PART III: CONSUMER INFORMATION

PrKALETRA® 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
  - apalutamide (e.g. Erleada™) – used for prostate cancer
  - astemizole*, terfenadine* - used to relieve allergy symptoms
  - cisapride* - used to relieve certain stomach problems
  - colchicine, when used in patients with renal and/or hepatic impairment - used to treat gout
  - dronedarone (e.g., Multaq®) - used to correct heart rhythm
  - elbasvir/grazoprevir (e.g., Zepatier™) - used to treat hepatitis C virus (HCV)
  - ergotamine*, dihydroergotamine (used to treat headaches), ergonovine, methylergonovine* (used after labour and delivery), such as Cafergot®, Migranal®, D.H.E. 45®*, Methergine™*, and others
  - fusidic acid (e.g., Fucidin®) - antibiotic
  - lurasidone (e.g., Latuda®), pimozide (e.g., Orap®*) - used to treat abnormal thoughts or feelings
  - neratinib (e.g., Nerlynx®) - used for breast cancer
  - sildenafil (e.g., Revatio®) - used to treat pulmonary arterial hypertension
  - triazolam, oral 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/your child's blood and make it less effective.
- are currently taking St. John's Wort (*Hypericum perforatum*), an herbal product sold as a dietary supplement, or products containing St. John's Wort. Talk with your/your child's doctor if you/your child 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®*), lomitapide (e.g., Juxtapid™) or simvastatin (e.g., Zocor®) because of possible serious reactions. Talk to your/your child's doctor before you/your child take any cholesterol-lowering medicines with KALETRA.
- are currently taking the PDE5 inhibitors vardenafil (e.g., Levitra®), used to treat erectile dysfunction, or sildenafil (e.g., 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/your child's doctor may switch your/your child's 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: 100/25 mg; 200/50 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/your child's doctor if you or your child develop symptoms, such as:

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

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

Do not take KALETRA once daily if you/your child:

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

BEFORE you use KALETRA, talk to your/your child's doctor or pharmacist if you or your child:

- have liver problems or are infected with hepatitis B or hepatitis C.
- have diabetes or symptoms, such as frequent urination and/or increase in thirst.
- have hemophilia. Patients taking KALETRA may have increased bleeding.
- are taking or planning to take other medicines, **including prescription, herbal and other medicines** you/your child can buy without a prescription.
- have heart disease or a heart condition, including conditions of Congenital Long QT Syndrome.
- have low potassium levels in your blood.
- are pregnant or planning to become pregnant; pregnant women should not take KALETRA unless specifically directed by the doctor. Be sure to tell your/your child's doctor immediately if you/your child are or may be pregnant. If you/your child take KALETRA while you/your child are pregnant, talk to your/your child's doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- are breastfeeding or planning to breast-feed. 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.

Severe liver problems, including deaths, have been reported in those using KALETRA. This has often occurred in those with advanced HIV disease, other liver disease or those taking many medications. There is no proven link to KALETRA use.

INTERACTIONS WITH THIS MEDICATION

KALETRA may interact with certain other medications with possible clinical effects. The following medicines should only be used together with KALETRA if advised by your/your child's physician:

