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Lopinavir and Ritonavir

pronounced as (loe pin' a veer) (ri toe' na veer)

Notice:

Lopinavir and ritonavir are currently being studied in several ongoing clinical studies for the treatment of coronavirus disease 2019 (COVID-19) either alone or with other medications. The use of lopinavir and ritonavir for the treatment of COVID-19 has not yet been established. Some scientists are hopeful because these medications have been used to treat similar viral infections.

Lopinavir and ritonavir should be taken ONLY under the direction of a doctor for the treatment of COVID-19.

Why is this medication prescribed?

The combination of lopinavir and ritonavir is used with other medications to treat human immunodeficiency virus (HIV) infection. Lopinavir and ritonavir are in a class of medications called protease inhibitors. They work by decreasing the amount of HIV in the blood. When lopinavir and ritonavir are taken together, ritonavir also helps to increase the amount of lopinavir in the body so that the medication will have a greater effect. Although lopinavir and ritonavir will not cure HIV, these medications may decrease your chance of developing acquired immunodeficiency syndrome (AIDS) and HIV-related illnesses such as serious infections or cancer. Taking these medications along with practicing safer sex and making other life-style changes may decrease the risk of transmitting the HIV virus to other people.

How should this medicine be used?

The combination of lopinavir and ritonavir comes as a tablet and a solution (liquid) to take by mouth. It is usually taken twice a day, but may be taken once a day by certain adults. The solution must be taken with food. The tablets may be taken with or without food. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take lopinavir and ritonavir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets whole; do not split, chew, or crush them.

If you are using the solution, shake it well before each use to mix the medication evenly. Use a dose-measuring spoon or cup to measure the correct amount of liquid for each dose, not a regular household spoon.

Continue to take lopinavir and ritonavir even if you feel well. Do not stop taking lopinavir and ritonavir without talking to your doctor. If you miss doses, take less than the prescribed amount, or stop taking lopinavir and ritonavir, your condition may become more difficult to treat.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking lopinavir and ritonavir,

- tell your doctor and pharmacist if you are allergic to lopinavir, ritonavir (Norvir), any other medications, or any of the ingredients in lopinavir and ritonavir tablets or solution. Ask your pharmacist for a list of the ingredients.
- tell your doctor if you are taking any of the following medications: alfuzosin (Uroxatral); apalutamide (Erleada); cisapride (Propulsid) (not available in the U.S.); colchicine (Colcrys, Mitigare) in people with kidney or liver disease; dronedarone (Multaq); elbasvir and grazoprevir (Zepatier); ergot medications such as dihydroergotamine (D.H.E. 45, Migranal), ergotamine (Ergomar, in Cafergot, in Migergot), and methylergonovine (Methergine); lomitapide (Juxtapid); lovastatin (Altoprev); lurasidone (Latuda); midazolam taken by mouth (Versed); pimozide (Orap); ranolazine (Ranexa); rifampin (Rimactane, Rifadin, in Rifamate, in Rifater); sildenafil (only Revatio brand used for lung disease); simvastatin (Zocor, in Vytorin); St. John's wort; or triazolam (Halcion). Your doctor will probably tell you not to take lopinavir and ritonavir if you are taking one or more of these medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven) and rivaroxaban (Xarelto); antifungals such as itraconazole (Onmel, Sporanox), isavuconazonium (Cresemba), ketoconazole (Nizoral), and voriconazole (Vfend); atovaquone (Mepron, in Malarone); bedaquiline (Sirturo); beta-blockers; bosentan (Tracleer); bupropion (Wellbutrin, Zyban, others); calcium-channel blockers such as felodipine, nifedipine (Cardene), and nifedipine (Adalat, Afeditab CR, Procardia); cholesterol-lowering medications such as atorvastatin (Lipitor, in Caduet), and rosuvastatin (Crestor); clarithromycin (Biaxin, in Prevpac); digoxin (Lanoxin); elagolix (Orilissa); fentanyl (Actiq, Duragesic, Onsolis, others); fosamprenavir (Lexiva); certain medications for cancer such as abemaciclib (Verzenio), dasatinib (Sprycel), encorafenib (Braftovi), ibrutinib (Imbruvica), ivosidenib (Tibsovo), neratinib (Nerlynx), nilotinib (Tasigna), venetoclax (Venclexta), vinblastine, and vincristine; certain medications for irregular heartbeat such as amiodarone (Cordarone, Nexterone, Pacerone), bepridil (no longer available in US; Vascor), lidocaine (Lidoderm; in Xylocaine with Epinephrine), and quinidine (in Nuedexta); certain medications for hepatitis C virus (HCV) such as boceprevir (Victrelis; no longer available in U.S.); glecaprevir and pibrentasvir (Mavyret); simeprevir (no longer available in U.S.; Olysio); sofosbuvir, velpatasvir, and voxilaprevir (Sovaldi, Epclusa, Vosevi); and paritaprevir, ritonavir, ombitasvir, and/or dasabuvir (Viekira Pak); certain medications for seizures such as carbamazepine (Equetro, Tegretol, Teril, others), lamotrigine (Lamictal), phenobarbital, phenytoin (Dilantin, Phenytek), and valproate; medications that suppress the immune system such as cyclosporine (Gengraf, Neoral, Sandimmune), sirolimus (Rapamune), and tacrolimus (Astagraf, Prograf); methadone (Dolophine, Methadose); oral or inhaled steroids such as betamethasone, budesonide (Pulmicort), ciclesonide (Alvesco, Omnaris), dexamethasone, fluticasone (Flonase, Flovent, in Advair), methylprednisolone

