KALETRA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking Kaletra?

Kaletra contains the active ingredients lopinavir and ritonavir. Kaletra is used to treat HIV (Human Immunodeficiency Virus) infection.
For more information, see Section 1. Why am I taking Kaletra? in the full CMI.

2. What should I know before I take Kaletra?

Check the list of ingredients at the end of the CMI. Do not take Kaletra if you have ever had an allergic reaction to any of them.
Talk to your doctor before you take this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I take Kaletra? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Kaletra and affect how it works, or Kaletra may interfere with other medicines and affect how they work.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Kaletra?

- Tablets for patients 35 kg and over: Take two (200 mg/50 mg) tablets together in the morning and two tablets together in the evening every day, unless your doctor advises otherwise.
- Oral Solution for patients 35 kg and over: Take 5 mL in the morning and in the evening every day, unless your doctor advises otherwise.
- Oral Solution for Children less than 40kg: The dose is calculated based on weight. Your doctor will advise the appropriate dose.

More instructions can be found in Section 4. How do I take Kaletra? in the full CMI.

5. What should I know while taking Kaletra?

Things you should do	• Call your doctor straightaway if you become pregnant while taking Kaletra • If you have diabetes, monitor your sugar levels regularly • Remind any doctor, dentist or pharmacist you visit that you are taking Kaletra.
Things you should not do	• Do not stop taking this medicine or change the dose unless your doctor tells you to • Do not give this medicine to a child younger than 2 years of age.
Driving or using machines	• There is no specific information on the effect of Kaletra on your ability to drive or use machines.
Drinking alcohol	• Tell your doctor if you drink alcohol, especially if you are taking Kaletra Oral Solution.
Looking after your medicine	• Kaletra Tablets should be kept in a cool dry place. • Kaletra Oral Solution should be kept in the refrigerator.

For more information, see Section 5. What should I know while taking Kaletra? in the full CMI.

6. Are there any side effects?

Go to your nearest hospital if you experience: a sudden, intense skin reaction; symptoms of an allergic reaction, such as difficulty breathing, swelling of the face, lips or tongue, hives, rash or itching; or very high sugar levels in the blood.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

KALETRA® (ka-lee-tra)

Active ingredient(s): *lopinavir* (loh-pin-a-veer) *and ritonavir* (rit-on-a-veer)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Kaletra. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Kaletra.**

Where to find information in this leaflet:

1. Why am I taking Kaletra?
2. What should I know before I take Kaletra?
3. What if I am taking other medicines?
4. How do I take Kaletra?
5. What should I know while taking Kaletra?
6. Are there any side effects?
7. Product details

1. Why am I taking Kaletra?

Kaletra contains the active ingredients lopinavir and ritonavir.

Kaletra is used to treat HIV (Human Immunodeficiency Virus) infection, the virus that causes AIDS.

2. What should I know before I take Kaletra?

Warnings

Do not take Kaletra Tablets or oral solution if:

- you are allergic to lopinavir or ritonavir, or any of the ingredients listed at the end of this leaflet
- you have or have had liver problems, including Hepatitis B or Hepatitis C
- you have kidney problems.

Do not take Kaletra Oral Solution if you are pregnant.

Do not give Kaletra Oral Solution to children younger than 2 years of age.

Check with your doctor if you:

- have diabetes
- have or have had problems with your heart, such as irregular heart beats
- you have high cholesterol or high triglycerides (a type of fat found in the blood)
- you have or have had had any problems with your pancreas
- you have haemophilia (a bleeding disorder)
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed.

Elderly

The use of Kaletra in patients older than 65 years is limited.

Children

Kaletra Oral Solution is suitable for use in HIV-infected children older than 2 years of age.

3. What if I am taking other medicines?

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

Some medicines may interfere with Kaletra and affect how it works, while Kaletra may affect how other medicines work.