- medicines used to treat erectile dysfunction, such as sildenafil (e.g., Viagra®) or tadalafil (e.g., Cialis®); vardenafil (e.g., Levitra®) should not be taken with KALETRA
- medicines used to treat pulmonary arterial hypertension, such as bosentan (e.g., Tracleer®) or tadalafil (e.g., Adcirca®)
- medicines used to lower blood cholesterol, such as rosuvastatin (e.g., Crestor®), atorvastatin (e.g., Lipitor®); lovastatin (e.g., Mevacor®*), lomitapide (e.g., Juxtapid™) or simvastatin (e.g., Zocor®) should not be taken with KALETRA
- some medicines affecting the immune system, such as cyclosporin, sirolimus (e.g., Rapamune®) and tacrolimus
- some medicines used to treat seasonal allergies and ear and eye infections, such as dexamethasone, fluticasone propionate (e.g., Flonase®) and triamcinolone
- medicines used to treat asthma, such as budesonide (e.g., Pulmicort®)
- contraceptives used to prevent pregnancy (e.g., ethinyl estradiol)
- medicines used to treat AIDS and related infections, such as amprenavir*, fosamprenavir (e.g., Telzir®), indinavir (e.g., Crixivan®*), nelfinavir (e.g., Viracept®), saquinavir (e.g., Invirase®), didanosine (e.g., Videx®), tenofovir (e.g., Viread®), efavirenz (e.g., Sustiva®), maraviroc (e.g., Celsentri®), nevirapine (e.g., Viramune®), rifabutin (e.g., Mycobutin®), etravirine (e.g., Intelence®), rilpivirine (e.g., Edurant®, Complera®), tipranavir (e.g., Aptivus®) when used with low-dose ritonavir
- medicines used to treat HCV and related infections, such as telaprevir (e.g., Incivek®*), boceprevir (e.g., Victrelis®*), glecaprevir/pibrentasvir (e.g., Maviret™), sofosbuvir/velpatasvir/voxilaprevir (e.g., Vosevi™), simeprevir (e.g., Galexos®*) and ombitasvir/paritaprevir/ritonavir with or without dasabuvir (e.g., Holkira® Pak*, Technivie™*)
- medicines used to treat depression, such as trazodone and bupropion (e.g., Wellbutrin® SR)
- certain heart medicines, such as calcium channel antagonists including felodipine (e.g., Plendil®), nifedipine (e.g., Adalat®) and nicardipine*
- medicines used to correct heart rhythm, such as amiodarone (e.g., Cordarone®*), flecainide (e.g., Tambocor®), bepridil*, systemic lidocaine, propafenone hydrochloride (e.g., Rythmol®), quinidine* and digoxin

- antifungals, such as ketoconazole (e.g., Nizoral®), itraconazole (e.g., Sporanox®) and voriconazole (e.g., Vfend®)
- morphine-like medicines (e.g., methadone)
- anticonvulsants, such as carbamazepine (e.g.,Tegretol®), lamotrigine (e.g., Lamictal®), phenytoin (e.g., Dilantin®), phenobarbital, and valproate (e.g., Depakene®)
- anticoagulants, such as warfarin or rivaroxaban (e.g., Xarelto®)
- certain antibiotics, such as clarithromycin (e.g., Biaxin®)
- medicines used to treat cancer, such as abemaciclib (e.g., Verzenio™), dasatinib (e.g., Sprycel®), ibrutinib (e.g., Imbruvica®), nilotinib (e.g., Tasigna®), venetoclax (e.g., Venclexta®), vincristine and vinblastine, as KALETRA may increase the concentrations of these drugs and increase adverse effects
- fentanyl (e.g., Duragesic®*) in all forms, as this interaction may reduce breathing
- colchicine, used to treat gout
- quetiapine, used to treat schizophrenia, bipolar disorder and major depressive disorder
- medicines to treat anxiety, such as midazolam (injected)
- medicines used to treat moderate to severe pain associated with endometriosis, such as elagolix (e.g. Orilissa™)

*** Products not marketed in Canada.**

If you/your child are taking KALETRA, you/your child 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/your child's doctor prescribed it. Even if you/your child feel better, do not stop taking KALETRA without talking to your/your child's doctor. Using KALETRA as recommended should give you/your child the best chance to delay the development of resistance to the product.

It is therefore important that you/your child remain under the supervision of your/your child's doctor while taking KALETRA.

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 as four 200/50 mg tablets (800/200 mg) once daily in combination with other anti-HIV medicines for some patients. Once daily dosing is not recommended for pregnant women.

The dose for children from 6 months to 18 years of age will be determined by your/your child's 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.

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

Your doctor may monitor blood levels of fats (lipids), cholesterol and glucose before and during KALETRA treatment.

