ABACAVIR/LAMIVUDINE VIATRIS

Consumer Medicine Information (CMI) summary

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

1. Why am I using ABACAVIR/ LAMIVUDINE VIATRIS?

ABACAVIR/LAMIVUDINE VIATRIS contains the active ingredients abacavir and lamivudine. ABACAVIR/ LAMIVUDINE VIATRIS is used together with other antiretrovirals to slow down the progression of human immunodeficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex or ARC).

For more information, see Section <u>1. Why am I using</u> <u>ABACAVIR/ LAMIVUDINE VIATRIS?</u> in the full CMI.

2. What should I know before I use ABACAVIR/LAMIVUDINE VIATRIS?

Do not use if you have ever had an allergic reaction to abacavir or lamivudine or any of the ingredients listed at the end of the CMI. Talk to your doctor if 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 <u>2. What should I know</u> before I use ABACAVIR/LAMIVUDINE VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ABACAVIR/ LAMIVUDINE VIATRIS and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I use ABACAVIR/LAMIVUDINE VIATRIS?

- The normal dose for adults and adolescents is one tablet once a day.
- ABACAVIR/LAMIVUDINE VIATRIS tablets should be swallowed whole with water and do not have to be taken with food.

More instructions can be found in Section <u>4. How do I</u> <u>use ABACAVIR/LAMIVUDINE VIATRIS?</u> in the full CMI.

5. What should I know while using ABACAVIR/ LAMIVUDINE VIATRIS?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using ABACAVIR/ LAMIVUDINE VIATRIS.
	 If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
	 For as long as you're taking ABACAVIR/ LAMIVUDINE VIATRIS, your doctor will arrange regular blood tests to check for side effects.
	 Keep in contact with your doctor, and don't stop taking KIVEXA without your doctor's advice.
Things you should not do	 Do not take ABACAVIR/ LAMIVUDINE VIATRIS to treat any other complaints unless your doctor tells you to. Do not stop taking ABACAVIR/

	LAMIVUDINE VIATRIS tablets or change the dose without first talking to your doctor.
Driving or using machines	 Don't drive or operate machinery unless you are sure you are not affected.
Looking after your medicine	 Keep your tablets in cool, dry place where it stays below 25°C Keep your ABACAVIR/LAMIVUDINE VIATRIS tablets in their pack until you take them.

For more information, see Section <u>5. What should I know</u> while using ABACAVIR/ LAMIVUDINE VIATRIS? in the full CMI.

6. Are there any side effects?

The most common side effects are feeling sick (nausea), diarrhoea, being sick (vomiting), stomach pain (abdominal pain), headache and rash. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI. PATIENTS TAKING ABACAVIR/LAMIVUDINE VIATRIS, WHICH CONTAINS ABACAVIR, MAY DEVELOP A HYPERSENSITIVITY REACTION (SERIOUS ALLERGIC REACTION) WHICH CAN BE LIFE-THREATENING IF TREATMENT WITH ABACAVIR/LAMIVUDINE VIATRIS IS CONTINUED. CONTACT YOUR DOCTOR IMMEDIATELY FOR ADVICE ON WHETHER YOU SHOULD STOP TAKING ABACAVIR/LAMIVUDINE VIATRIS IF:

1) YOU GET A SKIN RASH OR

2) YOU GET ONE OR MORE SYMPTOMS FROM AT LEAST TWO OF THE FOLLOWING GROUPS:

- FEVER
- SHORTNESS OF BREATH, SORE THROAT OR COUGH
- NAUSEA OR VOMITING OR DIARRHOEA OR ABDOMINAL PAIN
- SEVERE TIREDNESS OR ACHINESS OR GENERALLY ILL FEELING

IF YOU HAVE HAD A HYPERSENSITIVITY (ALLERGIC) REACTION TO ABACAVIR/ LAMIVUDINE VIATRIS TABLETS, NEVER TAKE ABACAVIR/LAMIVUDINE VIATRIS, OR ANY OTHER MEDICINAL PRODUCT CONTAINING ABACAVIR AGAIN AS YOU MAY DEVELOP A LIFE THREATENING REACTION WHICH CAN BE FATAL.

