

LOPINA VIR/RITONAVIR MYLAN

Lopinavir/Ritonavir film coated tablet 100/25mg, 200/50mg



What is in this leaflet

Please read this leaflet carefully before you start taking Lopinavir/Ritonavir Mylan.

This leaflet answers some common questions about Lopinavir/Ritonavir Mylan.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lopinavir/Ritonavir Mylan against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Lopinavir/Ritonavir Mylan is used for

Lopinavir/Ritonavir Mylan is used to treat

- HIV-1 infection, in combination with other antiretroviral agents in adults and children aged 2 years and older

Lopinavir/Ritonavir Mylan contains the active ingredients lopinavir and ritonavir. It belongs to a group of medicines called protease inhibitors.

It works by producing an immature, non-infectious virus and slows down

the spread of the infection in your body.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take Lopinavir/Ritonavir Mylan

When you must not take it

Do not take Lopinavir/Ritonavir Mylan if you have an allergy to:

- any medicine containing lopinavir or ritonavir.
- any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Lopinavir/Ritonavir Mylan if you have severe liver problems.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in Lopinavir/Ritonavir Mylan passes into breast milk and there is a

possibility that your baby may be affected.

Do not give this medicine to a child under the age of 2 years. Safety and effectiveness in children younger than 2 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not take Lopinavir/Ritonavir Mylan with any of the following medicines:

- Alfuzosin hydrochloride (used to treat enlarged prostate gland in men)
- Apalutamide (used to treat prostate cancer)
- Ranolazine (used to treat angina)
- Dronedarone (used to treat irregular heartbeat)
- Fusidic acid (an antibiotic)
- Colchicine (used to treat gout) if you have kidney and/or liver problems
- Astemizole or terfenadine (used to treat allergies)
- Blonanserin, lurasidone or pimozide (used to treat certain psychological and emotional conditions)
- Midazolam or triazolam (used to relieve anxiety and/or trouble sleeping)
- Ergotamine or dihydroergotamine (used to treat migraine and headache)
- Ergometrine or methylergometrine (used to stop excessive bleeding that may occur following childbirth or an abortion)
- Cisapride (used to relieve certain stomach problems)

- Products containing St John's Wort (*hypericum perforatum*)
- Elbasvir/grazoprevir (used to treat hepatitis C infection)
- Lomitapide, lovastatin or simvastatin (used to reduce blood cholesterol levels)
- Neratinib (used to treat breast cancer)
- Salmeterol (used to treat asthma)
- Sildenafil (used to treat pulmonary arterial hypertension or erectile dysfunction)

If you are currently taking any of these medicines, ask your doctor about switching to another medicine while you are taking Lopinavir/Ritonavir Mylan.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Lopinavir/Ritonavir Mylan is not a cure for HIV infection or AIDS.

People taking Lopinavir/Ritonavir Mylan may still develop infections or other illnesses associated with HIV disease and AIDS. It is therefore important that you remain under the supervision of your doctor while taking Lopinavir/Ritonavir Mylan.

Lopinavir/Ritonavir Mylan does not reduce the risk of passing HIV to others. Appropriate precaution should be taken to prevent passing the disease through sexual contact (e.g. use of a condom) or blood contamination.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Haemophilia, as Lopinavir/Ritonavir Mylan might increase the risk of bleeding.
- Diabetes, as increased blood sugars have been reported in patients receiving

Lopinavir/Ritonavir Mylan. Your doctor may recommend routine monitoring of your blood sugar levels.

- A history of liver problems. Regular blood tests may be required to check that your liver is working properly.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Pregnant or breastfeeding mothers should not take Lopinavir/Ritonavir Mylan unless specifically directed by their doctor.

It is recommended that HIV-infected women do not breastfeed their infants because there is a possibility that the baby can be infected with HIV through breast milk. Your doctor will discuss the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Lopinavir/Ritonavir Mylan.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Lopinavir/Ritonavir Mylan.