Overdose:

If you/your child realize you have taken more KALETRA than you/your child were supposed to, contact your/your child's doctor or local poison control centre right away, even if you/your child 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, 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/your child have liver disease, such as Hepatitis B and Hepatitis C, taking KALETRA may worsen your/your child's liver disease.
- Some patients have large increases in triglycerides and cholesterol (forms of fat that are found in your/your child's 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/your child's doctor know if you/your child have or develop these symptoms while taking KALETRA.
- Some patients with hemophilia have increased bleeding with protease inhibitors.

Changes to your/your child's immune system (Immune Reconstitution Inflammatory Syndrome) can happen when you/or your child start taking HIV-1 medicines. Your/your child's immune system may get stronger and begin to fight infections that have been hidden in your/your child's body for a long time.

Autoimmune disorders (when the immune system attacks healthy body tissue), may also occur after you start taking medicines for

HIV infection. Examples of this include: Grave's disease (which affects the thyroid gland), Guillain-Barré syndrome (which affects the nervous system), polymyositis (which affects the muscles), or autoimmune hepatitis (which affects the liver). Autoimmune disorders may occur at any time, even many months after the start of treatment.

If you or your child are experiencing new symptoms, call your doctor immediately, for example:

- high temperature (fever), redness, rash or swelling
- fatigue
- joint or muscle pain
- numbness, tingling, or weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations (chest pain) or rapid heart rate
- yellowing of the skin or eyes
- anxiety and irritability accompanied by tremor of your hands or fingers
- muscle weakness in your hips, thighs, shoulders, upper arms and neck

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		√	

Thisis not a complete list of side effects. For any unexpected effets while taking KALETRA, contact your doctor or pharmacist.

HOW TO STORE IT

Keep KALETRA and all other medicines out of the reach and sight of children.

KALETRA film-coated tablets should be stored between 15 and 30°C. It is recommended that the product be stored and dispensed in the original container.

It is important to keep KALETRA in the original package. Do not transfer to any other container.

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

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 three ways:

- **Report on line at:** www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- **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 1908C
  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.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

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

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for healthcare professionals, can be found at:

www.abbvie.ca
or by contacting the sponsor, AbbVie Corporation, St-Laurent, QC, H4S 1Z1 at 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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PART III: CONSUMER INFORMATION

PrKALETRA® Oral Solution
lopinavir/ritonavir

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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
  - apalutamide (e.g. Erleada™) – used for prostate cancer
  - astemizole*, terfenadine*- used to relieve allergy symptoms
  - cisapride* - used to relieve certain stomach problems
  - colchicine, when used in patients with renal and/or hepatic impairment - used to treat gout
  - dronedarone (e.g., Multaq®) - used to correct heart rhythm
  - elbasvir/grazoprevir (e.g., Zepatier™) - used to treat hepatitis C virus (HCV)
  - ergotamine*, dihydroergotamine (used to treat headaches), ergonovine, methylergonovine* (used after labour and delivery), such as Cafergot®, Migranal®, D.H.E. 45®*, Methergine™*, and others
  - fusidic acid (e.g., Fucidin®) - antibiotic
  - lurasidone (e.g., Latuda®), pimozide (e.g., Orap®*) - used to treat abnormal thoughts or feelings
  - neratinib (e.g., Nerlynx®) - used for breast cancer
  - sildenafil (e.g., Revatio®) - used to treat pulmonary arterial hypertension
  - triazolam, oral 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/your child's blood and make it less effective.
- are currently taking St. John's Wort (*Hypericum perforatum*), an herbal product sold as a dietary supplement, or products containing St. John's Wort. Talk with your/your child's doctor if you/your child 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®*), lomitapide (e.g., Juxtapid™) or simvastatin (e.g., Zocor®) because of possible serious reactions. Talk to your/your child's doctor before you/your child take any cholesterol-lowering medicines with KALETRA.
- are currently taking the PDE5 inhibitors vardenafil (e.g., Levitra®), used to treat erectile dysfunction, or sildenafil (e.g., 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/your child's doctor may switch your/your child's medication.

