

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lopinavir + Ritonavir Tablets 100mg +25mg

Lopinavir 100mg
Ritonavir 25mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Lopinavir/Ritonavir tablets 100 mg/25 mg is and what it is used for
2. Before you take Lopinavir/Ritonavir tablets 100 mg/25 mg
3. How to take Lopinavir/Ritonavir tablets 100 mg/25 mg
4. Possible side effects
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1. WHAT LOPINAVIR/RITONAVIR TABLETS 100 MG/25 MG IS AND WHAT IT IS USED FOR

Lopinavir/Ritonavir tablets 100 mg/25 mg is indicated for the treatment of human immunodeficiency virus (HIV). It inhibits the HIV protease enzyme, and thus helps control the HIV infection.

Lopinavir/Ritonavir tablets 100 mg/25 mg is for use by children who are infected with HIV, the virus that causes AIDS. The doctor has prescribed Lopinavir/Ritonavir tablets 100 mg/25 mg to help control your child's HIV infection. It will improve your child's immune system and reduce the risk of developing illnesses linked to HIV infection.

Lopinavir/Ritonavir tablets 100 mg/25 mg is prescribed for use in combination with other antiviral medicines. The doctor will determine which medicines are best for your child.

This product is intended for use in children. Safety information on use in adults is also provided.

2. BEFORE YOU TAKE LOPINAVIR/RITONAVIR TABLETS 100 MG/25 MG TABLETS

Your child should not be given Lopinavir/Ritonavir tablets 100 mg/25 mg:

- if he/she is hypersensitive (allergic) to lopinavir, ritonavir, or any of the other ingredients of Lopinavir/Ritonavir tablets 100 mg/25 mg
- if he/she has severe liver problems
- If he/she is taking any of the following medicines:
 - Amiodarone, bepridil, quinidine, propafenone, verapamil (drugs used to treat abnormal heartbeat)
 - Pimozide (used to treat schizophrenia)
 - Astemizole, terfenadine (used to treat allergy symptoms)
 - Cisapride (used to relieve certain stomach problems)
 - Triazolam, clorazepate, diazepam, estazolam, flurazepam, oral midazolam (sedatives, used to treat anxiety)
 - Ergotamine, dihydroergotamine, ergonovine, methylergonovine (used to treat migraine headaches)
 - Simvastatin and lovastatin (used to lower blood cholesterol)
 - Rifampicin (used for the treatment of tuberculosis)
 - Halofantrine (used for the treatment of malaria)
 - Fentanyl, propoxiphene, meperidine (opiate analgesics, used against pain)
 - Vardenafil (used to treat erectile dysfunction)
 - St John's Wort (herbal remedy against anxiety and depression)

If your child is currently taking any of these medicines, ask your doctor about switching to another medicine while you are taking Lopinavir/Ritonavir tablets 100 mg/25 mg.

Take special care with Lopinavir/Ritonavir tablets 100 mg/25 mg

This medicine helps to control the condition, but it is not a cure for HIV infection. Your child may continue to develop other infections and other illnesses associated with HIV disease (e.g. opportunistic infections). These will require specific and sometimes preventive treatment. You should keep in regular contact with your child's doctor or health care provider. Do not stop the medicine without first talking to the doctor or health care provider.

Lopinavir/Ritonavir tablets 100 mg/25 mg does not eliminate the risk of passing HIV to others through sexual contact or contamination with blood. Appropriate precautions (e.g. use of condom) should be taken to prevent passing on the disease to others.

It is important that your doctor or health care provider knows about all your child's symptoms even when you think they are not related to HIV infection.

Please speak to the doctor or health care provider if your child has a history of liver disease. Patients with chronic hepatitis B or C that are treated with antiretroviral agents

such as Lopinavir/Ritonavir tablets 100 mg/25 mg are at an increased risk for severe and potentially fatal liver adverse reactions, and may require blood tests to monitor liver function.

