

MEDICATION GUIDE

Lopinavir and Ritonavir (loe pin' a vir) (ri ton' na vir) Oral Solution USP

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

Lopinavir and ritonavir 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.** For more information, see "[Who should not take lopinavir and ritonavir?](#)"
- **Side Effects in babies taking lopinavir and ritonavir oral solution.** Lopinavir and ritonavir oral solution contains alcohol (ethanol) 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 can cause pancreatitis which may be serious and may lead to death. People who have high levels of a certain fat (triglycerides) have a risk for developing pancreatitis. If you have advanced HIV-1 disease, you may have an increased risk of high triglyceride levels in your blood, and pancreatitis. If you have a history of pancreatitis, you may have an increased risk of it coming back again during treatment with lopinavir and ritonavir. Tell your healthcare provider if you have any signs or symptoms of pancreatitis including:
 - nausea
 - vomiting
 - stomach-area (abdominal) pain
- **Liver problems.** Liver problems, including death, can happen in people who take lopinavir and ritonavir. Your healthcare provider should do blood tests before and during your treatment with lopinavir and ritonavir to check your liver function. If you have Hepatitis B or Hepatitis C, or other liver problems, you may have an increased risk for developing new or worsening of liver problems during treatment with lopinavir and ritonavir. Tell your healthcare provider right away if you have any signs and symptoms of liver problems including:
 - loss of appetite
 - yellow skin and whites of eyes (jaundice)
 - dark-colored urine
 - pale colored stools
 - itchy skin
 - 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:
 - have a history of abnormal heart rhythm or certain types of heart problems.
 - take other medicines that can affect your heart rhythm during treatment with lopinavir and ritonavir.

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

- dizziness
- lightheadedness
- fainting
- sensation of abnormal heartbeats

See "[What are the possible side effects of lopinavir and ritonavir?](#)" for more information about serious side effects.

What is lopinavir and ritonavir?

Lopinavir and ritonavir is 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 is safe and effective in children under 14 days old.

Who should not take lopinavir and ritonavir?**Do not take lopinavir and ritonavir if you:**

- are allergic to lopinavir, ritonavir, or any of the ingredients in lopinavir and ritonavir. See the end of this Medication Guide for a complete list of ingredients in lopinavir and ritonavir.
- if you take any of the following medicines:
 - alfuzosin
 - apalutamide
 - ranolazine
 - dronedarone
 - colchicine, if you have kidney or liver problems.
 - rifampin
 - lurasidone
 - pimozide
 - ergot containing medicines including:
 - dihydroergotamine mesylate
 - ergotamine tartrate
 - methylergonovine
 - cisapride
 - elbasvir/grazoprevir
 - lovastatin
 - simvastatin
 - lomitapide
 - sildenafil (Revatio[®]), when used for the treatment of pulmonary arterial hypertension
 - triazolam
 - midazolam when taken by mouth
 - 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.

Before taking lopinavir and ritonavir, 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 or had pancreas problems.
- 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. Lopinavir and ritonavir may cause increased bleeding.
- are pregnant or plan to become pregnant. It is not known if lopinavir and ritonavir will harm your unborn baby.

- Lopinavir and ritonavir oral solution contains alcohol (ethanol) 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.
- Lopinavir and ritonavir 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.
- **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.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - 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. 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.

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 with other medicines. Your healthcare provider may need to change the dose of other medicines during treatment with lopinavir and ritonavir.

How should I take lopinavir and ritonavir?

- Take lopinavir and ritonavir every day exactly as prescribed by your healthcare provider.
- Stay under the care of your healthcare provider during treatment with lopinavir and ritonavir.
- 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.
- Lopinavir and ritonavir oral solution must be taken with food.
- If you are taking both didanosine and lopinavir and ritonavir:
 - Take didanosine either 1 hour before or 2 hours after taking lopinavir and ritonavir oral solution.
- If you are pregnant:
 - Avoid use of **lopinavir and ritonavir oral solution.**
- 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 (ethanol). 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.

