

MEDICATION GUIDE

Lopinavir (loe pin' a veer) and Ritonavir (ri toe na veer) Tablets USP

What is the most important information I should know about lopinavir and ritonavir tablets?

- **Lopinavir and ritonavir tablets may cause serious side effects. Including:**
 - **Interactions with other medicines:** It is important to know the medicines that should not be taken with lopinavir and ritonavir tablets. For more information, see "Who should not take lopinavir and ritonavir tablets?"

- **Side Effects in babies taking lopinavir and ritonavir oral solution:** Lopinavir and ritonavir oral solution contains alcohol and propylene glycol. Call your healthcare provider right away if your baby appears too sleepy or their breathing changes.

- **Inflammation of your pancreas (pancreatitis):** Lopinavir and ritonavir tablets can cause pancreatitis which may be serious and may lead to death. People who have a history of pancreatitis, gallbladder disease, or alcohol use may be at a higher risk for developing pancreatitis. If you have pancreas disease, you may need to stop taking lopinavir and ritonavir tablets. Tell your healthcare provider if you have any signs or symptoms of pancreatitis including:

- o nausea
- o vomiting
- o stomach-area (abdominal) pain

- **Liver problems:** Liver problems, including death, can happen in people who take lopinavir and ritonavir tablets. Your healthcare provider should check tests before and during your treatment with lopinavir and ritonavir tablets to check for liver problems. You should not have alcohol or take medicines with Hepatitis C, other liver problems, or a history of liver problems while taking lopinavir and ritonavir tablets. Tell your healthcare provider right away if you have any signs and symptoms of liver problems including:

- o loss of appetite
- o yellow skin and whites of eyes (jaundice)
- o dark-colored urine
- o itchy skin
- o stomach area (abdominal) pain

- **Changes in your heart rhythm and the electrical activity of your heart:** These changes may be seen on an EKG (electrocardiogram) and can lead to serious heart problems. Your risk for these problems may be higher if you:

- o have a history of abnormal heart rhythm or certain types of heart problems.
- o take other medicines that can affect your heart rhythm during treatment with lopinavir and ritonavir tablets.

Tell your healthcare provider right away if you have any of these symptoms:

- o dizziness
- o lightheadedness
- o fainting
- o sensation of abnormal heartbeats

See "What are the possible side effects of lopinavir and ritonavir tablets?" for more information about serious side effects.

What are lopinavir and ritonavir tablets?

Lopinavir and ritonavir tablets are a prescription medicine that is used with other antiretroviral medicines to treat

Human Immunodeficiency Virus-1 (HIV-1) infection in adults and children 14 days of age and older.

HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if lopinavir and ritonavir tablets are safe and effective in children under 14 days old.

Who should not take lopinavir and ritonavir tablets?

- **Do not take lopinavir and ritonavir tablets if you:**
 - are allergic to lopinavir, ritonavir, or any of the ingredients in lopinavir and ritonavir tablets. See the end of this Medication Guide for a complete list of ingredients in lopinavir and ritonavir tablets.

- if you take any of the following medicines:

- o atazanavir
- o apalutamide
- o ranolazine
- o dromedaron
- o colchicine, if you have kidney or liver problems
- o ritampin
- o lurasidone
- o pimozide
- o ergot containing medicines including:
 - dihydroergotamine mesylate
 - ergotamine tartrate
 - methylergonovine
- o cisapride
- o elbasvir/grazoprevir
- o lovastatin
- o simvastatin
- o lomitapide
- o sildenafil (Revatio®), when used for the treatment of pulmonary arterial hypertension
- o triazolam
- o midazolam when taken by mouth
- o St. John's Wort (Hypericum perforatum®)

Serious problems can happen if you or your child takes any of the medicines listed above with lopinavir and ritonavir tablets.

Before taking lopinavir and ritonavir tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have ever had a serious skin rash or an allergic reaction to medicines that contain lopinavir or ritonavir.
- have liver problems, including Hepatitis B or Hepatitis C.
- have any heart problems, including if you have a condition called Congenital Long QT Syndrome.
- have low potassium in your blood.
- have diabetes.
- have high cholesterol in your blood.
- have hemophilia.
- are pregnant or plan to become pregnant. It is not known if lopinavir and ritonavir tablets will harm your unborn baby.

- o Lopinavir and ritonavir oral solution contains alcohol and propylene glycol. You should not take lopinavir and ritonavir oral solution during pregnancy because there is no safe level of alcohol exposure during pregnancy. Tell your healthcare provider if you become pregnant during treatment with lopinavir and ritonavir oral solution.

- o Lopinavir and ritonavir tablets may reduce how well hormonal birth control works. Females who may become pregnant should use another effective form of birth control or an additional barrier method of birth control during treatment with lopinavir and ritonavir tablets.

- o **Pregnancy Registry:** There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of the pregnancy registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take lopinavir and ritonavir tablets.**

- o You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

- o Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. **Many medicines interact with lopinavir and ritonavir tablets.**

Keep a list of your medicines to show your healthcare provider and pharmacist.

You can ask your healthcare provider or pharmacist for a list of medicines that interact with lopinavir and ritonavir tablets.

Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take lopinavir and ritonavir tablets with other medicines. Your healthcare provider may need to change the dose of other medicines during treatment with lopinavir and ritonavir tablets.

How should I take lopinavir and ritonavir tablets?

- Take lopinavir and ritonavir tablets every day exactly as prescribed by your healthcare provider.

