

LOPINAVIR/RITONAVIR (KALETRA)

USE:

Kaletra is an antiretroviral drug in the class called protease inhibitors. It has two drugs in one pill. These drugs are lopinavir and ritonavir (both are protease inhibitors). This drug is used in combination with other antiretroviral drugs in the treatment of HIV (Human Immunodeficiency Virus) Infections. This drug is not a cure for HIV.

AVAILABLE AS: A single capsule containing 133.3 milligrams (mg) lopinavir and 33.3mg ritonavir; Oral solution containing 400mg lopinavir and 100mg ritonavir per 5ml (80mg lopinavir/20mg ritonavir per ml).

HOW TO USE THIS MEDICATION:

Take this medication exactly as directed by your doctor. Do not stop taking this medication on your own without first consulting a physician. The normal dose of Kaletra is three capsules or 5ml solution (400/100mg) twice daily with food. This dose may be adjusted by your doctor if you are taking other medications that interact with Kaletra. Dosing for children is based on weight and will be determined by your doctor. Take Kaletra with food and plenty of water. Your doctor may want you to have occasional blood tests. Make sure you keep all of your appointments.

Both the capsules and oral solution of Kaletra should be stored in the refrigerator in order to be stable until its expiration date. If Kaletra is kept at room temperature, it should be thrown out after 2 months. Keep Kaletra away from excessive heat, light or moisture. Always keep medication out of the reach of children.

It is very important to take every dose of your medication in order for it to work correctly. If you miss a dose of Kaletra, take it as soon as you remember unless it is close to your next dose. If it is close to your next dose, skip the missed dose and take your next dose at the normal time. Do not take two doses at once.

CONTRAINDICATIONS:

Do not take Kaletra if you have had a prior allergic reaction to lopinavir or ritonavir (as Kaletra or Norvir) or any component of the medication. You should not take Kaletra if you are also taking flecainide (Tambocor), astemizole (Hismanal), terfenadine (Seldane), cisapride (Propulsid), propafenone (Rythmol), pimozide (Orap), midazolam (Versed), triazolam (Halcion), or ergot medications (Cafergot or Wigraine).

SIDE EFFECTS:

The most common side effects of Kaletra are diarrhea, headache, nausea, and feeling weak or tired. Children may also get a skin rash. Most of these minor side effects will go away with time. Changes in body fat may occur with this class of drug. Tell your doctor if you experience loss of fat in the arms, legs and face or increased fat in the upper back and neck, breast, and abdomen. Ask your doctor how to manage these side effects with diet, exercise, or medication. Kaletra may increase the values of some blood tests. Kaletra has been shown to increase triglycerides and cholesterol levels. This could increase the risk of long term complications such as heart attacks. Kaletra may also

increase blood sugar (hyperglycemia) in someone who already has diabetes or who does not have a past history of diabetes. Your doctor will have your blood tested for some of these side effects. Make sure you keep all of your appointments to have blood work.

Warning: Contact your doctor immediately if you experience any of the conditions listed below. Stop taking Kaletra immediately and seek medical attention if you experience an allergic reaction (difficulty breathing; closing of your throat; swelling of your lips, tongue, or face; or hives). Some people who take Kaletra will experience an inflammation of their pancreas (pancreatitis). Call your doctor right away if you have nausea, vomiting, or abdominal pain. This medication can also cause an increased chance of bleeding in people who have hemophilia (bleeding disorder). Liver problems may also occur with Kaletra. Tell your doctor if you have a history of liver disease, pancreatitis, diabetes, or hemophilia before taking Kaletra. Other side effects that must be reported to your doctor immediately include severe or ongoing diarrhea; increased thirst, hunger, or urination; weight loss; or sudden and severe stomach pain, nausea, vomiting and fever.

Notify your doctor if you are pregnant, planning to become pregnant or breastfeeding. The effects of Kaletra on an unborn baby are unclear. People with HIV should never breastfeed because of the risk of transmitting HIV to the infant.

This medication does not prevent the transmission of HIV to other people. Make sure you understand and practice safe sex and do not share needles with anyone.

DRUG INTERACTIONS:

Alert: Find out about medicines that should not be taken with Kaletra. Do not take Kaletra with the medications listed under “contraindications.” Medications that might lower the amount of Kaletra in your body include rifampin (Rimactane, Rifadin, Rifater, Rifamate), St. John’s wort (*hypericum perforatum*), efavirenz (Sustiva), nevirapine (Viramune), phenytoin (Dilantin), Phenobarbital, and carbamazepine (Tegretol). Your doctor may increase your dose of Kaletra or avoid its use with these medications. If you take Kaletra with rifabutin (Mycobutin), your doctor may lower the dose of rifabutin. Some drugs if taken with Kaletra will have an increased risk of serious side effects. These drugs include lovastatin (Mevacor), simvastatin (Zocor) and sildenafil (Viagra). Birth control pills may be less effective when taken with Kaletra. Talk to your doctor about using other forms of birth control. The anti-HIV drug didanosine (Videx) should be taken one hour before or two hours after Kaletra. If you are taking the oral solution of Kaletra, you should avoid metronidazole (Flagyl) or disulfiram (Antabuse). The solution contains alcohol that will cause a severe reaction when taken with either of these drugs.

This is not a complete list of interactions. Make sure your doctor knows all of the medications you are taking. Also, ask your doctor or pharmacist about any medications including over the counter, herbal, vitamin, and prescription products before using them with kaletra.

References: see references 29-32