THERE IS AN ALERT CARD INCLUDED IN THE ABACAVIR/LAMIVUDINE VIATRIS PACK, TO REMIND YOU AND MEDICAL STAFF ABOUT ABACAVIR HYPERSENSITIVITY. THIS CARD SHOULD BE REMOVED FROM THE PACK AND KEPT WITH YOU AT ALL TIMES. SEE MORE DETAILS UNDER BEFORE YOU TAKE ABACAVIR/ LAMIVUDINE VIATRIS.

ABACAVIR/ LAMIVUDINE VIATRIS

Active ingredient(s): abacavir (as sulfate) and lamivudine

Consumer Medicine Information (CMI)

This leaflet provides important information about using ABACAVIR/LAMIVUDINE VIATRIS. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ABACAVIR/LAMIVUDINE VIATRIS.

Where to find information in this leaflet:

1. Why am I using ABACAVIR/LAMIVUDINE VIATRIS?

2. What should I know before I use ABACAVIR/ LAMIVUDINE VIATRIS?

3. What if I am taking other medicines?

4. How do I use ABACAVIR/LAMIVUDINE VIATRIS?

5. What should I know while using ABACAVIR/ LAMIVUDINE VIATRIS?

6. Are there any side effects?

7. Product details

1. Why am I using ABACAVIR/ LAMIVUDINE VIATRIS?

ABACAVIR/LAMIVUDINE VIATRIS contains the active ingredients abacavir and lamivudine.

ABACAVIR/ LAMIVUDINE VIATRIS belong to a group of medicines called antiretrovirals.

These are also available as separate medicinal products.

ABACAVIR/LAMIVUDINE VIATRIS is used to treat human immunodeficiency virus (HIV) infection.

ABACAVIR/LAMIVUDINE VIATRIS tablets do not cure AIDS or kill the HIV virus, but delays further damage to the immune system by stopping production of new viruses.

You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. You will still be able to pass on the HIV virus by sexual activity or by contamination with infected blood. You should still use proper precautions to prevent this. Discuss with your doctor the precautions needed to avoid infecting other people.

ABACAVIR/LAMIVUDINE VIATRIS tablets are used together with other antiretrovirals to slow down the progression of human immunodeficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDSrelated Complex or ARC).

2. What should I know before I use ABACAVIR/LAMIVUDINE VIATRIS?

Warnings

Do not use ABACAVIR/LAMIVUDINE VIATRIS if:

- you have ever had an allergic reaction to abacavir.
- you are allergic to the active ingredient lamivudine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have a serious liver disease ABACAVIR/ LAMIVUDINE VIATRIS may not be suitable for you.
- you have severe kidney disease.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You must not take ABACAVIR/LAMIVUDINE VIATRIS tablets if you are pregnant, think you may be pregnant or are breastfeeding, unless your doctor tells you to.

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). When these people start treatment, the immune system becomes stronger, so that the body starts to fight these infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up against as the body fights them
- the immune system attacking healthy body tissue (autoimmune disorders).

The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection.

Symptoms may include:

- muscle weakness and/or muscle pain
- joint pain or swelling

- weakness beginning in the hands feet and moving towards the trunk of the body
- palpitations or tremor
- hyperactivity (excessive restlessness and movement).

If you get any symptoms of infection or if you notice any of the symptoms above tell your doctor immediately. Don't take other medicines for the infection without your doctors' advice.

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.

Abacavir or lamivudine in ABACAVIR/LAMIVUDINE VIATRIS tablets may interact with certain other medicines. ABACAVIR/LAMIVUDINE VIATRIS tablets should not be taken with emtricitabine.

Some medicines may interfere with ABACAVIR/ LAMIVUDINE VIATRIS and affect how it works.

