KALETRA

TABLETS and ORAL SOLUTION

lopinavir and ritonavir

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Kaletra.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Kaletra against the benefits they expect it will have on 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 KALETRA IS USED FOR

Kaletra is used to help control Human Immunodeficiency Virus (HIV) infection in adults and children 2 years of age and older. Kaletra does this by slowing down the spread of the infection in the body.

Kaletra is an antiretroviral medicine. It belongs to a group of medicines called protease inhibitors.

Kaletra is prescribed for use in combination with other antiviral medicines. Your doctor will determine which medicines are best for you.

Kaletra is available only with a doctor's prescription.

Kaletra is not addictive.

BEFORE YOU TAKE KALETRA

When you must not take it

Do not take Kaletra if you have an allergy to:

- any medicine containing lopinavir and/or ritonavir
- any of the ingredients listed at the end of this leaflet

Some 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
- hives, rash or itching of the skin.

Do not take Kaletra if you have severe liver problems.

Do not take Kaletra if you are pregnant.
If may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.
The active ingredient in Kaletra passes into breast milk and there is a possibility your baby may be affected.

Do not give Kaletra to a child under the age of 2 years.

Do not take Kaletra with any of the following medicines:

- alfuzosin hydrochloride (treatment of Benign Prostatic Hyperplasia in men);
- ranolazine to treat angina;
- dronedarone to correct heart rhythm;
- fusidic acid (an antibiotic);
- neratinib to treat breast cancer;
- apalutamide to treat prostate cancer;
- colchicine (a treatment for gout) if you have liver or kidney problems;
- astemizole or terfenadine (these antihistamine medicines may be available without prescription);
- blonanserin, lurasidone or pimozide (used to treat certain psychological and emotional conditions);
- midazolam or triazolam (used to relieve anxiety and/or trouble sleeping);
- ergotamine, dihydroergotamine, (used to treat migraine and headaches);
- ergometrine or ethylergometrine used to stop excessive bleeding that may occur following childbirth or an abortion;
- cisapride (used to relieve certain stomach problems);
- elbasvir/grazoprevir (used to treat hepatitis C infection);
- products that contain St John's Wort (Hypericum perforatum);
- lovastatin, simvastatin or lomitapide (used to reduce blood cholesterol levels);
- salmeterol (treatment for asthma);
- sildenafil if you suffer from a lung disease called pulmonary arterial hypertension that makes breathing difficult. Patients without this disease may use

sildenafil for erectile dysfunction under their doctor's supervision.

Additionally, do not take Kaletra Oral Solution with the following medicines:

- disulfiram (used for alcohol dependency);
- metronidazole (used to treat infections by certain parasites)

Read the list of medicines under 'Taking other medicines' for information on certain other medicines which require special care.
If you are currently taking any of these medicines, ask your doctor about switching to another medicine while you are taking Kaletra.

Do not take it after the expiry date printed on the bottle or if the packaging is damaged or shows signs of tampering.
If it has expired or is damaged return it to your pharmacist for disposal.

Important information

Take special care to keep all of your doctor's appointments

Kaletra is not a cure for HIV infection or AIDS.

People taking Kaletra 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 Kaletra.

Kaletra does not reduce the risk of passing HIV to others. Appropriate precautions 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 or pharmacist if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if any of the ingredients listed at the end of the leaflet concern you.

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

- Haemophilia, as Kaletra might increase the risk of bleeding.
- Diabetes, as increased blood sugars have been reported in patients receiving Kaletra.
- A history of liver problems - regular blood tests may be required to check that your liver is working properly.

Tell your doctor or pharmacist if you are pregnant, intend to become pregnant or are breastfeeding.
Pregnant or breastfeeding mothers should not take Kaletra 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 or pharmacist about any of the above, tell them before you take Kaletra.

