Package leaflet: Information for the user

Kaletra (80 mg + 20 mg) / ml oral solution
(lopinavir + ritonavir)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you or your child.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Kaletra is and what it is used for

- Your doctor has prescribed Kaletra to help to control your Human Immunodeficiency Virus (HIV) infection. Kaletra does this by slowing down the spread of the infection in your body.
- Kaletra is not a cure for HIV infection or AIDS.
- Kaletra is used by children 14 days of age and older, adolescents and adults who are infected with HIV, the virus which causes AIDS.
- Kaletra contains the active substances lopinavir and ritonavir. 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 discuss with you and determine which medicines are best for you.

2. What you need to know before you or your child takes Kaletra

Do not take Kaletra
- if you are allergic to lopinavir, ritonavir or any of the other ingredients of Kaletra (see section 6);
- if you have severe liver problems.

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);
- midazolam taken orally (taken by mouth), triazolam (used to relieve anxiety and/or trouble sleeping);
- pimozide (used to treat schizophrenia);
- quetiapine (used to treat schizophrenia, bipolar disorder and major depressive disorder);
- lurasidone (used to treat depression);
- ranolazine (used to treat chronic chest pain [angina]);
- cisapride (used to relieve certain stomach problems);
- ergotamine, dihydroergotamine, ergonovine, methylergonovine (used to treat headaches);
- amiodarone, dronedarone (used to treat abnormal heart beat);

- lovastatin, simvastatin (used to lower blood cholesterol);
- lomitapide (used to lower blood cholesterol);
- alfuzosin (used in men to treat symptoms of an enlarged prostate (benign prostatic hyperplasia (BPH));
- fusidic acid (used to treat skin infections caused by *Staphylococcus* bacteria such as impetigo and infected dermatitis). Fusidic acid used to treat long-term infections of the bones and joints may be taken under doctor's supervision (see **Other medicines and Kaletra** section);
- colchicine (used to treat gout) if you have kidney and/or liver problems (see the section on **Other medicines and Kaletra**);
- elbasvir/grazoprevir (used to treat chronic hepatitis C virus [HCV]);
- ombitasvir/paritaprevir/ritonavir with or without dasabuvir (used to treat chronic hepatitis C virus [HCV]);
- neratinib (used to treat breast cancer);
- avanafil or vardenafil (used to treat erectile dysfunction);
- sildenafil used to treat pulmonary arterial hypertension (high blood pressure in the pulmonary artery). Sildenafil used to treat erectile dysfunction may be taken under doctor's supervision (see **Other medicines and Kaletra** section);
- products that contain St John's wort (*Hypericum perforatum*).

Read the list of medicines below under 'Other medicines and Kaletra' for information on certain other medicines which require special care.

If you are currently taking any of these medicines, ask your doctor about making necessary changes either in the treatment for your other condition(s) or in your antiretroviral treatment.

Warnings and precautions

Talk to your doctor or pharmacist before taking Kaletra.

Important information

- 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.

Tell your doctor if you or your child have/had

- **Haemophilia** type A and B as Kaletra might increase the risk of bleeding.
- **Diabetes** as increased blood sugars has been reported in patients receiving Kaletra.
- A history of **liver problems** as patients with a history of liver disease, including chronic hepatitis B or C are at increased risk of severe and potentially fatal liver side effects.

Tell your doctor if you or your child 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.
- In some patients with advanced HIV infection and a history of opportunistic infection, 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 infections that may have been present with no obvious symptoms.

- In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.
- **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.
- Symptoms of dizziness, lightheadedness, fainting or sensation of abnormal heartbeats. Kaletra may cause changes in your heart rhythm and the electrical activity of your heart. These changes may be seen on an ECG (electrocardiogram).