Some medicines may interfere with Lopinavir/Ritonavir Mylan. These include:

- Medicines used to treat chronic pain (e.g. fentanyl)
- Antibiotics (e.g. rifabutin, rifampicin, clarithromycin, metronidazole, bedaquiline, delamanid)
- Medicines used to treat parasites (e.g. atovaquone)
- Medicines used to treat psychiatric disorders (e.g. quetiapine)

- Medicines used to treat cancer (e.g. abemaciclib, dasatinib, encorafenib, ibrutinib, ivosidenib, nilotinib, venetoclax, vincristine, vinblastine)
- Medicines used to treat depression (e.g. trazodone, bupropion)
- Medicines used to treat epileptic seizures (e.g. carbamazepine, lamotrigine, phenytoin, phenobarbital, valproate)
- Medicines used to treat fungal infections (e.g. ketoconazole, itraconazole, voriconazole)
- Medicines used to treat gout (e.g. colchicine)
- Medicines used to treat erectile dysfunction (e.g. sildenafil, avanafil, tadalafil, vardenafil)
- Medicines used to treat heart conditions (e.g. digoxin, calcium channel blockers including felodipine, nifedipine, nicardipine, and medicines used to correct heart rhythm including amiodarone, bepridil, lignocaine, quinidine)
- Certain other medicines used to treat HIV (e.g. maraviroc, efavirenz, nevirapine, delavirdine, rilpivirine, etravirine, amprenavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir, zidovudine, abacavir, tenofovir, tenofovir)
- Medicines used to treat hepatitis C infection (e.g. boceprevir, glecaprevir/pibrentasvir, ombitasvir/paritaprevir/ritonavir and dasabuvir, sofosbuvir/velpatasvir/voxilaprevir, simeprevir, telaprevir)
- Medicines used to lower blood cholesterol levels (e.g. atorvastatin, rosuvastatin)
- Medicines affecting the immune system (e.g. ciclosporin, siroimus (rapamycin), tacrolimus)
- Medicines used to help stop smoking (bupropion)
- Morphine-like medicines (e.g. methadone)
- Medicines used to treat alcohol dependences (e.g. disulfiram)
- Oral contraceptive or a patch contraceptive to prevent pregnancy (see section below titled Contraceptives)
- Steroids (e.g. budesonide, dexamethasone, fluticasone,

propionate, triamcinolone, ethinyloestradiol)

- Medicines used to open blood vessels to treat high blood pressure (e.g. bosentan)
- Blood thinning medicines (e.g. warfarin, rivaroxaban)
- Medicines used to treat pain associated with endometriosis (e.g. elagolix)
- Medicines used for low blood platelet count (fostamatinib)

Read the list of medicines under ‘Do not take Lopinavir/Ritonavir Mylan with any of the following medicines’ for information on medicines that you must not take with Lopinavir/Ritonavir Mylan.

Other interactions

Erectile dysfunction medicines (vardenafil, avanafil, sildenafil, tadalafil)

If you take sildenafil, tadalafil or vardenafil and Lopinavir/Ritonavir Mylan together, you may be at risk of side effects such as low blood pressure, passing out, visual changes and penile erection lasting more than 4 hours.

If an erection lasts longer than 4 hours, you should get medical help immediately to avoid permanent damage to your penis. Your doctor can explain these symptoms to you.

You must not take Lopinavir/Ritonavir Mylan with sildenafil if you also suffer from pulmonary arterial hypertension.

Contraceptives

If you are currently using an oral contraceptive or using a patch contraceptive to prevent pregnancy, you should use an additional or different type of contraception (e.g. condom) as Lopinavir/Ritonavir Mylan may reduce the effectiveness of oral and patch contraceptives

Lopinavir/Ritonavir Mylan does not reduce the risk of passing HIV to others. Appropriate precautions (e.g. use of a condom) should be taken to prevent passing on the disease through sexual contact.

Check with your doctor or pharmacist who will have a complete list of medicines that interfere with Lopinavir/Ritonavir Mylan.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Lopinavir/Ritonavir Mylan

Take Lopinavir/Ritonavir Mylan only as prescribed by your doctor.

Lopinavir/Ritonavir Mylan may be prescribed in combination with other appropriate medicines. Your doctor will tell you how much to take and when to take it.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual adult dose is 400 mg/100 mg (two 200 mg/50 mg tablets) twice a day i.e. every 12 hours in combination with other anti-HIV medicines.

Adult patients can also take Lopinavir/Ritonavir Mylan once daily as an 800 mg/200 mg dose (four 200 mg/50 mg tablets).

Lopinavir/Ritonavir Mylan should not be taken once daily with efavirenz, nevirapine, nelfinavir, amprenavir, carbamazepine, phenobarbital and phenytoin.

Lopinavir/Ritonavir Mylan should not be given to children once daily on its own.

For children, your doctor will decide the right dose of 100 mg/25 mg

tablets based on the child’s height and weight.

How to take it

Swallow the tablets whole with a full glass of water.

It is important that Lopinavir/Ritonavir Mylan tablets are swallowed whole and not chewed, broken or crushed.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Lopinavir/Ritonavir Mylan helps control HIV infection but does not cure it. You may continue to develop infections or other illnesses associated with HIV disease while you are taking Lopinavir/Ritonavir Mylan. Therefore, Lopinavir/Ritonavir Mylan must be taken every day.