- Stay under the care of your healthcare provider during treatment with lopinavir and ritonavir tablets.
- It is important to set up a dosing schedule and follow it every day.
- Do not change your treatment or stop treatment without first talking with your healthcare provider.
- Swallow lopinavir and ritonavir tablets whole. Do not chew, break, or crush lopinavir and ritonavir tablets.
- Lopinavir and ritonavir tablets can be taken with or without food.
 - Lopinavir and ritonavir tablets should be taken with food.
 - Didanosine can be taken at the same time as lopinavir and ritonavir tablets, without food.
 - Take didanosine either 1 hour before or 2 hours after taking lopinavir and ritonavir oral solution.
- If you are pregnant:
 - You **should not** take lopinavir and ritonavir tablets on a 1 time each day dose schedule.
- If your child is prescribed lopinavir and ritonavir:
 - Tell your healthcare provider if your child's weight changes.
- Lopinavir and ritonavir **should not** be given to children on a 1 time each day dose schedule. When giving lopinavir and ritonavir to your child, give lopinavir and ritonavir exactly as prescribed.
 - Use the dosing cup (supplied) or an oral syringe with mL (milliliter) markings to give the prescribed dose of lopinavir and ritonavir oral solution to your child. Your pharmacist should provide an oral syringe to you.
 - Lopinavir and ritonavir oral solution contains propylene glycol and a large amount of alcohol. Lopinavir and ritonavir oral solution **should not** be given to babies younger than 14 days of age unless your healthcare provider thinks it is right for your baby.
- You may have a greater chance of getting diarrhea if you take lopinavir and ritonavir tablets 1 time each day than if you take it 2 times each day.
 - You may have a greater chance of getting diarrhea if you take lopinavir and ritonavir tablets 1 time each day than if you take it 2 times each day.
- **Do not** miss a dose of lopinavir and ritonavir tablets. This could make the virus harder to treat. If you forget to take lopinavir and ritonavir tablets, take the missed dose right away. If it is almost time for your next dose, **do not** take the missed dose. Instead, follow your regular dosing schedule by taking your next dose at its regular time. **Do not** take more than one dose of lopinavir and ritonavir tablets at one time.
- **If you or your child take more than the prescribed dose of lopinavir and ritonavir tablets, call your healthcare provider or go to the nearest emergency room right away.**

What are the possible side effects of lopinavir and ritonavir tablets?

Lopinavir and ritonavir tablets can cause serious side effects, including:

- See "What is the most important information I should know about lopinavir and ritonavir tablets?"
- **Diabetes and high blood sugar (hyperglycemia).** You may develop new or worsening diabetes or high blood sugar during treatment with lopinavir and ritonavir tablets. Tell your healthcare provider if you get any of the following signs or symptoms:
 - urinate more often than usual
 - increased hunger or thirst
 - increase in your blood sugar levels
- Your healthcare provider may need to start you on medicine to treat high blood sugar or change your diabetes medicines.
 - **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Call your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- **Increases in certain fat (triglycerides and cholesterol) levels in your blood.** Large increases of triglycerides and cholesterol can be seen in blood test results of some people who take lopinavir and ritonavir tablets. Your healthcare provider should do blood tests to check your cholesterol and triglyceride levels before you start taking lopinavir and ritonavir tablets and during your treatment.
- **Changes in body fat** can happen in some people who take antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known at this time.
- **Increased bleeding in people with hemophilia.** Some people with hemophilia have increased bleeding with lopinavir and ritonavir tablets or similar medicines.
- **Skin rash, which can be severe,** can happen in people who take lopinavir and ritonavir tablets. Tell your healthcare provider if you have a history of skin rash with other medicine used to treat your HIV-1 infection or if you get any skin rash during treatment with lopinavir and ritonavir tablets.
- **Kidney stones**
 - Common side effects of lopinavir and ritonavir tablets include:
 - vomiting
 - diarrhea
 - nausea
 - increased fats in blood (triglycerides or cholesterol)

These are not all of the possible side effects of lopinavir and ritonavir tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store lopinavir and ritonavir tablets?

- Store lopinavir and ritonavir tablets at 68° to 77°F (20° to 25°C).
- Store lopinavir and ritonavir tablets in the original container.
- Do not keep lopinavir and ritonavir tablets out of the container it comes in for longer than 2 weeks, especially in areas where there is a lot of humidity.
- Keep the container closed tightly.
- Throw away any medicine that is out of date or that you no longer need.

Keep lopinavir and ritonavir tablets and all medicines out of the reach of children.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lopinavir and ritonavir tablets for a condition for which it was not prescribed. Do not give lopinavir and ritonavir tablets to other people, even if they have the same condition you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about lopinavir and ritonavir tablets that is written for health professionals.

What are the ingredients in lopinavir and ritonavir tablets?

Active ingredients: Lopinavir USP and ritonavir USP

Inactive ingredients:

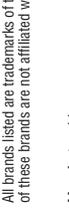
Lopinavir and Ritonavir Tablets USP, 200 mg/50 mg: colloidal silicon dioxide, copovidone, sodium stearyl fumarate, sorbitan monolaurate and opadry yellow which contains colloidal anhydrous silica, hypromellose, hydroxypropyl cellulose, iron oxide yellow, polyethylene glycol, polysorbate 80, talc and titanium dioxide.

Lopinavir and Ritonavir Tablets USP, 100 mg/25 mg: colloidal silicon dioxide, copovidone, sodium stearyl fumarate, sorbitan monolaurate and opadry yellow which contains colloidal anhydrous silica, hypromellose, hydroxypropyl cellulose, iron oxide yellow, polyethylene glycol, polysorbate 80, talc and titanium dioxide.

For more information, call 1-866-495-1995.

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