Other medicines and Kaletra

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.
- antibiotics (e.g. rifabutin, rifampicin, clarithromycin);
- anticancer medicines (e.g. abemaciclib, afatinib, apalutamide, ceritinib, encorafenib, ibrutinib, venetoclax, most tyrosine kinases inhibitors such as dasatinib and nilotinib, also vincristine and vinblastine);
- anticoagulants (e.g. dabigatran etexilate, edoxaban, rivaroxaban, vorapaxar and Warfarin);
- antidepressants (e.g. trazodone, bupropion);
- anti-epilepsy medicines (e.g. carbamazepine, phenytoin, phenobarbital, lamotrigine and valproate);
- antifungals (e.g. ketoconazole, itraconazole, voriconazole);
- anti-gout medicines (e.g. colchicine). You must not take Kaletra with colchicine if you have kidney and/or liver problems (see also '**Do not take Kaletra**' above);
- anti-tuberculosis medicine (bedaquiline, delamanid);
- antiviral medicine used to treat chronic hepatitis C virus (HCV) infection in adults (e.g. glecaprevir/pibrentasvir, simeprevir and sofosbuvir/velpatasvir/voxilaprevir);
- erectile dysfunction medicines (e.g. sildenafil and tadalafil);
- fusidic acid used to treat long-term infections of the bones and joints (e.g. osteomyelitis);
- heart medicines including:
  - digoxin;
  - calcium channel antagonists (e.g. felodipine, nifedipine, nicardipine);
  - medicines used to correct heart rhythm (e.g. bepridil, systemic lidocaine, quinidine);
- HIV CCR5-antagonist (e.g. maraviroc);
- HIV-1 integrase inhibitor (e.g. raltegravir);
- medicines used to treat low blood platelet count (e.g. fostamatinib);
- levothyroxine (used to treat thyroid problems);
- medicines used to lower blood cholesterol (e.g. atorvastatin, lovastatin, rosuvastatin or simvastatin);
- medicines used to treat asthma and other lung-related problems such as chronic obstructive pulmonary disease (COPD) (e.g. salmeterol);
- medicines used to treat pulmonary arterial hypertension (high blood pressure in the pulmonary artery) (e.g. bosentan, riociguat, sildenafil, tadalafil);
- medicines affecting the immune system (e.g. cyclosporin, sirolimus (rapamycin), tacrolimus);
- medicines used for smoking cessation (e.g. bupropion);

- pain-relieving medicines (e.g. fentanyl);
- morphine-like medicines (e.g. methadone);
- oral contraceptive or using a patch contraceptive to prevent pregnancy (see section below titled **Contraceptives**);
- protease inhibitors (e.g. fosamprenavir, indinavir, ritonavir, saquinavir, tipranavir);
- sedatives (e.g. midazolam administered by injection);
- steroids (e.g. budesonide, dexamethasone, fluticasone propionate, ethinyl oestradiol, triamcinolone);
- medicines that cause a reaction with alcohol (e.g. disulfiram).

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

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

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

- **Do not take Kaletra** if you are currently taking avanafil or vardenafil.
- You must not take Kaletra with sildenafil used to treat pulmonary arterial hypertension (high blood pressure in the pulmonary artery) (see also **Do not take Kaletra** section above).
- If you take sildenafil or tadalafil 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.

Pregnancy and breast-feeding

- Tell your doctor **immediately** if you are planning to have a baby, you are pregnant or think you may be pregnant.
- If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.
- If you are pregnant or breastfeeding, talk to your doctor or pharmacist before taking this medicine because it contains propylene glycol and alcohol.
- It is recommended that women living with HIV do not breast-feed their infants because there is a possibility that the baby can be infected with HIV through your breast milk.

Driving or using machines

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 contains 42% v/v alcohol. The amount of alcohol in this medicine may affect your ability to drive or use machines and may affect your judgement and reaction times.

Important information about some of the ingredients of Kaletra

Kaletra contains 42% v/v alcohol and 15% propylene glycol w/v. Each 1 ml of Kaletra oral solution contains 356.3 mg of alcohol and 152.7 mg of propylene glycol. Alcohol and propylene glycol are

potentially harmful for those suffering from liver disease, kidney disease, alcoholism, epilepsy, brain injury or disease, as well as for pregnant women and children. They may modify or increase the effect of other medicines.

At the recommended adult dose(s) of this medicine, the estimated blood alcohol concentration in your body is about 0.002 - 0.01 g/dL. This is similar to an adult drinking 4-22 ml of beer or 1-4 ml of wine.

Other medicines may also contain alcohol and alcohol may be consumed in food and drinks. The combined effects may lead to increased blood alcohol levels and increase the side effects of alcohol.

This medicinal product contains up to 0.8 g of fructose per dose when taken according to the dosage recommendations. 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 doctor.

Kaletra contains glycerol which is harmful in high doses. Can cause headache and stomach upset and diarrhoea.

Kaletra contains polyoxyl 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.

Kaletra contains 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.

Kaletra contains sodium as saccharin sodium, sodium chloride and sodium citrate, which may be harmful to people on a low sodium diet.

Kaletra contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially 'sodium-free'.

3. How to take Kaletra

Kaletra is recommended for use in adults and children 14 days of age and older who are infected with HIV.
Take care when dosing children. Dosing should be less than 5 ml twice daily for children weighing less than 40 kg.