Do not take Kaletra if you are taking any of the following medicines:

- **alfuzosin**, a medicine used to treat an increase in the size of the prostate gland (not due to cancer)
- **ranolazine**, a medicine used to treat angina
- **dronedarone**, a medicine used to treat certain heart conditions
- **fusidic acid**, a medicine used to treat infections caused by bacteria (antibiotic)
- **neratinib, apalutamide**, medicines used to treat certain cancers
- **colchicine**, a medicine used to treat gout. This is particularly important if you have problems with your liver or kidneys
- **astemizole, terfenadine**, medicines available over the counter to treat allergies (antihistamines)
- **blonanserin, lurasidone, pimozide**, medicines used to treat certain mental and emotional conditions
- **midazolam, triazolam**, medicines that work in the brain used to help you sleep
- **ergotamine, dihydroergotamine, ergometrine, methylergometrine**, medicines used to treat migraines and headaches, and/or in childbirth
- **cisapride**, a medicine to treat reflux or indigestion
- **St John's Wort**, a herbal product used to improve mood
- **elbasvir, grazoprevir**, medicines used to treat hepatitis C
- **lovastatin, simvastatin, lomitapide**, medicines used to lower cholesterol

- **salmeterol**, a medicine used to treat severe lung conditions, including asthma and chronic obstructive pulmonary disease (COPD)
- **sildenafil**, when used to treat high blood pressure in the lungs.
- suzetrigine, used to treat pain.

Do not take the following medicines if you are taking Kaletra Oral Solution specifically:

- **disulfiram**, a medicine used to treat alcohol dependency, or
- **metronidazole**, a medicine used to treat serious infections caused by bacteria and parasites.

Medicines that may <u>increase</u> the effect of Kaletra include:

- delavirdine, a medicine used to treat HIV.

Medicines that may <u>reduce</u> the effect of Kaletra include:

- efavirenz, amprenavir, nevirapine, fosamprenavir, tipranavir and nelfinavir, medicines used to treat HIV infection
- apalutamide, a medicine used to treat prostate cancer (*See the above list of medicines to avoid while taking Kaletra.)*
- phenytoin, carbamazepine or phenobarbital, medicines used to treat epilepsy to prevent convulsions, fits
- St John's Wort, a herbal product used to improve mood (*See the above list of medicines to avoid while taking Kaletra*)
- bosentan, a medicine used to treat high blood pressure in the lungs
- rifampicin, a medicine used to treat tuberculosis and other serious infections
- dexamethasone, steroids used in various conditions where there is inflammation
- boceprevir, a medicine used to treat hepatitis C

Medicines where Kaletra may <u>increase</u> their effect include:

- blonanserin, lurasidone, pimozide, medicines used to treat certain mental and emotional conditions (*See the above list of medicines to avoid while taking Kaletra*.)
- tenofavir, a medicine used to treat HIV and hepatitis B
- rilpivirine, amprenavir, maraviroc, saquinavir and indinavir, medicines used to treat HIV
- alfuzosin, a medicine used to treat an increase in the size of the prostate gland, not due to cancer (*See the above list of medicines to avoid while taking Kaletra*)
- fusidic acid, a medicine used to treat infections caused by bacteria (antibiotic) (*See the above list of medicines to avoid while taking Kaletra.*)
- fentanyl, a medicine used to treat strong and/or chronic pain
- ranolazine, a medicine used to treat angina (*See the above list of medicines to avoid while taking Kaletra*.)
- dronedarone, a medicine used to treat certain heart conditions. (*See the above list of medicines to avoid while taking Kaletra*.)
- amiodarone, digoxin and quinidine, medicines used to treat certain heart conditions.)
- bepridil, felodipine, nifedipine, and nicardipine, medicines that causes blood vessels to relax and widen which improves oxygen supply to the heart, and lowers blood pressure
- lignocaine, a medicine used to treat irregular heart beats
- clarithromycin, a medicine used to treat infections caused by bacteria (antibiotic)
- abemaciclib, a medicine used to treat breast cancer
- fostamatinib, dasatinib, nilotinib, ivosidenib ibrutinib and venetoclax, medicines used to treat certain types of blood cancers
- apalutamide, a medicine used to treat prostate cancer (*See the above list of medicines to avoid while taking Kaletra*.)
- encorafenib, a medicine used to treat melanoma, a type of skin cancer
- neratinib, a medicine used to treat breast cancer (*See the above list of medicines to avoid while taking Kaletra.*)
- vincristine and vinblastine, medicines used to treat several different cancers
- rivaroxaban and voropaxar, medicines used to prevent blood clots
- carbamazepine, a medicine used to treat epilepsy to prevent convulsions, fits
- trazodone, lurasidone, pimozide and quetiapine, medicines used to treat certain mental and emotional conditions
- ketoconazole and itraconazole, medicines used to treat or prevent fungal infections
- colchicine, a medicine used to treat gout (*See the above list of medicines to avoid while taking Kaletra*.)
- astemizole and terfenadine, medicines available over the counter to treat allergies (antihistamines) (*See the above list of medicines to avoid while taking Kaletra*.)
- bedaquiline, delamanid and rifabutin, medicines used to treat tuberculosis and other serious infections
- midazolam, triazolam, medicines that work in the brain used to help you sleep (*See the above list of medicines to avoid while taking Kaletra*.)
- salmeterol, a medicine used to treat severe lung conditions, including asthma and chronic obstructive pulmonary disease (COPD) (*See the above list of medicines to avoid while taking Kaletra*.)
- fluticasone, a steroid used to treat conditions of the nasal passages and asthma
- budesonide and triamcinolone, steroids used for various conditions where there is inflammation
- avanafil and vardenafil, medicines used to treat erectile dysfunction
- tadalafil and sildenafil, medicines used to treat high blood pressure in the lungs, and erectile dysfunction (*See the above list of medicines to avoid while taking Kaletra*.)
- ergotamine, dihydroergotamine, ergometrine and methylergometrine, medicines used to treat migraines