Taking other medicines

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

Some medicines and Kaletra may interfere with each other. These include:

- medicines used to treat chronic pain (e.g. fentanyl);
- antibiotics (e.g. rifabutin, rifampicin, bedaquiline, delamanid, clarithromycin, metronidazole);
- 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);
- medicine used to treat low platelet count (e.g. fostamatinib);
- 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);
- erectile dysfunction medicines (e.g. sildenafil, tadalafil and vardenafil);
- medicines used to treat heart conditions (eg digoxin; calcium channel antagonists including felodipine, nifedipine, nicardipine; and medicines used to correct heart rhythm including amiodarone, bepridil, systemic lignocaine, quinidine);
- antiretroviral medicines in the CCR5 class, used to treat HIV (e.g. maraviroc);
- medicines used to lower blood cholesterol (e.g. atorvastatin or rosuvastatin);
- medicines affecting the immune system (e.g. ciclosporin, sirolimus (rapamycin), tacrolimus);
- medicines used for smoking cessation (e.g. bupropion);
- morphine-like medicines (e.g. methadone);
- medicines used in alcohol dependence (e.g. disulfiram);
- antiretroviral medicines known as non-nucleoside reverse transcriptase inhibitors used to treat HIV (e.g. efavirenz, nevirapine, delavirdine, rilpivirine, etravirine);
- oral contraceptives or using a patch contraceptive to prevent pregnancy (see section below titled Contraceptives);

- antiretroviral medicines known as protease inhibitors used to treat HIV (e.g. amprenavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir);
- medicines used to treat hepatitis C infection (e.g. telaprevir, boceprevir, simeprevir, ombitasvir/paritaprevir/ritonavir and dasabuvir, glecaprevir/ pibrentasvir, sofosbuvir/ velpatasvir/voxilaprevir);
- 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 (eg warfarin, rivaroxaban).

Read the list of medicines under 'Do not take Kaletra with any of the following medicines' for information on medicines that you must not take with Kaletra.

Other interactions
Kaletra oral solution contains 42% v/v alcohol. While taking Kaletra oral solution you should not take medicines that cause a reaction with alcohol such as disulfiram or metronidazole.

If you are taking didanosine while taking Kaletra oral solution, it should be taken one hour before or two hours after taking Kaletra oral solution, remembering that Kaletra should be taken with food.

Erectile dysfunction medicines (vardenafil, sildenafil, tadalafil)
If you take sildenafil, tadalafil or vardenafil and Kaletra 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 Kaletra 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 Kaletra may reduce the effectiveness of oral and patch contraceptives.

Kaletra 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.

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

HOW TO TAKE KALETRA

Take Kaletra only as prescribed by your doctor.

Kaletra 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 and pharmacist carefully.
They may differ from the information contained in this leaflet.

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

How much to take and when to take it

The usual adult dose is 400mg/100mg (two 200mg/50mg tablets) or 5mL of the oral solution twice a day i.e. every 12 hours in combination with other anti-HIV medicines.

Adult patients can also take Kaletra tablets once daily as an 800mg/200mg dose (four 200mg/50mg tablets) or 10mL of the oral solution once daily.

Kaletra should not be taken once daily with efavirenz, nevirapine, nelfinavir, amprenavir, carbamazepine, phenobarbital and phenytoin.

Kaletra should not be given to children once daily on its own.

For children, your doctor will decide the right dose of oral solution or 100mg/25mg tablets based on the child's height and weight.

Kaletra oral solution can also be used for patients who cannot take tablets.

Take Kaletra at about the same time each day.
This will have the best effect on the HIV infection. It will also help you remember when to take your medicine.

How to take it

Tablets

Swallow the tablets whole with a full glass of water.
It is important that Kaletra tablets are swallowed whole and not chewed, broken or crushed.

Kaletra tablets can be taken with or without food.

Oral Solution

Kaletra is recommended for use in adults and children 2 years of age or older who are infected with HIV.

Take care when dosing children. Dosing should be less than 5mL twice daily for children weighing less than 40kg.

Kaletra oral solution should preferably be taken with meals.

This syringe is the only syringe you should use to measure your dose.
The oral solution dosage syringe has been specially designed to give you the right dose of Kaletra.

Open the childproof cap by pushing down on it with your palm and twisting it counter clockwise, i.e. in the direction of the arrow. Talk to your pharmacist if you have difficulty opening the bottle.

Five dosing syringes are included in each carton of Kaletra oral solution. Ask your pharmacist for instructions on how to use the syringe correctly.

After each dose of Kaletra separate the plunger and the syringe. Wash the plunger and the syringe with dish washing liquid and warm water as soon as you can; you may soak both in soapy water for up to 15 minutes.

Rinse the syringe and plunger with clean water. Put the syringes back together and draw up and expel tap water a few times to rinse. Let the syringe dry completely before you use that syringe for dosing.

How long to take it for

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

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

Do not stop or change the daily dose of Kaletra without first consulting with your doctor.

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

Using Kaletra as recommended should give you the best chance of delaying the development of resistance to this medicine.