If your child has haemophilia (a disorder of blood coagulation), Lopinavir/Ritonavir tablets 100 mg/25 mg may cause increased bleeding. If this happens, you should contact your doctor or health care provider.

Inform your doctor if you have elevated blood cholesterol. Treatment with Lopinavir/Ritonavir tablets 100 mg/25 mg may increase blood cholesterol and other blood lipids.

Therefore, you may require blood tests for monitoring.

In rare cases, patients receiving lopinavir and ritonavir (contained in Lopinavir/Ritonavir tablets 100 mg/25 mg) have developed pancreatitis (inflammation of the pancreas). You should contact your doctor or health care provider if your child gets symptoms such as abdominal pain, nausea and vomiting, which may be due to pancreatitis.

You should inform your doctor if your child has diabetes. Treatment with HIV protease inhibitors like Lopinavir/Ritonavir tablets 100 mg/25 mg has been reported to occasionally cause or aggravate diabetes.

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infection that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor or health care provider immediately.

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue). So far, this disease has been reported mainly in adults. Your risk of developing this disease may be higher, e.g. when your immune system is severely compromised or when you drink alcohol regularly.

However, if your child notices joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement, inform your doctor or health care provider.

On rare occasions Lopinavir/Ritonavir tablets 100 mg/25 mg may affect the heart rhythm. If your child has or has had any heart problems, you should inform your doctor prior to taking Lopinavir/Ritonavir tablets 100 mg/25 mg.

Lopinavir/Ritonavir tablets 100 mg/25 mg may interact with other medications, which may alter their effects. Prior to taking Lopinavir/Ritonavir tablets 100 mg/25 mg, you should inform your doctor or health care provider about all other medications that your child is taking. While taking Lopinavir/Ritonavir tablets 100 mg/25 mg your child should not start any new medications without informing the doctor.

If you are taking an oral contraceptive or using a patch contraceptive to prevent pregnancy, you should use an additional or different type of contraception (e.g. barrier contraceptives such as condoms) since Lopinavir/Ritonavir tablets 100 mg/25 mg may reduce the effectiveness of oral and patch contraceptives.

Lopinavir/Ritonavir tablets 100 mg/25 mg may interact with erectile dysfunction agents (e.g. sildenafil, tadalafil, vardenafil). One should never take vardenafil together with Lopinavir/Ritonavir tablets 100 mg/25 mg. If one is taking sildenafil or tadalafil together with Lopinavir/Ritonavir tablets 100 mg/25 mg, talk to your doctor or health care provider about possible interactions with other medicines and side effects.

Tell your doctor if your child is taking corticosteroids such as dexamethasone, prednisolone or fluticasone. This includes use of nasal or oral inhalators against rhinitis and asthma. Lopinavir/Ritonavir tablets 100 mg/25 mg may raise the blood levels of these drugs and cause serious side effect (Cushing's syndrome with hypertension, diabetes, a rounded face, loss of fat on arms and legs as well as a reduction in the body's production of the hormone cortisol). Your child's doctor may wish to reduce the steroid dose or monitor the side effects more closely.

Taking other medicines

It is important that you tell your child's doctor, health care provider or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Lopinavir/Ritonavir tablets 100 mg/25 mg, or Lopinavir/Ritonavir tablets 100 mg/25 mg may affect their action.

Side effects of either medicine may become worse and/or the medicines may become less effective. Sometimes your doctor may decide to adjust the dose of Lopinavir/Ritonavir tablets 100 mg/25 mg or of the other drug.

