

LOPINAVIR/RITONAVIR

Other NAMES: Kaletra®

WHY is this drug prescribed?

Lopinavir is an antiretroviral (anti-HIV) drug that belongs to a class of drugs called **protease inhibitors**. Protease inhibitors interfere with a different step in virus reproduction than other classes of drugs previously available to fight HIV.

Lopinavir is used together with other antiretrovirals to delay the progression of HIV infection. By doing this, your immune system should improve (increase in CD4⁺ count) and you will be better protected against infections.

Lopinavir does not cure AIDS or completely kill the HIV virus, but helps to prevent further damage by slowing down the production of new viruses. Treatment with lopinavir does not reduce the risk of passing infection on to others. You will still be able to pass HIV by sexual contact, by blood transfer or by sharing needles. You should always use appropriate precautions to prevent passing HIV on to others.

HOW should this drug be taken?

Lopinavir is available in combination with a small dose of ritonavir, another protease inhibitor. It is currently available in 3 formulations:

- Yellow tablet. Each tablet contains 200 mg of lopinavir and 50 mg of ritonavir.
- Pale yellow tablet. Each tablet contains 100 mg of lopinavir and 25 mg of ritonavir.
- Light yellow to orange oral liquid solution. Each mL of solution contains 80 mg lopinavir and 20 mg ritonavir.

The usual dose is 400 mg lopinavir and 100 mg ritonavir twice daily, if you are a therapy-experienced patient. In cases where you have not been this class of drugs before, it may be given as 800 mg lopinavir and 200 mg ritonavir once daily. Your doctor may need to adjust this dose depending on other drugs you are taking.

Your dosage is:

YELLOW tablet (lopinavir 200 mg/
ritonavir 50 mg):

___ tablets (___mg) ___ times a day
with or without food.

Pale YELLOW tablet (lopinavir 100 mg
/ritonavir 25 mg):

___ tablets (___mg) ___ times a day
with or without food.

ORAL SOLUTION
(lopinavir 80mg /ritonavir
20 mg per mL):

___mL (___mg) ___times a day
WITH FOOD.

Kaletra™ tablets should be swallowed whole, and may be taken with OR without food.

Kaletra™ oral solution must be taken with food.

What should you do if you FORGET a dose?

If you miss a dose of lopinavir, take it as soon as possible. However, if it is time for your next dose, do not double the dose, just carry on with your regular schedule.

Why should you not forget to take this drug?

If you miss doses of lopinavir, the amount of HIV virus in your blood (known as the viral load) will start increasing again and your immune system will be further damaged. A few missed doses

can be enough for lopinavir to stop being active. A phenomenon known as **resistance**. When this happens, other antiretrovirals that work in a similar way as lopinavir may also become inactive. **Therefore, missing doses of lopinavir can decrease treatment options for the future.** Even if you do not feel well, you should always take your doses of lopinavir. Please do not stop lopinavir without talking to your doctor first.

What ADVERSE EFFECTS can this drug cause? What should you do about them?

Most adverse effects reported with lopinavir / ritonavir are mild and may include diarrhea, loose stools, nausea, headache, weakness and rash. If these effects occur and bother you, please call the clinic or discuss them at your next visit.

Regular blood tests will be done to detect any changes in your liver or pancreas function. Also, your doctor will look for increases in your cholesterol, triglyceride and blood sugar level.

The long-term effects of lopinavir are unknown at this time. Further studies are being carried out. Abnormal weight gain or changes in body shape have been reported, but it is uncertain if lopinavir / ritonavir are responsible for these changes.

It is important that you keep your doctor appointments and come for your laboratory tests so that your progress can be followed.

What other PRECAUTIONS should you follow while using this drug?

You must make sure that you are taking the right dose. If you take higher doses of lopinavir than what is prescribed, you may increase the chance of having adverse effects. If you take lower doses of lopinavir than what is prescribed, the HIV virus may become resistant to lopinavir.

Certain drugs can increase or decrease the effect of lopinavir. Also, lopinavir and ritonavir might influence the effect of other drugs you are taking. Inform your doctor and pharmacist of all prescribed and non-prescribed drugs you are taking. As well, you should inform them of natural products you are taking. If you wish to start a new drug or natural product, please consult with your pharmacist before doing so.

Do NOT take the following medications with lopinavir / ritonavir:

- Astemizole (Hismanal®)
- Ergot derivatives [Ergotamine (Cafergot®, Bellergal®, Ergodryl™, Gravergol®), ergonovine, dihydroergotamine (Migranal®), methylergonovine (Methergine®)]
- HMG CoA Reductase Inhibitors (statins) [Mevacor™, Zocor™]
- Midazolam (Versed®)
- Pimozide (Orap®)
- Rifampin (e.g. Rifadin®, Rimactane®, Rofact™)
- Triazolam (Halcion®)
- St. John's Wort

The efficacy of birth control pills or other hormones used to prevent becoming pregnant may decrease if you are taking lopinavir / ritonavir. A second method of contraception should **always** be used. In general, even if you are not taking lopinavir / ritonavir, the use of condoms is always recommended to decrease the risk of passing HIV on to others.

The safety of lopinavir has not been established during pregnancy. Please inform your doctor if you are pregnant. Your doctor can recommend the appropriate treatment to help reduce the risk of passing the HIV virus on to your baby. Breastfeeding is NOT recommended if you have HIV as you can transmit the virus to your baby through your breast milk.

How should this drug be STORED?

Lopinavir/ritonavir TABLETS should be stored in a cool (15 - 25°C) dry place, protected from light and well out of the reach of children. Ensure that the drug has not expired by checking the expiry date ("EXP") shown on the outside of the package.

Lopinavir/ritonavir ORAL SOLUTION should be stored at (2°C - 8°C) until dispensed. Avoid exposure to excessive heat. If stored at room temperature up to 25°C, oral solution should be used within 42 days.

Do not store where there is heat and moisture (for example, in the bathroom or near the stove) as the drug may become less active.

If you have any questions or concerns about this drug or if you are experiencing adverse effects, please discuss them with your pharmacist, doctor or nurse.

Write questions or concerns down to ensure they are addressed.

The following pharmacist is available to answer questions:

Pharmacist: _____

Telephone: _____

Reference: Product Monograph Kaletra® (lopinavir / ritonavir). Saint-Laurent, QC, Canada: Abbott Laboratories Ltd, 2008. Prepared by the Ontario HIV Pharmacy Professional Specialty Group, 2009.

Additional medication fact sheets and updates may be found at: www.hivclinic.ca

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RITONAVIR***

(Kaletra®)

MEDICATION

FACT SHEET