Always keep enough Kaletra on hand so you don't run out.
When you travel or need to stay in the hospital make sure you will have enough Kaletra 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 getting an unwanted side effect.

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

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

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (Australia: Telephone - 13 11 26; New Zealand: Telephone - 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Kaletra. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep telephone numbers for these places/services handy.

WHILE YOU ARE TAKING KALETRA

Things you must do

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Kaletra.

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 that you are taking this medicine.

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 use this medicine to treat any other complaints unless your doctor tells you to.

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

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 Kaletra affects you.
Kaletra generally does not cause problems with your ability to drive a car or operate machinery. However, as with many medicines, Kaletra may cause dizziness, sleepiness and nausea in some people.

Make sure you know how you react to Kaletra before you drive a car or operate machinery.

SIDE EFFECTS

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

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.

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 Kaletra, 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 Kaletra.

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

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 count, 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.

The following side effects have also been reported:

- kidney stones

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.

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 and Toxic Epidermal Necrolysis)
- serious allergic reaction (anaphylaxis)
- high levels of sugar in the blood

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

Tell your doctor or pharmacist as soon as possible if you notice anything that is making you feel unwell while you are taking Kaletra.

Other side effects not listed above may also occur in some patients.

Ask your doctor or pharmacist for more information about side effects, as they have a more complete list of side effects.

Inform your doctor promptly about these or any other symptoms.

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

AFTER USING KALETRA

Storage

Keep your tablets and solution in the bottle until it is time to take them.
If you take the tablets or oral solution out of the bottle they may not keep well.

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.

Tablets in bottle
Kaletra tablets should be stored in a cool, dry place below 30°C and should be used within the expiry date shown on the bottle.

Oral Solution in bottle
Store at 2°C - 8°C (in a refrigerator). Use within the expiry date.

Refrigeration of Kaletra oral solution by the patient is not required if used within 42 days after dispensing and if the oral solution is not stored above 25°C. Avoid exposure to excessive heat.

Do not use after the expiry date stated on the pack.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.
Heat and dampness can destroy some medicines.

Disposal

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

PRODUCT DESCRIPTION

Kaletra comes in two dosage forms.

Tablets

Kaletra 200mg/50 mg tablets come in bottles containing 120 tablets.

Kaletra 100mg/25 mg tablets come in bottles containing 60 tablets.

Oral Solution

Kaletra oral solution comes in a multiple-dose 60 mL amber bottle. Five bottles of 60 mL are provided in one package.

Ingredients

200/50mg Tablets

Each tablet of Kaletra contains 200 mg of lopinavir and 50mg of ritonavir.

The other ingredients are:

- copovidone
- sorbitan monolaurate
- colloidal anhydrous silica
- sodium stearylfumarate.

The film coating components are:

- hypromellose
- titanium dioxide
- macrogol 400
- hyprolose
- talc
- colloidal anhydrous silica
- macrogol 3350
- iron oxide yellow CI 77492
- polysorbate 80

100/25 mg Tablets

Each tablet of Kaletra contains 100 mg of lopinavir and 25 mg of ritonavir.

The other ingredients are:

- copovidone
- sorbitan monolaurate
- colloidal anhydrous silica
- sodium stearylfumarate

The film coating components are:

- polyvinyl alcohol
- titanium dioxide
- talc
- macrogol 3350
- iron oxide yellow CI 77492

Oral Solution

Each mL of Kaletra contains 80 mg of lopinavir and 20 mg of ritonavir.

The other ingredients are:

- ethanol
- high fructose corn syrup
- propylene glycol
- purified water
- glycerol
- povidone
- Magnasweet-110 flavour (mixture of monoammonium glycyrrhizinate and glycerol)
- vanilla flavour
- PEG 40 hydrogenated castor oil
- cotton candy flavour
- acesulfame potassium
- saccharin sodium
- sodium chloride
- peppermint oil
- sodium citrate
- citric acid
- menthol

Sponsor

Kaletra is distributed by:

AbbVie Pty Ltd
241 O'Riordan Street
Mascot NSW 2020
Phone: 1800 225 311
(ABN 48 156 384 262)

AbbVie Limited
6th Floor, 156-158 Victoria St
Wellington, 6011
New Zealand

Australian registration numbers

Kaletra 200mg/50mg Tablets bottle - AUST R 121055

Kaletra 100mg/25mg Tablets bottle - AUST R 140509

Kaletra Oral Solution - AUST R 78627

Date of Preparation:

July 2020