

**OAK TREE CLINIC
INFORMATION FOR PARENTS/PATIENTS**

DRUG NAME: LOPINAVIR/RITONAVIR

BRAND NAME: KALETRA

THIS MEDICATION IS:

- A combination of two antiviral drugs lopinavir (LOP, also called ABT-378) and ritonavir (RTV)
- These antiviral drugs slow the growth of HIV, the virus associated with AIDS
- Lopinavir and ritonavir belong to a group of drugs called protease inhibitors. Protease inhibitors work by inhibiting the enzyme protease (also called proteinase) which is needed for HIV to multiply. Inhibiting this enzyme produces incomplete, noninfectious HIV particles. Other protease inhibitors are indinavir, nelfinavir and saquinavir. Lopinavir/ritonavir is always used in combination with other anti-HIV agents

BENEFITS OF LOPINAVIR/RITONAVIR:

- It reduces the amount of HIV virus (viral load) and increases the number of CD4 cells (T cells or immune cells) in the blood.
- By reducing the amount of HIV virus it decreases the chance infections that happen when the immune system is weak (opportunistic infections).

AVAILABILITY OF LOPINAVIR/RITONAVIR:

- Lopinavir/ritonavir is available as capsules each containing lopinavir 133.3 mg with ritonavir 33.3 mg or an alcohol based oral solution containing lopinavir 400 mg with ritonavir 100 mg in each 5 mls (1 teaspoonful).
- Refrigerated capsules and oral solution are stable until the expiry date printed on the label.
- Capsules and oral solution should be used within 42 days if stored at room temperature.

HOW TO TAKE LOPINAVIR/RITONAVIR:

- The usual dose for adults and children 12 years of age and older is 3 capsules (400/100 mg) or 5 ml (1 teaspoonful) of oral solution twice a day (morning and evening).
- The usual dose for children from 6 months to 12 years of age is based on the child's weight.
- Lopinavir/ritonavir should be taken with food to help it work better.
- Lopinavir/ritonavir should be started at the full dose. Do not interrupt therapy. Skipping doses or taking drug holidays can lead to the development of a virus resistant to lopinavir/ritonavir.

DOSING OF LOPINAVIR/RITONAVIR

Your dose of LOPINAVIR/RITONAVIR is _____ mg / mL _____ times a day.

IF YOU MISS A DOSE:

- Take the dose as soon as you remember that day.
- If it is almost time for the next dose (within 6 hours), skip the missed dose and take the next dose at the regular time.
- **DO NOT** double the dose.

PROBLEMS WHICH MAY BE ENCOUNTERED:

This list of side effects is NOT complete. If you have questions about side effects, please contact your doctor, nurse or pharmacist.

Check with your doctor IMMEDIATELY if any of the following side effects occur:

- nausea, vomiting or severe abdominal pain. These may be signs of pancreatitis.

The following side effects sometimes happen. Call the clinic pharmacist, nurse, or doctor if they continue or are very bothersome.

- abnormal stools (bowel movements), diarrhea, feeling weak/tired, headache and nausea.
- children may get a skin rash

The following side effects may occur and will be monitored by your doctor with regular blood tests:

- It is important that the doctor's visits be kept as scheduled so that the blood can be checked regularly, especially when the drug is first started.
- liver enzyme tests may become elevated.
- some patients have large increases in triglycerides and cholesterol.
- diabetes and high blood sugar (hyperglycemia) may occur. If you notice increased thirst, hunger and urination, contact your doctor as soon as possible.

Lipodystrophy:

- some patients that have been on antiretroviral therapy for a long time (usually more than 6 months) notice changes in the location of their body fat - this is called lipodystrophy.
- patients may notice a loss of fat in their face, arms or legs, while others notice increased fat in the stomach, neck or breast areas. Talk to your doctor if you notice these changes. These changes may not be reversible.

Increased bleeding episodes:

- patients with hemophilia may have increased bleeding with protease inhibitors. If you have hemophilia, make sure you report any increase in bleeding episodes to your doctor.

DRUGS WHICH CAN CAUSE PROBLEMS WHEN TAKEN WITH LOPINAVIR/RITONAVIR:

There are many drugs that may interact with lopinavir/ritonavir. Please discuss **ALL** medications that you are currently taking with your doctor or pharmacist.

DO NOT take the following medications while you are on lopinavir/ritonavir. Serious or life threatening reactions may result when lopinavir/ritonavir is combined with these medications.

- Cafegot, Migranal, dihydroergotamine, ergonovine, DHE 45, methergine and other ergot alkaloids
- Halcion (triazolam)
- Hismanal (astemizole)
- Seldane (terfenadine)
- Rythmol (propafenone)
- Tambocor (flecainide)
- Prepulsid (cisapride)
- Orap (pimozide)
- Versed (midazolam)

Special Considerations:**DO NOT combine these medications:**

Drugs	Effect	Action
St. John's Wort (hypericum perforatum)	St. John's Wort may decrease lopinavir/ritonavir levels and make it less effective	Do not take with St. John's Wort
Lipid lowering agents: Mevacor (lovastatin), Zocor (simvastatin), Lipitor (atorvastatin) and Baycol (cerivastatin)	Lovastatin and simvastatin may cause serious reactions. Atorvastatin and cerivastatin have an increased risk of drug interactions.	Do not take with lovastatin or simvastatin.
Flagyl (metronidazole) or Antabuse (disulfiram)	Lopinavir/ritonavir oral solution contains alcohol. Severe nausea and vomiting may occur.	This is not a concern with the capsule formulation of Kaletra
Videx (didanosine) Antacids	The antacid alone and that in didanosine can interfere with the absorption of lopinavir/ritonavir.	Take didanosine or antacids one hour before or two hours after lopinavir/ritonavir.

Dosage adjustment is required with these medications:

Drugs	Effect	Action
Rimactane, Rifadin, Rifater or Rifamate (rifampin)	Rifampin may lower the amount of lopinavir/ ritonavir in your blood and make it less effective	The dose of lopinavir/ritonavir may have to be increased.
Viagra (sildenafil)	Lopinavir/ritonavir will increase the side effects of sildenafil (low blood pressure, vision changes, penis erection)	If an erection lasts longer than 4 hours, seek immediate medical help. You should not take more than 25 mg of sildenafil in any 2 day period.
Oral Contraceptives ("the pill")	Lopinavir/ritonavir may decrease the effectiveness of oral contraceptives.	Additional birth control is required. A non-hormonal method of birth control should be used (ie. male or female condoms)
Sustiva (efavirenz) or Viramune (nevirapine)	Efavirenz or nevirapine may lower the levels of lopinavir/ritonavir in your blood.	The dose of lopinavir/ritonavir may have to be increased.
Mycobutin (rifabutin)	Lopinavir/ritonavir can increase rifabutin levels and possibly cause toxicity.	The dose of rifabutin should be lowered.
Anticonvulsants: phenobarbital, Dilantin (phenytoin) and Tegretol (carbamazepine)	Some anticonvulsants lower the levels of lopinavir/ritonavir making it less effective. Lopinavir/ritonavir may increase the levels of anticonvulsants.	Additional blood tests may be required to monitor the effect of lopinavir/ritonavir on blood levels.

CAUTIONS:

- Throw away any expired or leftover medication.

- Keep out of reach of children.

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