and headaches, and/or in childbirth (*See the above list of medicines to avoid while taking Kaletra*.)
- cisapride, a medicine to treat reflux or indigestion
- elbasvir, grazoprevir, medicines used to treat hepatitis C (*See the above list of medicines to avoid while taking Kaletra*.)
- dasabuvir, glecaprevir, paritaprevir, sofosbuvir, velpatasvir, voxilaprevir, simeprevir, ombitasvir, medicines used to treat hepatitis C
- ciclosporin, a medicine used for suppressing the immune system to treat various conditions
- sirolimus and tacrolimus, medicines used to help in organ transplants
- lovastatin, simvastatin, lomitapide, medicines used to lower cholesterol (*See the above list of medicines to avoid while taking Kaletra*.)
- atorvastatin and rosuvastatin, medicines used to lower cholesterol
- bosentan and riociguat, medicines used to treat high blood pressure in the lungs
- elagolix, a medicine used to treat pain associated with endometriosis in women.

Medicines where Kaletra may <u>reduce</u> their effect include:

- abacavir, zidovudine and etravirine, medicines used in the treatment of HIV
- bupropion, a medicine used to assist in giving up smoking cigarettes
- phenytoin, lamotrigine and sodium valproate, medicines used to treat epilepsy to prevent convulsions, fits
- voriconazole, a medicine used to treat or prevent fungal infections
- methadone, a medicine used to treat strong pain and to help with addiction to drugs like heroin
- ethinyloestradiol, a medicine used in certain contraceptive pills and hormone replacement therapies
- boceprevir and telaprevir, medicines used to treat hepatitis C, warfarin, medicines used to prevent blood clots
- atovaquone, a medicine used to treat and prevent malaria
- levothyroxine, a medicine used to treat an under-active thyroid.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Kaletra.

4. How do I take Kaletra?

How much to take

Tablets

Patients 35 kg and over:

- Take two (200 mg/50 mg) tablets in the morning and two tablets in the evening every day, unless your doctor advises otherwise.
- Do not break, crush or chew the tablets. Swallow them whole with a full glass of water.

Oral Solution

- **Patients 35 kg and over:** Take 5 mL in the morning and 5 mL in the evening every day, unless your doctor advises otherwise.
- **Children less than 40 kg:** The dose is calculated based on weight. Your doctor will advise the appropriate dose.
- Use the syringe supplied with the medicine to make sure the dose is accurate.
- Take Kaletra Oral Solution with a meal or immediately after a meal.

In some instances, Kaletra needs to be taken with other medicines. Your doctor will let you know which medicines, how to take them and how long to take them.

Follow all instructions given to you and use Kaletra until your doctor tells you to stop.

When to take Kaletra

Take Kaletra in the morning and evening every day for as long as your doctor tells you to.