(Medrol), mometasone (in Dulera), prednisone (Rayos), and triamcinolone; other antiviral medications such as abacavir (Ziagen, in Epzicom, in Trizivir, others); atazanavir (Reyataz, in Evotaz), delavirdine (Rescriptor), efavirenz (Sustiva, in Atripla), indinavir (Crixivan), maraviroc (Selzentry), nelfinavir (Viracept), nevirapine (Viramune), ritonavir (Norvir, in Kaletra), tenofovir (Viread, in Atripla, in Truvada), tipranavir (Aptivus), saquinavir (Invirase), and zidovudine (Retrovir, in Combivir, in Trizivir); quetiapine (Seroquel); rifabutin (Mycobutin); salmeterol (Serevent, in Advair); sildenafil (Viagra); tadalafil (Adcirca, Cialis); trazodone; and vardenafil (Levitra). If you are taking the oral solution, also tell your doctor if you are taking disulfiram (Antabuse) or metronidazole (Flagyl, in Nuversa, in Vandazole). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- if you are taking didanosine, take it 1 hour before or 2 hours after you take lopinavir and ritonavir solution with food. If you are taking lopinavir and ritonavir tablets, you may take them on an empty stomach at the same time as you take didanosine.
- tell your doctor if you have or have ever had a prolonged QT interval (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death), an irregular heartbeat, a low level of potassium in your blood, hemophilia, high cholesterol or triglycerides (fat) in the blood, pancreatitis (swelling of the pancreas), or heart or liver disease.
- you should know that lopinavir and ritonavir may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, or injections). Talk to your doctor about using another form of birth control.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking lopinavir and ritonavir, call your doctor. You should not breast-feed if you are infected with HIV or if you are taking lopinavir and ritonavir.
- you should know that certain ingredients in lopinavir and ritonavir solution may cause serious and life-threatening side effects in newborn babies. Lopinavir and ritonavir oral solution should not be given to full-term babies younger than 14 days old or to premature babies younger than 14 days past their original due date, unless a doctor thinks there is a good reason for the baby to receive the medication right after birth. If your baby's doctor chooses to give your baby lopinavir and ritonavir solution immediately after birth, your baby will be monitored carefully for signs of serious side effects. Call your baby's doctor immediately if your baby is very sleepy or has changes in breathing during his or her treatment with lopinavir and ritonavir oral solution.
- you should be aware that your body fat may increase or move to different areas of your body, such as your upper back, neck ("buffalo hump"), breasts, and around your stomach. You may notice a loss of body fat from your face, legs, and arms.
- you should know that you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication, even if you do not already have diabetes. Tell your doctor immediately if you have any of the following symptoms while you are taking lopinavir and ritonavir: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar that is not treated can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include: dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.
- you should know that while you are taking medications to treat HIV infection, your immune system may get stronger and begin to fight other infections that were already in your body. This may cause you to develop symptoms of those infections. If you have new or worsening symptoms after starting treatment with lopinavir and ritonavir, be sure to tell your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Lopinavir and ritonavir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- weakness
- diarrhea
- gas
- heartburn
- weight loss
- headache
- difficulty falling asleep or staying asleep
- muscle pain
- numbness, burning, or tingling in the hands or feet
- stomach pain, nausea, and vomiting

Some side effects can be serious. If you experience any of the following symptoms, call your doctor immediately or get emergency medical treatment:

- nausea
- vomiting
- stomach pain
- extreme tiredness
- loss of appetite
- pain in the upper right part of the stomach
- yellowing of the skin or eyes
- itchy skin
- dizziness
- lightheadedness
- fainting
- irregular heartbeat

- blisters
- rash

Lopinavir and ritonavir may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store the tablets at room temperature and protect them from excess moisture. It is best to keep the tablets in the container they came in; if you must take them out of the container, you should use them within 2 weeks. You may keep the oral solution in the refrigerator until the expiration date printed on the label, or you may store it at room temperature for up to 2 months.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

It is especially important to get medical help right away if a child drinks more than the usual dose of the solution. The solution contains a large amount of alcohol and other ingredients that could be very harmful to a child.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to lopinavir and ritonavir.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names of combination products

- Kaletra[®] (containing Lopinavir, Ritonavir)

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