- sorbitol-containing medicines (usually liquids) used regularly
- trimethoprim-sulphamethoxazole (also known as co-trimoxazole), (an antibiotic used to treat PCP -Pneumocystis jiroveci pneumonia (often referred to as PCP) or toxoplasmosis).

If you are taking methadone, your doctor may need to adjust your methadone dose, as abacavir increases the rate at which methadone leaves your body. This is unlikely to affect most methadone users.

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

4. How do I use ABACAVIR/ LAMIVUDINE VIATRIS?

How much to take

- The normal dose for adults and adolescents is one tablet once a day.
- Follow the instructions provided and use ABACAVIR/ LAMIVUDINE VIATRIS until your doctor tells you to stop.

When to take ABACAVIR/LAMIVUDINE VIATRIS

 ABACAVIR/ LAMIVUDINE VIATRIS should be used swallowed whole with water. ABACAVIR/ LAMIVUDINE VIATRIS tablets do not have to be taken with food.

If you forget to take ABACAVIR/LAMIVUDINE VIATRIS

ABACAVIR/LAMIVUDINE VIATRIS should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then continue as before.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you take too much ABACAVIR/LAMIVUDINE VIATRIS

If you think that you have used too much ABACAVIR/ LAMIVUDINE VIATRIS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ABACAVIR/LAMIVUDINE VIATRIS?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ABACAVIR/LAMIVUDINE VIATRIS tablets.

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 or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

Keep all of your doctor's appointments so that your progress can be checked.

If you have stopped taking ABACAVIR/LAMIVUDINE VIATRIS tablets for any reason, it is important that you contact your doctor before restarting. This is especially so if you think you are having side-effects or have another illness. In some cases your doctor will ask you to restart ABACAVIR/LAMIVUDINE VIATRIS tablets where medical care can be readily accessed by yourself or others.

You will need regular blood tests

For as long as you're taking ABACAVIR/LAMIVUDINE VIATRIS, your doctor will arrange regular blood tests to check for side effects.

Stay in regular contact with your doctor

- ABACAVIR/LAMIVUDINE VIATRIS helps to control your condition, but does not cure HIV infection, you will need to take the tablets every day to stop your illness from getting worse. While taking ABACAVIR/ LAMIVUDINE VIATRIS tablets and/or any other therapy for HIV disease, you may continue to develop other infections and other complications of HIV infection.
- You should keep in regular contact with the doctor who is looking after you.
- Do not stop taking ABACAVIR/LAMIVUDINE VIATRIS tablets or change the dose without first talking to your doctor.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use ABACAVIR/LAMIVUDINE VIATRIS tablets to treat any other complaints unless your doctor tells you to.
- If you have hepatitis B infection, you should not stop ABACAVIR/LAMIVUDINE VIATRIS tablets without instructions from your doctor, as you may have a

recurrence of your hepatitis. This may occur due to you suddenly stopping lamivudine.

Hypersensitivity reaction

- ABACAVIR/LAMIVUDINE VIATRIS contains abacavir. Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction, which can be lifethreatening if treatment with abacavir containing products is not stopped.
- Research has found that people with a gene called HLA-B (type 5701) are more likely to have a hypersensitivity reaction to abacavir. However, even if you do not have this gene type it is still possible for you to get this reaction. If you know you have this gene type, be sure to tell your doctor before you take abacavir.
- The most common symptoms of this reaction include high temperature (fever) and a skin rash. Other most frequently seen symptoms include nausea, vomiting, diarrhoea or abdominal pain; severe tiredness or body aches or generally feeling ill; headache; shortness of breath, sore throat or cough. If you develop any of these symptoms call your doctor IMMEDIATELY WHO WILL ADVISE YOU WHETHER YOU SHOULD STOP TAKING ABACAVIR/LAMIVUDINE VIATRIS tablets. If your doctor is not available you must urgently seek other medical advice (e.g. the Accident and Emergency unit of the nearest hospital) before taking the next dose.
- Other symptoms may include joint or muscle pain, swelling of the neck or itchy skin. Occasionally

inflammation of the eye (conjunctivitis), ulcers in the mouth, tingling or numbness of the hands or feet or low blood pressure may occur. The symptoms of this allergic reaction can occur at any time during treatment with ABACAVIR/LAMIVUDINE VIATRIS tablets. However they usually occur in the first six weeks of treatment, and get worse with continued treatment.