If you or your child is able to swallow tablets, Kaletra is also supplied as film-coated tablets containing 200 mg of lopinavir and 50 mg of ritonavir and film-coated tablets containing 100 mg of lopinavir and 25 mg of ritonavir.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure how you should take your medicine.

How much Kaletra should be taken and when?

For children 14 days and older and weighing up to 15 kg

- Your doctor will decide the right dose based on the child's height and weight.
- It is important that all doses of Kaletra oral solution are taken with food.
- Use the **2 ml** oral syringe provided to measure the dose.

For children weighing more than 15 kg

- Your doctor will decide the right dose based on the child's height and weight.

- It is important that all doses of Kaletra oral solution are taken with food.
- Use the **5 ml** oral syringe provided to measure the dose.

Use in adults

- The usual adult dose is 5 ml of the oral solution twice a day i.e. every 12 hours, in combination with other anti-HIV medicines. Your doctor will advise on the amount of Kaletra to be taken.
- It is important that all doses of Kaletra oral solution are taken with food.
- Use the **5 ml** oral syringe provided to measure the dose.

How do I measure the correct dose?

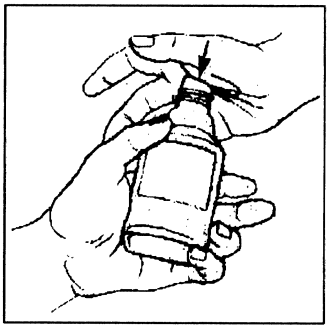
- If the dose is up to 2 ml - use the **2 ml** oral dosing syringe to prepare a dose.
- If the dose is between 2 ml and 5 ml - use the **5 ml** oral dosing syringe to prepare a dose.

Check with your pharmacist that you have the correct size of syringe. If you are not sure how to use the oral dosing syringe ask your doctor, pharmacist or nurse. They will tell you how to use the syringe correctly.

Before the first time you use the dosing syringe, wash the plunger and syringe in warm water and washing-up liquid. Rinse with clean water and allow to air dry.

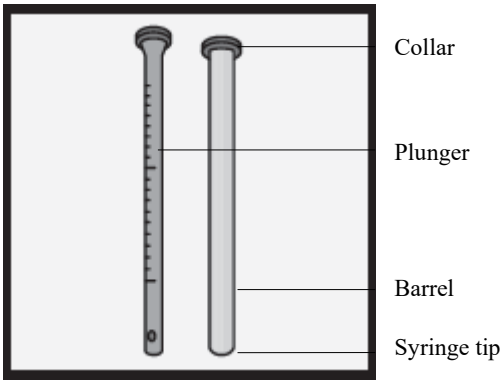
Do not shake the bottle – this is because air bubbles can form which will affect how well you can measure the dose.

Open the child-proof cap by pushing down on it with your palm and twisting it counter clockwise, or in the direction of the arrow on the top of the cap. Talk to your pharmacist if you have difficulty opening the bottle.

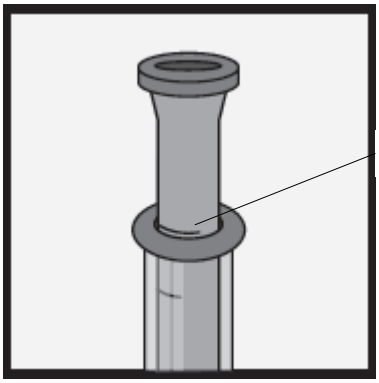


Using the 2 ml oral dosing syringe for doses up to 2 ml

The syringe has two main parts, a 'plunger' and a 'barrel'. In this picture we have pulled out the plunger so that you can see each part clearly.



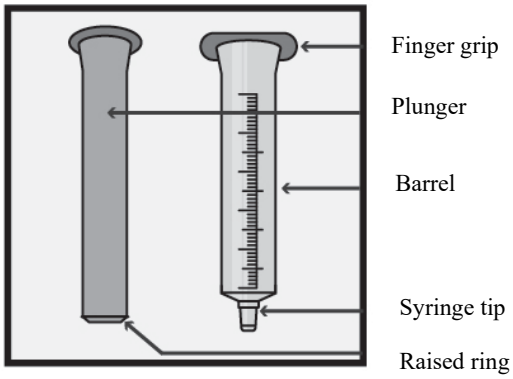
1. Push the plunger all of the way into the barrel.
2. Place the tip of the syringe into the liquid.
3. Pull up the plunger until the correct dose amount is shown on the plunger. You should see the 'ml' marking aligned to the top of the collar of the barrel.
4. Turn the syringe so that the tip is pointing up, gently tap it and push plunger to remove any air bubbles.
5. After removing the air bubbles, look at the dose mark.
   - If the 'ml' mark on the collar is more than the prescribed dose, push the plunger to the prescribed dose.
   - If the 'ml' mark on the collar is less than the prescribed dose, draw up more solution to the prescribed dose.
6. Place the dosing syringe in your child's mouth towards the cheek and gently push the plunger down to release the medicine.



