KALETRA *lopinavir / Ritonavir*

(200mg tablets)

WHAT IS IN THIS LEAFLET

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

WHAT IS KALETRA USED FOR

- Your doctor has prescribed Kaletra to help control your Human Immunodeficiency Virus (HIV) infection. Kaletra does this by slowing down the spread of the infection in your body.
- Kaletra is used by children 2 years of age or older and adults who are infected with HIV, the virus which causes AIDS. Kaletra should not be administered to children younger than 2 years of age unless specifically directed by their doctor.
- 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 has <u>not</u> been shown to decrease the chance of transmitting HIV to a sexual partner. You must continue to use safe sexual practices (eg condoms) while taking Kaletra.
- Kaletra is available only with a doctor's prescription.
- Kaletra is not addictive.

BEFORE YOU TAKE KALETRA

Do <u>not</u> take Kaletra if

- you are allergic (hypersensitive) to lopinavir, ritonavir or any of the other ingredients of Kaletra.
- you have severe liver problems.
- the packaging is torn or shows signs of tampering.
- the expiry date printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

Do not take Kaletra with any of the following medicines:

- Astemizole or terfenadine (commonly used to treat allergy symptoms – these medicines may be available without prescription);
- Blonanserin (used to treat certain mental and emotional conditions);
- Midazolam, triazolam (used to relieve anxiety and/or trouble sleeping);
- Ergotamine, dihydroergotamine, ergometrine, methylergometrine (used to treat headaches);
- Cisapride (used to relieve certain stomach problems);
- Products that contain St John's Wort (Hypericum perforatum).

- Lovastatin or simvastatin (used to reduce blood cholesterol levels);
- Salmeterol (used to treat asthma);
- Pimozide (used to treat schizophrenia);
- Sildenafil (used to treat high blood pressure in the blood vessels in the lung)

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.

Take special care with Kaletra

Important information

- 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.

Tell your doctor if you have/had:

- Haemophilia type A and B 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 as patients with a history ofliver disease, including chronic hepatitis B or C are at increased risk of severe and potentially fatal liver side effects.

Taking other medicines

Kaletra can be taken with acid-reducing agents (such as omeprazole and ranitidine) with no dose adjustment.

Tell your doctor if you are taking any of the medicines listed below, as special care should then be taken:

- Analgesics (e.g. fentanyl);
- Antibiotics (e.g. rifabutin, rifampin, clarithromycin, metronidazole);
- Anticancer medicines (e.g. dasatinib, nilotinib, vincristine, vinblastine);
- Antidepressants (e.g. trazodone, bupropion);
- Anticonvulsant medicines (e.g. carbamazepine, phenytoin, phenobarbital); Antifungals (e.g. ketoconazole, itraconazole, voriconazole);
- Erectile dysfunction medicines (e.g. sildenafil, tadalafil and vardenafil);
- Heart medicines including:
  - Digoxin;
  - Calcium channel antagonists (e.g. felodipine, nifedipine, nicardipine);
  - Medicines used to correct heart rhythm (e.g. amiodarone, bepridil, systemic lignocaine, quinidine);
- Medicines used to lower blood cholesterol (e.g. atorvastatin or rosuvastatin);
- Medicines affecting the immune system (e.g. cyclosporin, 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);
- Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g. efavirenz, nevirapine);
- Oral contraceptive or using a patch contraceptive to prevent pregnancy (see section below titled Contraceptives);
- Protease inhibitors (e.g. amprenavir, indinavir, nelfinavir, ritonavir, saquinavir); Steroids (e.g. budesonide,

dexamethasone, fluticasone propionate, ethinyl oestradiol);
- Warfarin.

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 with your meal.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

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.

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.

Pregnancy and breastfeeding

- Tell you doctor immediately if you are
- pregnant, think you may be pregnant or if you 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 of taking Kaletra when breast-feeding.

HOW TO TAKE KALETRA

Kaletra may be prescribed in combination with other appropriate medicines. Your doctor will tell you how much to take and when to take it. Take Kaletra only when prescribed by your doctor.

How much Kaletra should be taken and when?

- 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 who have not previously taken other antiviral medicines 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.

- 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.

Carefully follow all directions given to you by your doctor. This may differ from the information contained in this leaflet.

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

How to take it

Tablets.

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.

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

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.

Can I stop taking Kaletra or change my dose?

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.

Continue taking Kaletra for as long as your doctor prescribes.

- Do not stop or change the daily dose of Kaletra without first consulting with your doctor.
- Using Kaletra 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 Kaletra as directed tell your doctor right away.
- 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 Kaletra

- 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.
- If you are not sure whether to skip the dose, talk to your doctor or pharmacist.
- Do not take a double dose to make up for the dose you missed.
- If you have trouble remembering to take your Kaletra, ask your pharmacist for some hints.