- Talk with your healthcare provider if you plan to take or give lopinavir and ritonavir oral solution through a feeding tube. Lopinavir and ritonavir oral solution contains propylene glycol and alcohol (ethanol), and should not be used with certain feeding tubes.
- You may have a greater chance of getting diarrhea if you take lopinavir and ritonavir 1 time each day than if you take it 2 times each day.
- **Do not** miss a dose of lopinavir and ritonavir. This could make the virus harder to treat. If you forget to take lopinavir and ritonavir, 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 at one time.
- **If you or your child take more than the prescribed dose of lopinavir and ritonavir, call your healthcare provider or go to the nearest emergency room right away.**

What are the possible side effects of lopinavir and ritonavir?

Lopinavir and ritonavir can cause serious side effects, including:

- See [“What is the most important information I should know about lopinavir and ritonavir?”](#)
- **Diabetes and high blood sugar (hyperglycemia).** You may develop new or worsening diabetes or high blood sugar during treatment with lopinavir and ritonavir. Tell your healthcare provider if you get any of the following signs or symptoms:
 - urinate more often than usual
 - increased hunger or thirst
 - unusual weight loss
 - 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. Your healthcare provider should do blood tests to check your cholesterol and triglyceride levels before you start taking lopinavir and ritonavir 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 or similar medicines.
- **Skin rash, which can be severe,** can happen in people who take lopinavir and ritonavir. 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.
- **Kidney stones**

Common side effects of lopinavir and ritonavir include:

- diarrhea
- nausea
- vomiting
- increased fats in blood (triglycerides or cholesterol)

These are not all of the possible side effects of lopinavir and ritonavir. 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?

Lopinavir and ritonavir oral solution:

- Store lopinavir and ritonavir oral solution in a refrigerator, between 36°F to 46°F (2°C to 8°C). Lopinavir and ritonavir oral solution that is kept refrigerated may be used until the expiration date printed on the label.
- Lopinavir and ritonavir oral solution that is stored at room temperature (less than 77°F or 25°C) should be used within 2 months.
- Keep lopinavir and ritonavir away from high heat.
- Throw away any medicine that is out of date or that you no longer need.

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

General information about the safe and effective use of lopinavir and ritonavir.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lopinavir and ritonavir for a condition for which it was not prescribed. Do not give lopinavir and ritonavir 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 that is written for health professionals.

What are the ingredients in lopinavir and ritonavir?

Active ingredients: lopinavir and ritonavir

Inactive ingredients:

Lopinavir and ritonavir oral solution: bubble gum flavor, ethanol, glycerin, high fructose corn syrup, malic acid, polyoxyl 40 hydrogenated castor oil, povidone, propylene glycol, sodium hydroxide, sucralose, and water.

Lopinavir and ritonavir oral solution contains approximately 42% ethanol (a type of alcohol) and approximately 15% propylene glycol. See [“How should I take lopinavir and ritonavir?”](#)

For more information about lopinavir and ritonavir call 1-844-834-0530.

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INSTRUCTIONS FOR USE
Lopinavir and Ritonavir
(loe pin' a vir) (ri ton' na vir)
Oral Solution USP

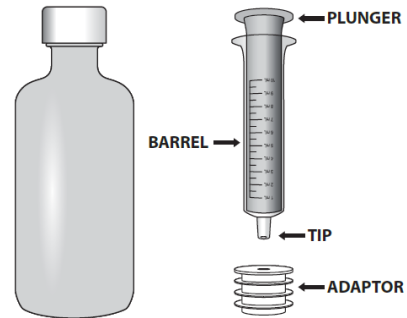
Read this Instructions for Use before you start taking lopinavir and ritonavir oral solution and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your doctor about your medical condition or treatment.

Important information about measuring lopinavir and ritonavir oral solution:


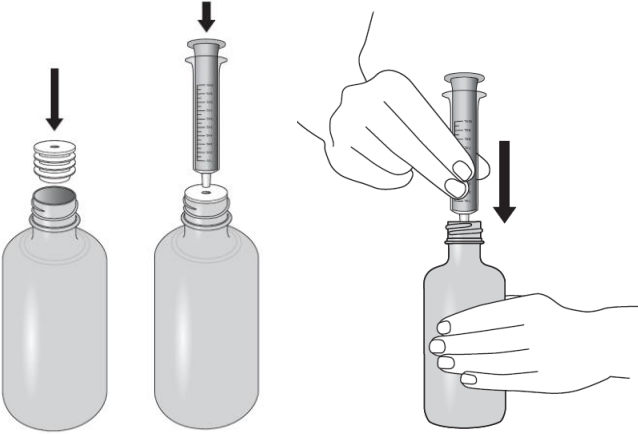
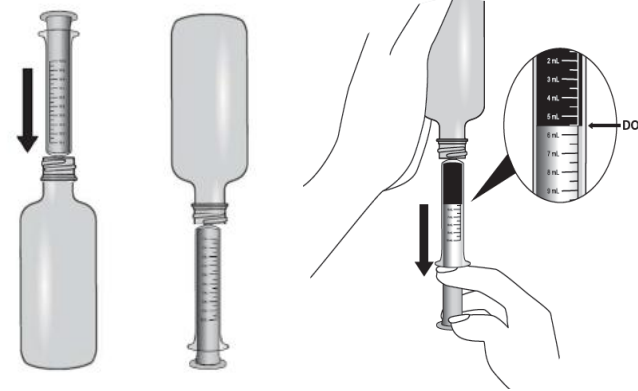
Always use the oral syringe that comes with your lopinavir and ritonavir oral solution to measure your prescribed dose. Ask your doctor or pharmacist to show you how to measure your prescribed dose.

Each lopinavir and ritonavir oral solution carton contains:

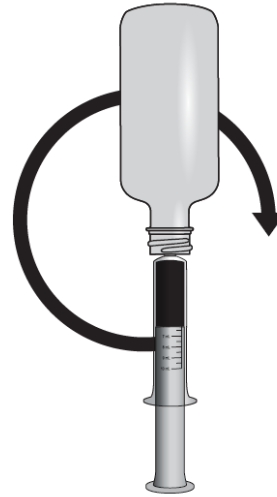
- 1 Lopinavir and Ritonavir Oral Solution bottle
- 1 Bottle adapter
- 1 Oral syringe
- 1 Prescribing Information
- 1 Medication Guide and Instructions for Use



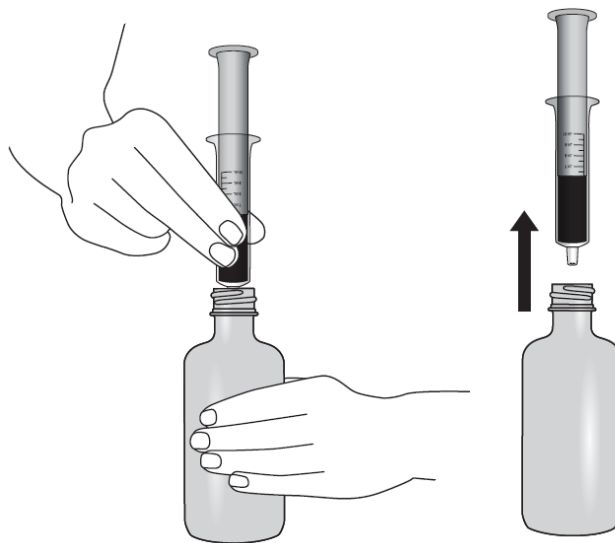
<p>Step 1: Remove the lopinavir and ritonavir oral solution bottle, bottle adapter, and oral syringe from the carton.</p> <p>Step 2: Open the bottle by pressing downward firmly on the child-resistant cap and twisting it in the direction of the arrow in the figure (counter-clockwise).</p> <p>Do not throw away the child-resistant cap.</p>	
<p>Step 3: Check the dose in milliliters (mL) as prescribed by your doctor. Find this number on the oral syringe.</p>	

<p>Step 4: Push the oral syringe plunger to the bottom of the barrel of the oral syringe (toward its tip) to remove excess air.</p>	
<p>Step 5: Remove bottle cap and insert bottle adapter into bottle opening.</p> <p>Insert the oral syringe tip into the upright bottle through the opening of the bottle adapter until it is firmly in place.</p>	
<p>Step 6: With the oral syringe in place, turn the bottle upside down. Pull the plunger to withdraw the dose prescribed by your doctor (the amount of oral solution in Step 3).</p> <p>If you see air bubbles in the oral syringe, fully push the plunger so that the oral solution flows back into the bottle. Then withdraw your prescribed dose of oral solution.</p>	

Step 7: Leave the oral syringe in the bottle adapter and turn the bottle to an upright position.



Step 8: Place the bottle on a flat surface. Remove the oral syringe from the bottle adapter and bottle by pulling straight up on the oral syringe.