Examples of drugs that are or may be unsuitable to take together with Lopinavir/Ritonavir tablets 100 mg/25 mg, or where dose adjustments may be necessary, include:

Efavirenz (against HIV)

Rifampicin, rifabutin (against tuberculosis)

Chlarithromycin, erythromycin (against bacterial infections)

Voriconazole, itraconazole, ketokonazole (against fungal infections)

Atovaquone, halofantrine, quinine, chloroquine (against malaria)

Methadone, fentanyl, propoxiphene, meperidine (opiate analgetics, to treat severe pain)

Amiodarone, bepridil, quinidine, propafenone, digoxin, verapamil (against abnormal heartbeat)

Theophylline (to treat asthma)

Ifosfamide, vincristine, vinblastine, etoposide (to treat cancer)

Warfarin (to prevent blood clots)

Carbamazepine, phenytoin, lamotrigine, phenobarbital (to treat seizures)

Trazodone, bupropion (against depression)

Pimozide, clozapine (against schizophrenia)

Astemizole, terfenadine (against allergies)

Diltiazem, amlodipine, felodipine, nifedipine, nicardipine (calcium channel blockers, to treat high blood pressure)

Simvastatin, lovastatin, atorvastatin, rosuvastatin (to lower blood cholesterol)

Cyclosporine A, tacrolimus, sirolimus (to reduce the body's immune response, e.g. after organ transplantation)

Ethinylestradiol, norethindrone (contraceptives)

Sildenafil, tadalafil, vardenafil (to treat erectile dysfunction (male "impotence"))

Triazolam, clorazepate, diazepam, estazolam, flurazepam, midazolam, alprazolam (sedatives, used to treat anxiety and to help you sleep)

Fluticasone, prednisolone (corticosteroids, for the treatment of inflammations and other diseases, such as asthma or rheumatoid arthritis)

Alfuzosine (against prostate enlargement)

Dihydroergotamine, ergonovine, ergotamine, methylergoline (to treat migraine headaches)

Cisapride (against some stomach problems)

St John's wort (herbal remedy used against anxiety and depression)

Taking Lopinavir/Ritonavir tablets 100 mg/25 mg with food and drink

Lopinavir/Ritonavir tablets 100 mg/25 mg may be taken with or without food.

Pregnancy and breast-feeding

Pregnant or breast-feeding women should not take Lopinavir/Ritonavir tablets 100 mg/25 mg unless specifically directed by the doctor. The doctor should be told immediately if one is or may be pregnant.

If a mother wants to breastfeed her baby, her doctor or healthcare provider should be asked for advice on the risks and benefits. Treatment of mother and/or child with medicines may be needed. Generally it is recommended that HIV-infected women should not breast-feed their infants because of the possibility that the baby may be infected with HIV through the breast milk.

Driving and using machines

Lopinavir/Ritonavir tablets 100 mg/25 mg may cause side effects such as drowsiness or headache that can impair the patient's ability to drive and to use machines.

3. HOW TO TAKE LOPINAVIR/RITONAVIR TABLETS 100 MG/25 MG

Lopinavir/Ritonavir tablets 100 mg/25 mg should always be given exactly as described by the doctor or health care provider. You should check with the prescribing doctor, health care provider or pharmacist if you are not sure.

Children weighing 10 kg or more:

The usual dose depends on the body weight as detailed in the table below.

Body Weight	Number of tablets	
	morning	evening
10-13.9 kg	2	1
14-19.9 kg	2	2
20-24.9 kg	3	2
25-34.9 kg	3	3

The prescribing doctor or health care provider may adjust the dose in case of co-treatment e.g. with certain other anti-HIV drugs.

Children weighing less than 10 kg:

Lopinavir/Ritonavir tablets 100 mg/25 mg is not recommended for use in children weighing less than 10 kg.

Children weighing 35 kg or more, adolescents and adults:

For these patient groups other fixed-dose formulations with higher amounts of the active substances are available.

Take each dose of Lopinavir/Ritonavir tablets 100 mg/25 mg approximately 12 hours apart. Lopinavir/Ritonavir tablets 100 mg/25 mg tablets should be swallowed whole and not chewed, broken or crushed.

Swallow Lopinavir/Ritonavir tablets 100 mg/25 mg with water or another drink.

Lopinavir/Ritonavir tablets 100 mg/25 mg can be taken with or without food.