Please look for the QR code on the medicine pack. Scan this code with your smart phone for more information on Kaletra.

If you forget to take Kaletra

It is important that you take Kaletra at the same time each day.

If you miss a dose take it as soon as possible, and then go back to taking it at your usual time.

If you miss your dose and it is time for you next dose, skip the missed tablets and take your next dose at your usual time.

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

If you take too much Kaletra

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appears to be no signs of discomfort or poisoning.

5. What should I know while taking Kaletra?

Things you should do

Speak to your doctor about how to avoid passing on HIV to others, even though you are taking Kaletra.

Call your doctor straight away if you:

- become pregnant while taking Kaletra
- are diabetic and your blood sugar levels are no longer controlled

Keep all appointments, including for blood tests. Some side effects are picked up in blood tests even before you have any symptoms.

If you are having any blood tests, tell the clinic you are taking Kaletra.

Remind any doctor, dentist or pharmacist you visit that you are taking Kaletra.

Things you should not do

- Do not stop using this medicine or change the dose without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Kaletra affects you.

Drinking alcohol

Tell your doctor if you drink alcohol, especially if you are taking Kaletra Oral Solution.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Store **Kaletra Tablets** in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

Store **Kaletra Oral Solution** in the refrigerator (at 2°C - 8°C).

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor advises that you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gut: • diarrhoea • feeling sick or vomiting • tummy pain • indigestion • wind **Brain and nerves:** • headache • difficulty sleeping **Skin:** • rash • tingling, prickling or numbness on the skin **General:** • feeling weak or tired • chills or fever	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
General: • Symptoms of a build-up of lactic acid in the body, including nausea, vomiting, pain in the tummy, difficulty breathing, severe weakness in the legs and arms • Symptoms of diabetes including feeling thirsty, needing to pass urine frequently, blurred vision, sudden loss of weight • symptoms of an infection, including fever, chills, a cold or flu, problems with your teeth or gums, pain when passing urine, blood in the urine • stiffness, aches and pains in the joints, especially the hip, knee or shoulder, and difficulty moving • sharp pain in the side or back, burning when passing urine, blood in the urine.	**Call your doctor straight away, if you notice any of these serious side effects.**

Very serious side effects

Very serious side effects	What to do
Skin: • a sudden, intense skin reaction **General:** • symptoms of very high sugar levels, including headache, blurred vision, confusion, needing to past urine frequently, nausea and vomiting, tummy pain • symptoms of a severe allergic reaction (anaphylaxis), including difficulty breathing, swelling of the face, lips, tongue or other parts of the body, hives, rash or itching of the skin.	**Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Kaletra (200 mg/ 50 mg) Tablets contains

Active ingredient (main ingredient)	• lopinavir • ritonavir
Other ingredients (inactive ingredients)	• copovidone • sorbitan monolaurate • colloidal anhydrous silica • hypromellose • sodium stearylfumarate • titanium dioxide • macrogol 400 • hyprolose • purified talc • colloidal anhydrous silica • macrogol 3350 • iron oxide red polysorbate 80.

What Kaletra Oral Solution contains

Active ingredient (main ingredient)	• lopinavir • ritonavir
Other ingredients (inactive ingredients)	• ethanol • high fructose maize syrup • propylene glycol • purified water • glycerol • povidone • Magnasweet-110 flavour • vanilla flavour • PEG 40 hydrogenated castor oil • cotton candy flavour • acesulfame potassium • saccharin sodium • sodium chloride • peppermint oil • sodium citrate • citric acid • menthol.

Do not take this medicine if you are allergic to any of these ingredients.

Kaletra does not contain gluten or lactose.

What Kaletra looks like

- **Kaletra 200 mg/50 mg Tablets** are red, oval, film-coated , debossed with the code 'AL' on one side.

  They are supplied in a plastic bottle containing 120 tablets. (Aust R 121055).

- **Kaletra Oral Solution** is a light yellow to golden clear liquid.

  It is supplied in a pack of 5 bottles of 60 mL each. (Aust R 78627).

(Not all presentations may be available)

Who distributes Kaletra?

Kaletra is distributed in Australia by:

AbbVie Pty Ltd

241 O'Riordan Street

MASCOT NSW 2020

Australia

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