

ABACAVIR/LAMIVUDINE VIATRIS



Abacavir (as sulfate) & Lamivudine Film coated tablets 600mg/300mg

What is in this leaflet

Please read this leaflet carefully before you start taking Abacavir/Lamivudine Viatris.

This leaflet answers some common questions about Abacavir/Lamivudine Viatris.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Abacavir/Lamivudine Viatris against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Abacavir/Lamivudine Viatris is used for

Abacavir/Lamivudine Viatris contains the active ingredients abacavir (as sulfate) and lamivudine. It belongs to a group of medicines called antiretrovirals.

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 (eg AIDS-related Complex or ARC).

This medicine belongs to a group of medicines called antiretrovirals.

Abacavir/Lamivudine Viatris tablets does not cure AIDS or kill the HIV virus, but delays further damage to the immune system by stopping production of new viruses.

While taking Abacavir/Lamivudine Viatris 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.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Before you take Abacavir/Lamivudine Viatris

When you must not take it

Do not take Abacavir/Lamivudine Viatris if you have an allergy to:

- any medicine containing abacavir or lamivudine
- any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you have a serious liver disease Abacavir/Lamivudine Viatris may not be suitable for you.

Special Warning

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.

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. If your doctor is not available you must urgently seek other medical advice (eg. 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. 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, **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.

On very rare occasions, hypersensitivity has been reported when Abacavir/Lamivudine Viatris were re-started in patients who had no symptoms of hypersensitivity before stopping.

If you have stopped taking Abacavir/Lamivudine Viatris 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 again. It is important that you follow this advice.

If you are hypersensitive to Abacavir/Lamivudine Viatris you should return all of your unused Abacavir/Lamivudine Viatris to your doctor or pharmacist for proper disposal.

Do not give this medicine to a child under the age of 12 years or weighing less than 40 kg. Safety and effectiveness in children younger than 12 years have not been established.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any other illness.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Abacavir/Lamivudine Viatris.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Abacavir/Lamivudine Viatris.

Abacavir or lamivudine in Abacavir/Lamivudine Viatris may interact with certain other medicines. **Abacavir/Lamivudine Viatris tablets should not be taken with emtricitabine.**

Some medicines may interfere with Abacavir/Lamivudine Viatris. These include:

- 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).

These medicines may be affected by Abacavir/Lamivudine Viatris or may affect how well it works. You

may need different amounts of your medicines, or you may need to take different medicines.

Tell your doctor or pharmacist if you are taking any of these.

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.

If you are taking riociguat (a medicine used to treat high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs) your doctor may need to reduce your riociguat dose, as abacavir (one of the active substances in Abacavir/Lamivudine Viatris) may increase riociguat blood levels.

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

How to take Abacavir/Lamivudine Viatris

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

Take Abacavir/Lamivudine Viatris as directed by your doctor or pharmacist. The normal dose for adults and adolescents is one tablet once a day. Your doctor may prescribe a different dosage.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Do not stop taking Abacavir/Lamivudine Viatris or change the dose without first talking to your doctor.

If you forget to take it

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

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

While you are taking Abacavir/Lamivudine Viatris

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Abacavir/Lamivudine Viatris.

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.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

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

If you have stopped taking Abacavir/Lamivudine Viatris 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 where medical care can be readily accessed by yourself or others.

Things you must not do

Do not take Abacavir/Lamivudine Viatris to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you have hepatitis B infection, you should not stop Abacavir/Lamivudine Viatris without instructions from your doctor, as you may have a recurrence of your hepatitis. This may occur due to you suddenly stopping lamivudine.

Things to be careful of

Be careful driving or operating machinery until you know how Abacavir/Lamivudine Viatris affects you.

No studies on the effects of Abacavir/Lamivudine Viatris 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 before considering driving or using machines.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Abacavir/Lamivudine Viatris. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Abacavir/Lamivudine Viatris. This medicine helps most people

but it may have unwanted side effects in a few people.

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.

Hypersensitivity Reaction

Abacavir/Lamivudine Viatrix 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 "Special warning" under "Before you take Abacavir/Lamivudine Viatrix", of this leaflet.

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

As Abacavir/Lamivudine Viatrix contains both abacavir and lamivudine, the side effects reported for each of these have been combined.

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

The most common side-effects (could affect at least one to ten in every 100 people) are:

- nausea, vomiting
- diarrhoea
- upper abdominal pain
- headache
- high temperature
- lethargy, fatigue, loss of appetite
- hair loss
- joint and muscle pain
- abacavir hypersensitivity
- skin rash (without any other illness).

Uncommon side-effects (could affect less than one in every 100 people) are:

- 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 clotting).

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 (could affect less than one in every 1,000 people) are:

- breakdown of muscle tissue, increases of an enzyme called amylase
- inflammation of the pancreas (pancreatitis).

Very rare side-effects (could affect less than one in every 10,000 people) are:

- serious skin reactions
- severe anaemia.

Changes in the amounts of fatty substances and glucose in the blood have also been reported. 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, 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 the risk of suffering from side effects.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Lactic acidosis

Some people taking Abacavir/Lamivudine Viatrix, 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 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 Viatrix include wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever,

lumpy rash (hives) or fainting.

- Old infections may flare up

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, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

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

After taking Abacavir/ Lamivudine Viatris

Storage

Keep your tablets in the pack until it is time to take them. Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Abacavir/Lamivudine Viatris or any other medicine in the bathroom or near a sink. Do not

leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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.

Disposal

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

Product description

What it looks like

A white, film-coated, modified capsule shaped, biconvex tablet debossed with AL12 on one side of the tablet and M on the other side. Dimensions: approx. 20.8 mm x 9.2 mm.

Ingredients

Active ingredient(s):

Abacavir/Lamivudine Viatris contains 600 mg of abacavir (as sulfate) and 300 mg of lamivudine as the active ingredients.

Inactive ingredient(s):

Abacavir/Lamivudine Viatris also contains:

- microcrystalline cellulose
- crospovidone
- magnesium stearate
- colloidal silicon dioxide
- talc
- hypromellose (E464)
- titanium dioxide (E171)
- macrogol 400
- polysorbate 80 (E433).

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Abacavir/Lamivudine Viatris is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

30 March 2023
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