- If you have had this serious reaction to ABACAVIR/ LAMIVUDINE VIATRIS tablets, NEVER take ABACAVIR/LAMIVUDINE VIATRIS or any other medicinal product containing abacavir again as within hours you may experience a life-threatening lowering of your blood pressure or death.
- Occasionally life threatening hypersensitivity reactions have occurred when ABACAVIR/LAMIVUDINE VIATRIS tablets was restarted in patients who reported only one of the symptoms on the Alert Card before stopping.
- On very rare occasions, hypersensitivity has been reported when ABACAVIR/LAMIVUDINE VIATRIS tablets were restarted in patients who had no symptoms of hypersensitivity before stopping.
- If you have stopped taking ABACAVIR/LAMIVUDINE VIATRIS tablets for any reason it is important that you contact your doctor before restarting. This is especially so if you think you are having side-effects from other medicines or have another illness. Your doctor will check whether any symptoms you had before stopping may be related to this hypersensitivity reaction. If your doctor thinks there is a possibility that they were related, you may be told never to take ABACAVIR/

LAMIVUDINE VIATRIS tablets again. It is important that you follow this advice.

 If you are hypersensitive to ABACAVIR/LAMIVUDINE VIATRIS tablets you should return all of your unused ABACAVIR/LAMIVUDINE VIATRIS tablets to your doctor or pharmacist for proper disposal.

Kidney disease

 If you have moderate kidney disease you should be monitored as you are at higher risk of some side effects. See additional information under Section <u>6</u>. <u>Are there any side effects</u>?

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ABACAVIR/ LAMIVUDINE VIATRIS affects you.

No studies on the effects of ABACAVIR/LAMIVUDINE VIATRIS tablets on the ability to drive and use machines have been performed. However, you should take into account the state of your health and the possible side effects of ABACAVIR/LAMIVUDINE VIATRIS tablets before considering driving or using machines.

Looking after your medicine

- Keep your ABACAVIR/LAMIVUDINE VIATRIS tablets in their pack until you take them.
- Store below 25°C.

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

Store it 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
- in the car or on window sills.

Keep it where young children cannot reach it, such as a locked cupboard.

Getting rid of any unwanted medicine

If you no longer need to use 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.

Check with your doctor as soon as possible if you think you are experiencing any side-effects or allergic reactions while taking ABACAVIR/LAMIVUDINE VIATRIS tablets, even if the problem is not listed in this leaflet.

Hypersensitivity Reaction

ABACAVIR/LAMIVUDINE VIATRIS contains abacavir. Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction, which can be life-threatening if treatment with abacavir containing products is not stopped. This is described in the section <u>5. What should</u> <u>I know while using ABACAVIR/ LAMIVUDINE VIATRIS?</u>.

It is important that you read and understand the information about this serious reaction.

As ABACAVIR/LAMIVUDINE VIATRIS tablets contains both abacavir and lamivudine, the side effects reported for each of these have been combined.

Less serious side effects	What to do
Very common side- effects	Speak to your doctor if you have any of these
These may affect at least one to ten in every 100 people:	less serious side effects and they worry you.
Gastrointestinal:	
 feeling sick (nausea) being sick (vomiting) diarrhoea 	
 stomach pain (abdominal pain) 	
General:	

Less serious side effects

Less serious side effects	What to do
 lethargy, fatigue, loss of appetite 	
Nervous system:	
 headache high temperature 	
Musculoskeletal:	
 joint and muscle pain Skin related: 	
 abacavir hypersensitivity skin rash (without any other illness) hair loss 	
Uncommon side effects	
These may affect less than one in every 100 people:	
From blood tests:	
 increases in enzymes produced by the liver anaemia (low red blood cell count) neutropenia (low white blood cell count) reduction in the number of platelets (blood cells important for blood cells important for blood clotting). 	