If your child takes more Lopinavir/Ritonavir tablets 100 mg/25 mg than you should

If your child has taken too many tablets or if someone accidentally swallows some, there is no immediate danger. However, you should contact your child's doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to give Lopinavir/Ritonavir tablets 100 mg/25 mg

If you accidentally miss a dose and notice within 6 hours have the child take the missed dose as soon as possible.

The next regular dose should be taken as scheduled. If you notice later, then simply have the child take his/her normal dose when the next one is due. Do not give a double dose to make up for forgotten individual doses.

If your child stops taking Lopinavir/Ritonavir tablets 100 mg/25 mg

Because the medicine controls and does not cure the condition, your child will normally need to take it continuously. The treatment should not be stopped unless your child's doctor or health care provider tells you so.

Using Lopinavir/Ritonavir tablets 100 mg/25 mg as directed should give the best chance to avoid the development of resistance of the virus to the product. If a side effect is preventing your child from taking Lopinavir/Ritonavir tablets 100 mg/25 mg as directed, tell your child's doctor right away.

If you have any further questions on the use of this product, ask your doctor or health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lopinavir/Ritonavir tablets 100 mg/25 mg can cause side effects, although not everybody gets them. When treating HIV infection, it is not always possible to differentiate between unwanted effects caused by Lopinavir/Ritonavir tablets 100 mg/25 mg and those caused by any other medicines you may be taking at the same time, and by the HIV disease. For this reason, it is important that you inform your doctor or health care provider of any change in your child's health.

The side effects listed below were reported mainly in studies with adults. In children, the nature of the side effects is similar to that seen in adults.

VERY COMMON side effects (affects more than 1 user in 10):

- Diarrhoea;
- Abnormalities in the following blood tests: - Increased cholesterol (a form of fat)
- Increased triglycerides (a form of fat)
- Increased GGT (a type of liver enzyme)

Further information about increased cholesterol and triglycerides:

The long-term risks for complications such as heart attacks or stroke due to increased triglycerides and cholesterol are not known at this time.

Your doctor will monitor your child and may prescribe other medicines if needed.

Large increases in the amount of triglycerides (fats in the blood) have been considered a risk factor for pancreatitis.

COMMON side effects (affects 1 to 10 users in 100):

- Changes in body shape due to changes in fat distribution (redistribution, accumulation or loss of body fat). These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump'). The cause and long-term health effects of these conditions are not known at this time. Tell your doctor or health care provider if you notice any changes in your child's body shape due to changes in fat distribution.
- Headache
- Difficulty in sleeping;
- Lack of strength and energy;
- Nausea, vomiting, abdominal pain. Tell your doctor or health care provider if your child experience these side effects, as they may be suggestive of pancreatitis.
- Abnormal stools, upset stomach, flatulence
- Taste perversion
- Pain
- Fever
- Rash, acne
- Tingling, prickling or numbness of the skin.
- Abnormalities in the following blood tests: - Increased glucose
 - Increased amylase (a digestive enzyme)
 - abnormal liver function tests

UNCOMMON side effects (affects 1 to 10 users in 1,000):