*** Products not marketed in Canada.**

What the medicinal ingredients are:

lopinavir and ritonavir

What the important non-medicinal ingredients are:

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

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

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Tell your/your child's doctor if you or your child develop symptoms, such as:

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

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

Do not take KALETRA once daily if you/your child:

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

BEFORE you/your child use KALETRA, talk to your/your child's doctor or pharmacist if you/your child:

- have liver problems or are infected with hepatitis B or hepatitis C.
- have diabetes, or symptoms, such as frequent urination and/or increase in thirst.
- have hemophilia. Patients taking KALETRA may have increased bleeding.
- are taking or planning to take other medicines, **including prescription, herbal and other medicines** you/your child can buy without a prescription.
- have heart disease or a heart condition, including conditions of Congenital Long QT Syndrome.
- have low potassium levels in your/your child's blood.
- are pregnant or planning to become pregnant; pregnant women should not take KALETRA oral solution unless specifically directed by the doctor. Be sure to tell your/your child's doctor immediately if you/your child are or may be pregnant. If you/your child take KALETRA while you/your child are pregnant, talk to your/your child's doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- are breast-feeding or planning to breast-feed. 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.
- have hereditary fructose intolerance as this product contains fructose.
- have kidney problems or inability to metabolize propylene glycol as this medication contains propylene glycol.
- suffer from alcoholism, liver problems, epilepsy or brain injury, as this medication contains alcohol.

Severe liver problems, including deaths, have been reported in those using KALETRA. This has often occurred in those with advanced HIV disease, other liver disease or those taking many medications. There is no proven link to KALETRA use.

INTERACTIONS WITH THIS MEDICATION

KALETRA may interact with certain other medications with possible clinical effects. The following medicines should only be used together with KALETRA if advised by your/your child's physician:

- medicines used to treat erectile dysfunction, such as sildenafil (e.g., Viagra®) or tadalafil (e.g., Cialis®); vardenafil (e.g., Levitra®) should not be taken with KALETRA
- medicines used to treat pulmonary arterial hypertension, such as bosentan (e.g., Tracleer®) or tadalafil (e.g., Adcirca®)
- medicines used to lower blood cholesterol, such as rosuvastatin (e.g., Crestor®), atorvastatin (e.g., Lipitor®), lovastatin (e.g., Mevacor®*), lomitapide (e.g., Juxtapid™) or simvastatin (e.g., Zocor®) should not be taken with KALETRA
- some medicines affecting the immune system, such as cyclosporin, sirolimus (e.g., Rapamune®) and tacrolimus
- some medicines used to treat seasonal allergies and ear and eye infections, such as dexamethasone, fluticasone propionate (e.g., Flonase®) and triamcinolone
- medicines used to treat asthma, such as budesonide (e.g., Pulmicort®)
- contraceptives used to prevent pregnancy (e.g., ethinyl estradiol)
- medicines used to treat AIDS and related infections, such as amprenavir*, fosamprenavir (e.g., Telzir®), indinavir (e.g., Crixivan®*), nelfinavir (e.g., Viracept®), saquinavir (e.g., Invirase®), didanosine (e.g., Videx®), tenofovir (e.g., Viread®), efavirenz (e.g., Sustiva®), maraviroc (e.g., Celsentri®), nevirapine (e.g., Viramune®), rifabutin (e.g., Mycobutin®), etravirine (e.g., Intelence®), rilpivirine (e.g., Edurant®, Complera®), tipranavir (e.g., Aptivus®) when used with low-dose ritonavir
- medicines used to treat HCV and related infections, such as telaprevir (e.g., Incivek®*), boceprevir (e.g., Victrelis®*), glecaprevir/pibrentasvir (e.g., Maviret™), sofosbuvir/velpatasvir/voxilaprevir (e.g., Vosevi™), simeprevir (e.g., Galexos®*) and ombitasvir/paritaprevir/ritonavir with or without dasabuvir (e.g., Holkira® Pak*, Technivie™*)
- medicines used to treat depression, such as trazodone and bupropion (e.g., Wellbutrin® SR)
- certain heart medicines, such as calcium channel antagonists including felodipine (e.g., Plendil®), nifedipine (e.g., Adalat®) and nicardipine*
- medicines used to correct heart rhythm, such as