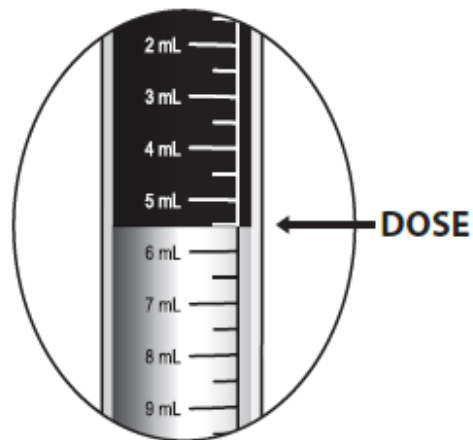


Step 9: Check that the correct dose was drawn up into the oral syringe.

Measure the dosage from the base of the plunger.

If the dose is not correct, insert the oral syringe tip firmly into the bottle adapter. Fully push in the plunger so that the oral solution flows back into the bottle.

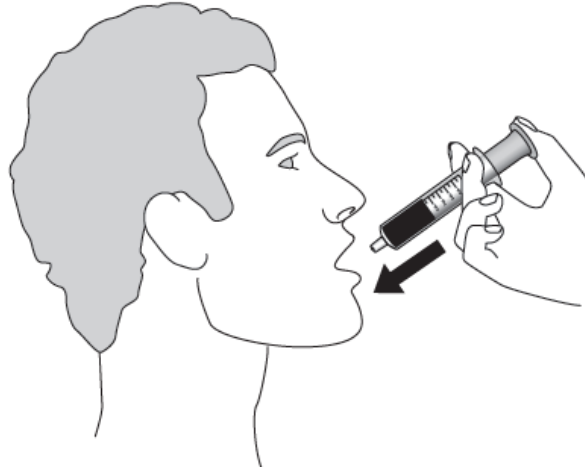
Repeat Steps 6 through 8, if required.



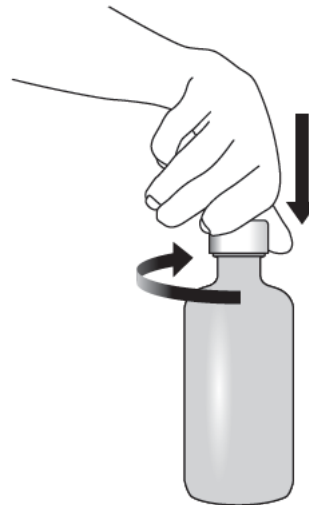
Step 10: Take the dose of lopinavir and ritonavir oral solution.

- Swallow the lopinavir and ritonavir oral solution directly from the oral syringe.
- Place the tip of the oral syringe in your mouth, point towards your cheek. Close your lips around the barrel of the oral syringe.
- Slowly push down the oral syringe plunger until the oral syringe is empty.

Note: There may be some medicine that remains in the tip of the oral syringe. No additional action is necessary to account for residual medication remaining in the tip.



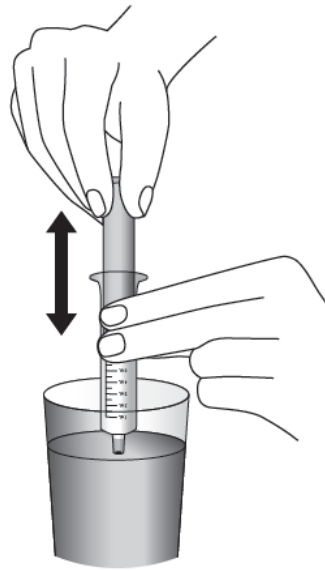
Step 11: Put the child-resistant cap back on the bottle. The cap will fit over the bottle adapter.



Step 12: Rinse the oral syringe with tap water after each use.

- Remove the plunger from the oral syringe barrel.
- Rinse the oral syringe barrel and plunger with water and let them air dry.
- When the oral syringe barrel and plunger are dry, put the plunger back into the oral syringe barrel for the next use.

Do not throw away the oral syringe.



How should I store lopinavir and ritonavir oral solution?

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- Lopinavir and ritonavir oral solution that is stored at room temperature (less than 77°F or 25°C) should be used within 2 months.
- Keep lopinavir and ritonavir oral solution away from high heat.

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