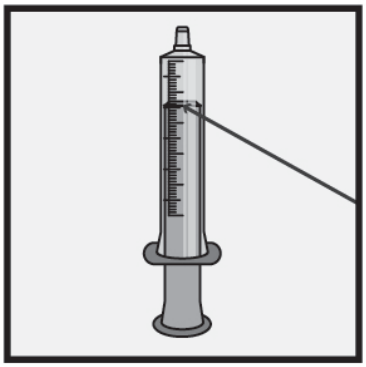
Replace the bottle cap after each dose.

Using the 5 ml oral dosing syringe for doses more than 2 ml

The syringe has two main parts, a 'plunger' and a 'barrel'. In this picture we have pulled out the plunger so that you can see each part clearly.



1. Push the plunger all of the way into the barrel.
2. Place the tip of the syringe into the liquid.
3. Pull up the plunger until the raised ring is on the correct dose 'ml' mark on the barrel.
4. Turn the syringe so that the tip is pointing up, gently tap it and push plunger to remove any air bubbles.
5. After removing the air bubbles, look at the dose mark.
   - If the 'ml' mark on the raised ring is more than the prescribed dose, push the plunger to the prescribed dose.
   - If the 'ml' mark on the raised ring is less than the prescribed dose, draw up more solution to the prescribed dose.



6. Place the dosing syringe in your child's mouth towards the cheek and gently push the plunger down to release the medicine.

Replace the bottle cap after each dose.

After each dose of Kaletra separate the plunger and the syringe. Wash the plunger and the syringe with washing up 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 syringe 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.

Do not use the dosing syringes supplied with Kaletra oral solution to administer any other medicines you or your child may be taking.

If you or your child take more Kaletra than you should

- If you realise you have taken more Kaletra than you were supposed to, contact your doctor right away.
- If you cannot contact your doctor, go to the hospital.

If you or your child forget to take Kaletra

– If you notice you miss a dose within 6 hours of your normal dosing time, take your missed dose as soon as possible, and then continue with your normal dose at the regular time as prescribed by your doctor.

– If you notice you miss a dose by more than 6 hours after your normal dosing time, do not take the missed dose. Take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you or your child stop taking Kaletra

- Do not stop or change the daily dose of Kaletra without first consulting with your doctor.
- Kaletra should always be taken twice every day to help control your HIV infection, no matter how much better you feel.
- Taking Kaletra as recommended should give you the best chance of delaying the development of resistance to the product.
- 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.
- Continue to take this medicine until your doctor tells you otherwise.

4. Possible side effects

Like all medicines, Kaletra can cause side effects, although not everybody gets them. It may be difficult to tell which side effects have been caused by Kaletra and which may occur due to other medicines you take at the same time or by the complications of the HIV infection.

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

The following side effects have been reported by patients who took this medicine. You should tell your doctor promptly about these or any other symptoms. If the condition persists or worsens, seek medical attention.

Very common: may affect more than 1 in 10 people
- diarrhoea;
- nausea;
- upper respiratory tract infection.

Common: may affect up to 1 in 10 people
- inflammation of the pancreas;
- vomiting, enlarged abdomen, pain in the lower and upper stomach area, passing wind, indigestion, decreased appetite, reflux from your stomach to your oesophagus which may cause pain;
  - **Tell your doctor** if you experience nausea, vomiting or abdominal pain as these may be suggestive of pancreatitis (inflammation of the pancreas).
- swelling or inflammation of the stomach, intestines and colon;
- increased cholesterol levels in your blood, increased triglycerides (a form of fat) levels in your blood, high blood pressure;
- decreased ability of the body to handle sugar including diabetes mellitus, weight loss;
- low number of red blood cells, low number of white blood cells which are usually used to fight infection;
- rash, eczema, accumulation of scales of greasy skin;
- dizziness, anxiety, difficulty in sleeping;
- feeling tired, lack of strength and energy, headache including migraine;
- haemorrhoids;
- inflammation of the liver including increased liver enzymes;
- allergic reactions including hives and inflammation in the mouth;
- lower respiratory tract infection;
- enlargement of the lymph nodes;
- impotence, abnormally heavy or extended menstrual flow or a lack of menstruation;
- muscle disorders such as weakness and spasms, pain in the joints, muscles and back;
- damage to nerves of the peripheral nervous system;
- night sweats, itching, rash including raised bumps on the skin, infection of the skin, inflammation of skin or hair pores, accumulation of fluid in the cells or tissues.