Do not stop or change the daily dose of Lopinavir/Ritonavir Mylan without first consulting with your doctor.

Lopinavir/Ritonavir Mylan should always be taken every day to help control your HIV infection, no matter how much better you feel.

Using Lopinavir/Ritonavir Mylan as recommended should give you the best chance of delaying the development of resistance to this medicine.

If a side effect is preventing you from taking Lopinavir/Ritonavir Mylan as directed tell your doctor right away.

Always keep enough Lopinavir/Ritonavir Mylan on hand, so you don't run out.

When you travel or need to stay in the hospital make sure you will have enough Lopinavir/Ritonavir Mylan to last until you can get a new supply.

If you forget to take it

If it is almost time for you to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Lopinavir/Ritonavir Mylan

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Lopinavir/Ritonavir Mylan.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Lopinavir/Ritonavir Mylan to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not let yourself run out of medicine over weekends or on holidays.

Things to be careful of

Be careful driving or operating machinery until you know how Lopinavir/Ritonavir Mylan affects you.

Lopinavir/Ritonavir Mylan does not cause problems with your ability to drive a car or operate machinery. However, as with many medicines, Lopinavir/Ritonavir Mylan may cause dizziness, sleepiness and nausea in some people. Make sure you know how you react to Lopinavir/Ritonavir Mylan before you drive a car or operate machinery.

Be careful when drinking alcohol while you are taking this medicine.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much

Lopinavir/Ritonavir Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lopinavir/Ritonavir Mylan.

This medicine helps most people with HIV infection, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

It is very important to inform your doctor of any change in your condition.

Frequently, it is difficult to tell whether side effects are the result of taking Lopinavir/Ritonavir Mylan, effects of the HIV disease or side effects of other medicines you may be taking.

Your doctor may want to change your dose or advise you to stop taking Lopinavir/Ritonavir Mylan.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Diarrhoea
- Laboratory test results: changes in blood test results (such as blood chemistry and blood account, as well as increased levels of cholesterol, glucose, liver enzymes and triglycerides)
- Headache
- Difficulty in sleeping
- Lack of strength and energy
- Nausea, vomiting, abdominal pain, abnormal stools, indigestion, wind, problems with your digestive system
- Pain
- Rash, acne
- Tingling, prickling or numbness of the skin

The above list includes the more common side effects of your medicine.

They are usually mild and short-lived.

Further information about nausea, vomiting or abdominal pain

Tell your doctor if you experience nausea, vomiting or abdominal pain, as these may be suggestive of pancreatitis.

Tell your doctor as soon as possible if you notice any of the following:

- Nausea, vomiting, abdominal pain, difficulty breathing and severe weakness of the muscles in the legs and arms
- Thirst, frequent urination, blurred vision or weight loss
- Signs and symptoms of inflammation from previous infections soon after anti-HIV treatment is started
- Joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement
- Muscle pain, tenderness or weakness, particularly in

combination with these medicines.

- Kidney stones have also been reported following treatment with lopinavir/ritonavir.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Severe or life threatening skin reaction including blisters (Stevens Johnson syndrome or Toxic Epidermal Necrolysis);
- Serious allergic reaction (anaphylaxis)
- High levels of sugar in blood

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell while you are taking Lopinavir/Ritonavir Mylan.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Lopinavir/Ritonavir Mylan

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays at or below 25°C.

Do not store Lopinavir/Ritonavir Mylan or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Lopinavir/Ritonavir Mylan 100 mg/25 mg: White, film coated, ovaloid, biconvex bevelled edge tablet debossed with 'MLR4' on one side of the tablet and plain on the other side.

Lopinavir/Ritonavir Mylan 200 mg/50 mg: White, film coated, ovaloid, biconvex bevelled edge tablet debossed with 'MLR3' on one side of the tablet and plain on the other side.

Ingredients

Active ingredients:

Lopinavir/Ritonavir Mylan contains 100 mg/25 mg or 200 mg/50 mg of lopinavir/ritonavir as active ingredients.

Inactive ingredient(s):

Lopinavir/Ritonavir Mylan also contains:

- Copovidone
- Sorbitan Laurate
- Colloidal anhydrous silica
- Sodium stearyl fumarate
- Opadry white

Contains sulfites and sorbate.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Lopinavir/Ritonavir Mylan is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

05 December 2023
(Based on datasheet dated 05 December 2023)