amiodarone (e.g., Cordarone®*), flecainide (e.g., Tambocor®), bepridil*, systemic lidocaine, propafenone hydrochloride (e.g., Rythmol®), quinidine* and digoxin
- antifungals, such as ketoconazole (e.g., Nizoral®), itraconazole (e.g., Sporanox®) and voriconazole (e.g., Vfend®)
- morphine-like medicines (e.g., methadone)
- anticonvulsants, such as carbamazepine (e.g.,Tegretol®), lamotrigine (e.g., Lamictal®), phenytoin (e.g., Dilantin®), phenobarbital, and valproate (e.g., Depakene®)
- anticoagulants, such as warfarin or rivaroxaban (e.g., Xarelto®)
- certain antibiotics, such as clarithromycin (e.g., Biaxin®)
- medicines used to treat cancer, such as abemaciclib (e.g., Verzenio™), dasatinib (e.g., Sprycel®), ibrutinib (e.g., Imbruvica®), nilotinib (e.g., Tasigna®), venetoclax (e.g., Venclexta®), vincristine and vinblastine as KALETRA may increase the concentrations of these drugs and increase adverse effects
- fentanyl (e.g., Duragesic®*) in all forms as this interaction may reduce breathing
- colchicine used to treat gout
- quetiapine used to treat schizophrenia, bipolar disorder and major depressive disorder
- medicines to treat anxiety, such as midazolam (injected)
- medicines used to treat moderate to severe pain associated with endometriosis, such as elagolix (e.g. Orilissa™)

*** Products not marketed in Canada.**

If you/your child are taking KALETRA, you/your child 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/your child's doctor prescribed it. Even if you/your child feel better, do not stop taking KALETRA without talking to your/your child's doctor. Using KALETRA as recommended should give you/your child the best chance to delay the development of resistance to the product.

It is therefore important that you/your child remain under the supervision of your/your child's 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 oral solution should not be used during pregnancy, due to the content of alcohol and propylene glycol in the KALETRA oral solution.

The dose for children from 6 months to 18 years of age will be determined by your/your child's 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.

Your doctor may monitor blood levels of fats (lipids), cholesterol and glucose before and during KALETRA treatment.

Overdose:

If you/your child realize you have taken more KALETRA than you/your child were supposed to, contact your/your child's doctor or local poison control centre right away, even if you/your child 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 could kill 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/your child have liver disease, such as Hepatitis B and Hepatitis C, taking KALETRA may worsen your/your child's liver disease.
- Some patients have large increases in triglycerides and cholesterol (forms of fat that are found in your/your child's 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/your child's doctor know if you/your child have or develop these symptoms while taking KALETRA.
- Some patients with hemophilia have increased bleeding with protease inhibitors.

Changes to your/your child's immune system (Immune

Reconstitution Inflammatory Syndrome) can happen when you/or your child start taking HIV-1 medicines. Your/your child's immune system may get stronger and begin to fight infections that have been hidden in your/your child's body for a long time.

Autoimmune disorders (when the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection. Examples of this include: Grave's disease (which affects the thyroid gland), Guillain-Barré syndrome (which affects the nervous system), polymyositis (which affects the muscles), or autoimmune hepatitis (which affects the liver). Autoimmune disorders may occur at any time, even many months after the start of treatment.

If you or your child are experiencing new symptoms, call your doctor immediately, for example:

- high temperature (fever), redness, rash or swelling
- fatigue
- joint or muscle pain
- numbness, tingling, or weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations (chest pain) or rapid heart rate
- yellowing of the skin or eyes
- anxiety and irritability accompanied by tremor of your hands or fingers
- muscle weakness in your hips, thighs, shoulders, upper arms and neck

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 and all other medicines out of the reach and sight of children.

KALETRA oral solution should be stored between 2 and 8°C in a refrigerator. If you keep KALETRA 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 in the original package. Do not transfer to any other container.

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

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 three ways:

- **Report on line at:** www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- **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 1908C
  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.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

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

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for healthcare professionals, can be found at:

www.abbvie.ca
or by contacting the sponsor, AbbVie Corporation, St-Laurent, QC, H4S 1Z1 at 1-888-704-8271.

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