- Low number of red blood cells, low number of white blood cells. If the number of red blood cells is reduced one may have symptoms of tiredness or breathlessness and a reduction in the child's white blood cell count can make him/her more prone to infections.
- Enlargement of the lymph nodes
- A sound in one ear or both ears, such as buzzing, ringing or whistling
- Abnormal vision, eye disorder
- Feeling the heart racing, 'skipping a beat' or pounding, heart attack, swelling and/or fluid accumulation in the lungs (lung oedema)
- Enlarged abdomen, constipation, dry mouth, difficulty swallowing, inflammation of the small and large intestine, burping, inflammation of the food pipe, inability to control your bowels, inflammation of the stomach and intestine, bloody diarrhoea, mouth ulcerations, inflammation of the pancreas; inflammation of a salivary gland, inflammation in the mouth, mouth ulcer, inflammation of the gums
- Chest pain, chills, fever, flu-like symptoms, accumulation of fluid in one's legs or around the ankles (oedema).
- Lack of functioning of the testes, Cushing syndrome (a condition caused by high levels of cortisol in the blood), under-function of the thyroid
- Inflammation of the middle ear, inflammation of the bronchi, inflammation of the sinuses, recurring boils, bacterial infection, viral infection
- Decreased glucose tolerance, weight gain, weight loss, increased bilirubin (a bile pigment), hormone level altered.
- Kidney stones, urine abnormality, albumin in the urine, high levels of calcium in the urine, excess uric acid in the blood
- Inflammation of the gall bladder, inflammation of the liver, enlarged liver, fatty deposits in the liver, liver tenderness
- vitamin deficiency, dehydration, accumulation of fluid in the cells or tissues, increased appetite, excess lactic acid in the blood, obesity, anorexia, diabetes mellitus, high glucose in the blood, low cholesterol in the blood
- Painful joints, inflammation in the joints, muscle pain, back pain, joint disorder
- Dizziness, loss or impairment of memory, loss in the ability to co-ordinate muscular movement, degenerative brain disease, loss of power of voluntary movement in the facial muscles, increased muscle tension, disease or abnormality of the nervous system, damage to nerves of the peripheral nervous system, sleepiness, tremor, altered sense of taste, migraine, abnormal involuntary movements
- Abnormal dreams, agitation, anxiety, confusion, depression, impairment in the ability to control movements, emotional instability, decreased sexual desire, nervousness, abnormal thinking
- Abnormal ejaculation, breast enlargement, enlargement of male breasts, impotence, abnormally heavy or extended menstrual flow
- Shortness of breath, irritation and inflammation of the nose, increased cough
- Hair loss, dry skin, eczema, scaling of the skin, flat red rash with pimples or spots, nail disorder, itching, accumulation of scales of greasy skin, skin discoloration, skin ulcer, facial swelling, sweating, stretch marks

- Benign skin tumour, cyst
- High blood pressure, vein inflammation related to a blood clot, inflammation of the blood vessels, varicose vein, deep vein inflammation related to a blood clot, vascular disorder.

RARE side effects (affects 1 to 10 users in 10,000):

- Infection of the skin, inflammation of skin or hair pores, abscess around your rectal area;
- Enlarged spleen size
- Decreased appetite, decrease in blood phosphate levels
- Abnormally increased hearing, vertigo
- Atrioventricular block on an electrocardiogram
- Haemorrhoids
- Inflammation of small blood vessels
- Increased blood alkaline phosphatase levels
- Immune reconstitution syndrome.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor, health care provider or pharmacist as soon as possible.

5. HOW TO STORE LOPINAVIR/RITONAVIR TABLETS 100 MG/25 MG

Keep out of the reach and sight of children.

Do not store above 30°C. Store in the original container.

Do not use Lopinavir/Ritonavir tablets 100 mg/25 mg after the expiry date which is stated on the label, carton, and strip. The expiry date refers to the last day of that month.

Do not use Lopinavir/Ritonavir tablets 100 mg/25 mg if you notice broken or swollen tablets.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Lopinavir/Ritonavir tablets 100 mg/25 mg contains

The active ingredient is Lopinavir and Ritonavir

The other ingredients are:

Copovidone, Sorbitan Monolaurate, Colloidal Silicon Dioxide, Anhydrous Dibasic Calcium Phosphate, Colloidal Silicon Dioxide, Sodium Stearyl Fumarate, coloring agency contains, polyvinyl alcohol-part hydrolyzed, Titanium dioxide, Polyethylene Glycol, Talc, Iron oxide Yellow.

What Lopinavir/Ritonavir tablets 100 mg/25 mg looks like and contents of the pack

Pale yellow colored, capsule shaped, biconvex, film-coated tablets debossed with “M31” on one side and plain on other side.

60s Container Pack : 60 tablets packed in 75cc heavy weight HDPE container, 38 mm Child –resistant closure along with the pack insert.

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