetes and high blood sugar (hyperglycemia) may occur in patients taking protease inhibitors such as KALETRA®. Symptoms of diabetes or high blood sugar may include frequent urination or increased thirst. Let your doctor know if you have or develop these symptoms while taking KALETRA®.
- Some patients with hemophilia have increased bleeding with protease inhibitors.
- Changes in body fat have been seen in some patients taking antiretroviral therapy. These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breasts, 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.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Diarrhea	√		
	Rash	√		
	Headache	√		
	Nausea	√		
	Vomiting	√		
	Tingling feeling in hands, feet and around lips	√		
Uncommon	Chest pain		√	
	Pancreatitis		√	
	- Abdominal pain		√	
	- Nausea		√	
	- Vomiting		√	

***This is not a complete list of side effects. For any unexpected effects while taking KALETRA®, contact your doctor or pharmacist.***

**HOW TO STORE IT**

Keep KALETRA<sup>®</sup> and all other medicines out of the reach of children.

KALETRA<sup>®</sup> oral solution should be stored between 2 and 8°C in a refrigerator. If you keep KALETRA<sup>®</sup> outside of the refrigerator, do not store above 25°C and discard any unused contents after 42 days (6 weeks). Avoid exposure to excessive heat.

It is important to keep KALETRA<sup>®</sup> in the original package. Do not transfer to any other container.

Do not use after the expiry date stated on the pack.

**REPORTING SUSPECTED SIDE EFFECTS**

**You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:**

- **Report on line at: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)**
  - **Call toll-free at 1-866-234-2345**
  - **Complete a Canada Vigilance Reporting Form and:**
    - **Fax toll-free to 1-866-678-6789**
    - **Mail to : Canada Vigilance Program**  
**Health Canada**  
**Postal Locator 0701C**  
**Ottawa, ON K1A 0K9**
- Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).**

*Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full Product Monograph, prepared for health professionals can be found at:

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited,  
 Saint-Laurent, Qc H4S 1Z1 at:  
 1-800-699-9948.

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Adalat<sup>®</sup>, Adcirca<sup>®</sup>, Advair<sup>®</sup>, Agenerase<sup>®</sup>, Cafegot<sup>®</sup>, Cardene<sup>®</sup>, Cialis<sup>®</sup>, Cordarone<sup>®</sup>, Crestor<sup>®</sup>, Crixivan<sup>®</sup>, Desyrel<sup>®</sup>, D.H.E. 45<sup>®</sup>, Dilantin<sup>®</sup>, Duragesic<sup>®</sup>, Ergostrate<sup>®</sup> Maleate, Flonase<sup>®</sup>, Fucidin<sup>®</sup>, Halcion<sup>®</sup>, Hismanal<sup>®</sup>, Levitra<sup>®</sup>, Lipitor<sup>®</sup>, Invirase<sup>®</sup>, Mevacor<sup>®</sup>, Migranal<sup>®</sup>, Mycobutin<sup>®</sup>, Nizoal<sup>®</sup>, Orap<sup>®</sup>, Plendil<sup>®</sup>, Prepulsid<sup>®</sup>, Rapamune<sup>®</sup>, Revatio<sup>®</sup>, Rifadin<sup>®</sup>, Rifater<sup>®</sup>, Rifamate<sup>®</sup>, Rimactane<sup>®</sup>, Seldane<sup>®</sup>, Serevent<sup>®</sup>, Sporanox<sup>®</sup>, Sprycel<sup>®</sup>, Sustiva<sup>®</sup>, Tambocor<sup>®</sup>, Tasigna<sup>®</sup>, Tegretol<sup>®</sup>, Telzir<sup>®</sup>, Tracleer<sup>®</sup>, Vascor<sup>®</sup>, Versed<sup>®</sup>, Vfend<sup>®</sup>, Videx<sup>®</sup>, Viracept<sup>®</sup>, Viramune<sup>®</sup>, Viread<sup>®</sup>, Viagra<sup>®</sup>, Wellbutrin<sup>®</sup> SR, Xatral<sup>®</sup> and Zocor<sup>®</sup> are trademarks of their respective owners and are not trademarks of Abbott Laboratories, Limited.