If you take too much Kaletra (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (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

- Use another or different type of contraception. If you are using oestrogen-based hormonal contraceptives, Kaletra may reduce the effectiveness of oral contraceptives.
- Tell your doctor if you become pregnant while taking Kaletra.
- You should not take medicines that cause a reaction with alcohol such as disulfiram while taking Kaletra oral solution.
- Tell your doctor or pharmacist that you are taking Kaletra if you are about to be started on any new medicine.
- Tell all the doctors, dentists, and pharmacists who are treating you that you are taking Kaletra.

Things you must not do

- Do not stop taking Kaletra or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over weekends or on holidays.
- Do not give this medicine to any one else, even if they have the same condition as you.

Things to be careful of

Kaletra has not specifically been tested for its possible effects on the ability to drive a car or operate machines. Do not drive a car or operate machinery if you experience any side effects (e.g. nausea) that impact your ability to do so safely. Instead, contact your doctor.

Kaletra oral solution contains 42% v/v alcohol.

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

Important information about some of the ingredients of Kaletra oral solution

Kaletra oral solution contains:

- 42% v/v alcohol. Each dose contains up to 1.7 g of alcohol. This may be potentially harmful for those suffering from liver disease, alcoholism, epilepsy, brain injury or disease as well as for pregnant women and children. May modify or increase the effect of other medicines.
- Up to 0.8 g of fructose per dose when taken according to the dosage recommendations. Kaletra oral solution is unsuitable in hereditary fructose intolerance. Due to the possibility of undetected fructose intolerance, this medicinal product should only be given to babies and infants after consultation with a physician.
- Glycerol, which is harmful in high doses. Can cause headache and stomach upset and diarrhoea.
- PEG 40 hydrogenated castor oil. This may cause nausea, vomiting, colic, severe purgation at high doses. It should not be given when intestinal obstruction is present.
- Potassium as acesulfame potassium, which may be harmful to people on a low potassium diet. High potassium in the

blood can cause stomach upset and diarrhoea.
- Sodium as saccharin sodium, sodium chloride and sodium citrate, which may be harmful to people on a low sodium diet.

POSSIBLE SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Kaletra.

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.

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. For this reason, it is very important to inform your doctor of any change in your condition. 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.

Some very common side effects when using Kaletra are:
- Diarrhoea;
- Increased cholesterol;
- Increased GGT (a type of liver enzyme);
- Increased triglycerides (a form of fat).

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 you 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.

Some common side effects of Kaletra are:
- Abnormal liver function tests;
- Changes in body shape due to changes in fat distribution;
- Headache;
- Increased glucose, increased amylase (a digestive enzyme), increased liver enzymes;
- 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.

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 if you experience:

- Nausea, vomiting, abdominal pain, difficulty breathing and severe weakness of the muscles in the legs and arms as these symptoms may indicate raised lactic acid levels.
- Thirst, frequent urination, blurred vision or weight loss as this may indicate raised sugar levels in the blood.
- Nausea, vomiting, abdominal pain as large increases in the amount of triglycerides (fats in the blood) have been considered a risk factor for pancreatitis (inflammation of the pancreas) and these symptoms may suggest this condition.

- **Changes in body shape** due to changes in fat distribution. 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.

- **Signs and symptoms of inflammation** from previous infections 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 infections that may have been present with no obvious symptoms.

- **Joint stiffness, aches and pains** (especially of the hip, knee and shoulder) and difficulty in movement as some patients taking these medicines may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression (reduction in the activity of the immune system), higher body mass index, among others, may be some of the many risk factors for developing this disease.

- **Muscle pain**, tenderness or weakness, particularly in combination with these medicines. On rare occasions these muscle disorders have been serious (rhabdomyolysis).

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. If the condition persists or worsens, seek medical attention.

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

Tell your doctor if you notice anything that is making you feel unwell.

AFTER USING KALETRA

Storage

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 below 30°C and should be used within the expiry date shown on the bottle.

Oral Solution

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.

It is important to keep Kaletra in the bottle it came in. Do not transfer it to any other container.

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

Disposal

- 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 protect the environment.

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
- Silica-colloidal anhydrous
- Sodium stearylfumarate

The film coating components are:

- Hypromellose
- Titanium dioxide
- Macrogol 400
- Hydroxypropylcellulose
- Talc,
- Silica-colloidal anhydrous
- 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
- Silica-colloidal anhydrous
- Sodium stearylfumarate.

The film coating components are:

- Polyvinyl alcohol
- Titanium dioxide
- Talc
- Macrogol 3350
- Iron oxide yellow CI 77492

Oral Liquid

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:

Australia

Abbott Australasia Pty Ltd
32-34 Lord Street
Botany NSW 2019
Phone: 1800 225 311
(ABN 95 000 180 389)

New Zealand

Abbott Laboratories (NZ) Ltd
4 Pacific Rise
Mt Wellington
Auckland
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

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