Uncommon: may affect up to 1 in 100 people
- abnormal dreams;
- loss or changed sense of taste;
- hair loss;
- an abnormality in your electrocardiogram (ECG) called atrioventricular block;
- plaque building up inside your arteries which could lead to heart attack and stroke;
- inflammation of blood vessels and capillaries;
- inflammation of the bile duct;
- uncontrolled shaking of the body;
- constipation;
- deep vein inflammation related to a blood clot;
- dry mouth;
- inability to control your bowels;
- inflammation of the first section of the small intestine just after the stomach, wound or ulcer in the digestive tract, bleeding from the intestinal tract or rectum;
- red blood cells in the urine;
- yellowing of the skin or whites of eyes (jaundice);
- fatty deposits in the liver, enlarged liver;
- lack of functioning of the testes;
- a flare-up of symptoms related to an inactive infection in your body (immune reconstitution);
- increased appetite;

- abnormally high level of bilirubin (a pigment produced from the breakdown of red blood cells) in the blood
- decreased sexual desire;
- inflammation of the kidney;
- bone death caused by poor blood supply to the area;
- mouth sores or ulcerations, inflammation of the stomach and intestine;
- kidney failure;
- breakdown of muscle fibres resulting in the release of muscle fibre contents (myoglobin) into the bloodstream;
- a sound in one ear or both ears, such as buzzing, ringing or whistling;
- tremor;
- abnormal closure of one of the valves (tricuspid valve in your heart);
- vertigo (spinning feeling);
- eye disorder, abnormal vision;
- weight gain.

Rare: may affect up to 1 in 1,000 people
- severe or life-threatening skin rashes and blisters (Stevens-Johnson syndrome and erythema multiforme).

Not known: frequency cannot be estimated from the available data
- kidney stones.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website:www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Kaletra

- Keep this medicine out of the sight and reach of children.
- Do not use Kaletra after the expiry date which is stated on the bottle.
- Do not use this medicine if you notice the solution is discoloured or contains particles.

How should I store Kaletra and for how long?

- Store in a refrigerator (2°C - 8°C).
- In use storage: If kept outside of the refrigerator, do not store above 25°C and discard any unused contents after 42 days (6 weeks). It is advised to write the date of removal from the refrigerator on the package.
- It is important to keep Kaletra in the bottle it came in and replace the bottle cap after each dose. Do not transfer it to any other container.

How should I dispose of any unused Kaletra?

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Kaletra contains

The active substances are lopinavir and ritonavir.
Each ml of Kaletra oral solution contains 80 mg of lopinavir and 20 mg of ritonavir.

The other ingredients are:

Alcohol, high fructose corn syrup, propylene glycol, purified water, glycerol, povidone, magnasweet-110 flavour (mixture of monoammonium glycyrrhizinate and glycerol), vanilla flavour (containing p-hydroxybenzoic acid, p-hydroxybenzaldehyde, vanillic acid, vanillin, heliotropin, ethyl vanillin), polyoxyl 40 hydrogenated castor oil, cotton candy flavour (containing ethyl maltol, ethyl vanillin, acetoin, dihydrocoumarin, propylene glycol), acesulfame potassium, saccharin sodium, sodium chloride, peppermint oil, sodium citrate, citric acid, levomenthol.

What Kaletra looks like and contents of the pack

Kaletra oral solution comes in a multiple-dose 60 ml amber bottle. Each ml of Kaletra contains 80 mg of lopinavir and 20 mg of ritonavir.

Two pack sizes are available:

- 120 ml (2 bottles x 60 ml). The 2 bottle pack also contains two 2 ml syringes with 0.1 ml graduations.
  For volumes up to 2 ml. For larger volumes an alternative pack is available.
- 300 ml (5 bottles x 60 ml). The 5 bottle pack also contains five 5 ml syringes with 0.1 ml graduations.
  For volumes greater than 2 ml. For smaller volumes an alternative pack is available.

Marketing Authorisation Holder:
AbbVie Ltd, Maidenhead, SL6 4UB, UK

Manufacturer:
AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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