Less serious side effects	What to do
If the production of red blood cells is reduced, you may have symptoms of tiredness or breathlessness.	
A reduction in your white blood cell count can make you more prone to infection. If you have a low platelet count, you may notice that you bruise more easily.	
Rare side-effects	
These may affect less than one in every 1,000 people):	
General:	
 inflammation of the pancreas (pancreatitis). 	
Less serious side effects	What to do

Less serious side effects	What to do
 Musculoskeletal: breakdown of muscle tissue, increases of an enzyme called amylase Very rare side-effects 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
These may affect less than one in every 10,000 people):	
General:	
 severe anaemia Skin related: 	
 serious skin reactions Other observations: 	
 Fat gain and loss Changes in the amounts of fatty substances and glucose in the blood. Within the first few weeks of treatment with anti- HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (e.g. pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, 	

Less serious side effects	What to do
previously suppressed by HIV. If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, please discuss with your doctor immediately.	
In babies and infants exposed to Nucleoside Reverse Transcriptase Inhibitors (NRTIs) during pregnancy or labour small temporary increases in blood levels of a substance called lactate have been observed. Additionally there have been very rare reports of diseases that affect the nervous system such as a delayed development and seizures. Overall, in children whose mothers took NRTIs during pregnancy, the benefit from the reduced chance of being infected with HIV is likely to be greater than	

Less serious side effects	What to do
the risk of suffering from side effects.	

Serious side effects

Serious side effects	What to do
 Lactic Acidosis: Some people taking ABACAVIR/ LAMIVUDINE VIATRIS, or other medicines like it (NRTIs), develop a condition called lactic acidosis, together with an enlarged liver. Lactic acidosis is caused by a build-up of lactic acid in the body. It is rare; if it happens, it usually develops after a few months of treatment. It can be life- threatening, causing failure of internal organs. Lactic acidosis is more likely to develop in people who have liver 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
 disease, especially in women. Signs of lactic acidosis include: deep, rapid, difficult breathing drowsiness numbness or weakness in the limbs feeling sick (nausea), being sick (vomiting) 	
 stomach pain. Allergic (anaphylactic) reaction 	
 The symptoms of an allergic (anaphylactic) reaction which may occur soon after starting ABACAVIR/LAMIVUDINE VIATRIS include wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. 	

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 <u>www.tga.gov.au/reporting-problems</u>. 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 ABACAVIR/LAMIVUDINE VIATRIS contains

Active ingredient (main ingredient)	600 mg of abacavir as the sulfate salt and 300 mg of lamivudine
Other ingredients	 microcrystalline
(inactive ingredients)	cellulose crospovidone magnesium stearate

	 silicified microcrystalline cellulose colloidal anhydrous silica talc OPADRY II complete film coating system 13B58894 White (ARTG PI No: 13119) containing: hypromellose, titanium dioxide, macrogol 400 and polysorbate 80.
Potential allergens	ABACAVIR/LAMIVUDINE VIATRIS tablets contain sorbates and sulfites.

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

What ABACAVIR/ LAMIVUDINE VIATRIS looks like

ABACAVIR/ LAMIVUDINE VIATRIS is white, filmcoated, modified capsule shaped, biconvex tablet debossed with AL12 on one side of the tablet and M on the other side (AUST R 266516).

ABACAVIR/LAMIVUDINE VIATRIS tablets are supplied in blister packs containing 30 tablets.

Who distributes ABACAVIR/ LAMIVUDINE VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you the individual advice you need. You may also be able to find out more information about your disease from books, for example in public libraries.

Counselling is also available from your local AIDS council.

This leaflet was prepared in Jan 2023.

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